PROPOSED RULEMAKING

ENVIRONMENTAL QUALITY BOARD

[25 PA. CODE CHS. 215, 221, 225, 230 AND 240]

Radiological Health

The Environmental Quality Board (Board) proposes to amend Chapters 215, 221, 225, 230 and 240. The purpose of this proposed rulemaking is to correct the citation of Federal rules or protocols incorporated by reference; clarify the purpose and scope of civil penalties; clarify definitions and terms; clarify healings arts screening requirements for mammography; and update or delete references and to remove attestation requirements from license applications for radon services.

This proposed rulemaking was adopted by the Board at its meeting of September 19, 2006.

A. *Effective Date*

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

B. *Contact Persons*

For further information, contact Louis Ray Urciuolo, Chief, Division of Radiation Control, P. O. Box 8469, Rachel Carson State Office Building, Harrisburg, PA 17105-8469, (717) 787-3720; or Richard Morrison, Assistant Counsel, Bureau of Regulatory Counsel, P. O. Box 8464, Rachel Carson State Office Building, Harrisburg, PA 17105-8464, (717) 787-7060. Information regarding submitting comments on this proposed rulemaking appears in Section I of this preamble. Persons with a disability may use the AT&T Relay Service, (800) 654-5984 (TDD users) or (800) 654-5988 (voice users). This proposed rulemaking is available on the Department of Environmental Protection's (Department) website: www.depweb.state.pa.us.

C. *Statutory Authority*

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

These amendments are also proposed under 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). Subsequently, in 2004, the Board published a final-form rulemaking at 34 Pa.B. 3823 (July 17, 2004) that corrected cross-references in the regulations for radiological health that were no longer accurate.

In the period following the 2004 amendments to the regulations for radiological health, there has been substantive changes to Federal regulations incorporated by reference, most notably 10 CFR Part 71 (relating to packaging and transportation of radioactive material). It is required that these references be corrected for the Commonwealth to have coherent regulations that are compatible with the NRC for submission as part of its application to become an agreement state with the NRC and assume authority over Federally regulated radioactive materials. Under the Energy Policy Act of 2005 , the act of August 8, 2005 (Pub. L. No. 109-58, 119 Stat. 594), the Commonwealth may otherwise lose authority over accelerator-produced radioactive materials and discrete radium sources in 2009 if agreement state status is not attained. This proposed rulemaking also takes advantage of the opportunity to provide further clarification of the regulations in general regarding X-ray use and radon.

As required by section 301(c)(14) of the act, 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 27, 2005, and December 26, 2005, the RPAC met and reviewed the proposed amendments. The RPAC accepted the regulations as proposed with minimal discussion. The RPAC, by letter dated December 29, 2005, from the chairperson, recommended that the amendments to the radiological health regulations be sent to the Board as proposed rulemaking.

E. *Summary of Regulatory Requirements*

The proposed rulemaking reflects, and is 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 when there is no Federal jurisdiction, such as in the use of radiation-producing machines and radon services. The main objective of this proposed rulemaking is to correct pointers to Federal regulations that have changed, most notably in 10 CFR Part 71, regarding transportation regulations, to restore a written reporting requirement for notification of industrial X-ray system malfunctions conducted in shielded rooms, to clarify X-ray and radon references and definitions and simplify applications for radon services.

The substantive parts of this proposed rulemaking are summarized as follows.

Chapter 215. General Provisions

Section 215.1(e)(13) (relating to purpose and scope) lists which NRC regulations in revised 10 CFR Part 71 are incorporated by reference and which are excluded from incorporation as exclusive NRC jurisdiction.

In § 215.2 (relating to definitions), the definition of "radiation source" is expanded for clarity to also include any device, equipment or radiation-producing machine emitting or capable of emitting ionizing radiation.

Section 215.23 (relating to penalties) is expanded to clarify the Department's policy of assessing civil penalties at least sufficient to recover the costs expended by the Department in response to violations of the regulations.

Chapter 221. X-Rays in the Healing Arts

§ 221.2. Definitions.

The definition of "portable radiation system" is changed to "portable X-ray system" for coherency since the reference is directed to "X-ray equipment."

The definition of "radiation detector" is changed to "detector" and moved to § 221.201 (relating to definitions) as it is only referred to there and only in relation to the definition of "gantry."

The following term are deleted, as they are no longer cited in the regulations: "ACR," "cephalometric device," "direct scattered radiation," "protective glove," "response time" and "variable-aperture beam-limiting device."

Section 221.3 (relating to sale and installation) is rescinded as redundant of § 215.21 (relating to sale or installation of radiation sources), which prohibits sale or installation of radiation sources, not just healing arts X-ray machines that do not meet the requirements of the regulations.

Section 221.13(b) (relating to information to be submitted by persons requesting approval to conduct healing arts screening) is reworded to clarify the Department's policy that an application need not be submitted to the Department for approval to conduct a mammography healing arts screening program. The Department incorporates the requirements of 21 CFR Part 900 (relating to mammography).

Section 221.13 (b)(14), regarding compliance with 21 CFR Part 900, is moved to new subsection (c) since it is not an application item and subsection (b) refers to information to be submitted in an application to conduct healing arts screening. Subsection (b)(15) is renumbered as (b)(14).

The heading of § 221.30 (relating to exposure reproducibility) is amended to add "for noncertified systems" to clarify that the requirement applies only to noncertified X-ray systems. Diagnostic systems incorporating one or more certified components must comply with 21 CFR 1020.30—1020.33 (relating to radiographic equipment; fluoroscopic equipment; and computed tomography (CT) equipment). See § 221.21 (relating to diagnostic equipment requirements).

In § 221.32a(i) (relating to radiographic beam limitation), the reference to "portable radiographic systems" was changed to "portable x-ray systems" for consistency with the change of the definition of "portable x-ray system" in § 221.2 (relating to definitions).

In § 221.71(i) (relating to equipment requirements), the word "times" is replaced with "timers" for coherency since the references in subsection (i)(1)—(6) refer to "timer."

The definition of "detector" in § 221.201 (relating to definitions) was changed from "radiation detector" in § 221.2 and moved here, as it is only referred to in relation to the definition of "gantry."

Chapter 225. Radiation Safety Requirements for Industrial Radiographic Operations

Section 225.102(d) (relating to shielded room X-ray radiography) restores a reference to important requirements for written reports to the Department within 30 days under § 225.76 (relating to reporting requirements) of certain equipment malfunctions. This reference was inadvertently omitted at 34 Pa.B. 3823.

Chapter 230. Packaging and Transportation of Radioactive Material

Certain regulations of the NRC are incorporated by reference in § 230.3 (relating to incorporation by reference). The NRC has made substantial changes to the regulations in 10 CFR Part 71 regarding the packaging and transportation of radioactive material. Subsection (b) has been corrected to show which regulations are excluded from incorporation by reference and reserved for the NRC.

Chapter 240. Radon Certification

The requirements to have applications for radon services attested to by a notary or district justice have been removed from §§ 240.103, 240.113, 240.123 and 240.133 as unnecessarily burdensome. The signatory is bound by an unsworn oath.

The time intervals in § 240.303(b) (relating to reporting of information) have been corrected to be consistent with the Department and United States Environmental Protection Agency approved mitigation testing protocols.

The titles of the following documents have been updated in § 240.308 (relating to testing and mitigation protocols). The "Interim Protocols for Screening and Follow-up Radon and Radon Decay Product Measurements" have become finalized in the document "Protocols for Radon and Radon Decay Product Measurements in Homes," the "Guidelines for Radon Mitigation of Residential Dwellings" have become "Pennsylvania Radon Mitigation Standards." Misquoting of the approved "Indoor Radon and Radon Decay Product Measurement Device Protocols" document has also been corrected.

F. *Benefits, Costs and Compliance*

Benefits

The primary benefits of this proposed rulemaking are to: (1) correct 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 to provide compatibility necessary to be an agreement state and to provide additional clarity and coherency; (2) restore shielded room radiography equipment malfunction report requirements so appropriate regulatory response can be considered and others in the regulated community potentially affected can be alerted; and (3) relieve radon services applicants of the unnecessary burden of attestation and to provide updated references to approved radon standards and protocols and reporting intervals. This is part of a comprehensive effort to provide additional clarity to the regulations for radiological health to make it easier for the regulated community to understand and comply. Compatible regulations are necessary for an agreement state that will eventually result in a net savings to the regulated community by eliminating duplicative State and NRC licenses, lowering total license fees, decreasing time lost to inspection and providing more responsive local regulation. Changes to the healing arts screening regulations will allow the Department to make more informed decisions regarding applications for approval to conduct screenings. The removal of notary requirements for radon service applications will speed up the application process and potentially save on application costs.

Compliance costs

The majority of proposed amendments represent clarifications of requirements. Thus, the underlying requirements have not actually changed so there is no additional cost to comply. The failure of shielded room radiography equipment is not common and the additional cost to supply a written report should be negligible since a facility would investigate any serious failure anyway.

Compliance assistance plan

The majority of proposed amendments clarifying references and definitions are self-explanatory. The updated guidance on radon measurement protocols and standards is freely available. There is a free radon hotline for additional assistance with radon guidance and applications.

Paperwork requirements

Most proposed amendments are not associated with paperwork requirements. The time to report an equipment malfunction involving shielded room radiography of 30 days should not be a burden. The removal of notary requirements from radon services applications lessens the paperwork requirements for filing an application.

G. *Sunset Review*

This proposed rulemaking will be reviewed in accordance with the sunset review schedule published by the Department to determine whether the regulations effectively fulfills 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 November 2, 2006, the Department submitted a copy of this proposed rulemaking and a copy of a Regulatory Analysis Form to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the House and Senate Environmental Resources and Energy Committees. 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 rulemaking within 30 days of the close of the public comment period. The comments, recommendations or objections must specify the regulatory review criteria which have not been met. The Regulatory Review Act specifies detailed procedures for review, prior to final publication of the rulemaking, by the Department, the General Assembly and the Governor of comments, recommendations or objections raised.

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, 16th 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 December 18, 2006. 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 December 18, 2006. 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@state.pa.us and must also be received by the Board by December 18, 2006. 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: 7-402. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 25. ENVIRONMENTAL PROTECTION

PART I. DEPARTMENT OF ENVIRONMENTAL PROTECTION

Subpart D. ENVIRONMENTAL HEALTH AND SAFETY

ARTICLE V. RADIOLOGICAL HEALTH

CHAPTER 215. GENERAL PROVISIONS

GENERAL PROVISIONS

§ 215.1. Purpose and scope.

* * * * *

(e) Title 10 Chapter I (Nuclear Regulatory Commission) Parts 19, 20, 30, 31, 32, 33, 34, 35, 36, 39, 40, 70, 71 and §§ 150.1, 150.2, 150.3, 150.11 and 150.20 of the CFR are 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).

* * * * *

(13) Sections 71.2, 71.6, **[71.13(c) and (d), 71.24,] 71.14(b), 71.19,** 71.31, 71.33, 71.35, 71.37, 71.38, 71.39, 71.41, 71.43, 71.45, 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, 71.99 **[and],** 71.100**, 71.101(c)(2), (d) and (e), 71.107, 71.109, 71.111, 71.113, 71.115, 71.117, 71.119, 71.121, 71.123 and 71.125** are not incorporated.

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§ 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:

* * * * *

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

* * * * *

PROHIBITIONS AND RESTRICTIONS

§ 215.23. Penalties.

A person who violates this article is subject to the civil and criminal penalties in the act. **At a minimum, civil penalties may be assessed in an amount sufficient to recover the costs expended by the Department in the correction of the violation or abatement of the resulting radiological nuisance.**

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:

* * * * *

[***ACR*—American College of Radiology.** **]**

* * * * *

[***Cephalometric device*—A device intended for the radiographic visualization and measurement of the dimensions of the human head.** **]**

* * * * *

[***Direct scattered radiation*—The scattered radiation coming directly from material irradiated by the useful beam and not scattered by other material.** **]**

* * * * *

Portable **[** ***radiation*** **]** ***X-ray*** *system*—See X-ray equipment.

* * * * *

[***Protective glove*—A glove incorporating radiation absorbing materials.**

***Radiation detector*—A device which provides a signal or other indication suitable for measuring one or more quantities of incident radiation.** **]**

* * * * *

[***Response time*—The time required for an instrument system to reach 90% of its final reading when the instrument system is exposed to a step change from zero radiation flux to a flux sufficient to provide a steady state midscale reading.** **]**

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[***Variable-aperture beam-limiting device*—A beam-limiting device which has capacity for stepless adjustment of the X-ray field size.** **]**

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§ 221.3. **[Sale and installation] (Reserved)**.

[No person may sell or install a radiation-producing machine that does not meet the provisions of this article.]

ADMINISTRATIVE CONTROLS

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

* * * * *

(b) A person requesting that the Department approve a healing arts screening program **other than mammography** shall submit in writing the following information for evaluation by the Department. If information submitted to the Department becomes invalid or outdated, the registrant shall immediately notify the Department.

* * * * *

(14) **[Mammography facilities shall comply with 21 CFR Part 900 (relating to mammography).**

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

(c) Mammography facilities shall comply with 21 CFR Part 900 (relating to mammography).

DIAGNOSTIC INSTALLATIONS GENERAL REQUIREMENTS

§ 221.30. Exposure reproducibility **for noncertified systems**.

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§ 221.32a. Radiographic beam limitation.

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(i) Mobile or portable **[radiographic] x-ray** systems, other than intraoral dental X-ray systems, shall be provided with a means to limit the source-to-skin distance to at least 30 centimeters.

* * * * *

THERAPEUTIC X-RAY SYSTEMS WITH ENERGIES LESS THAN 1 MEV

§ 221.71. Equipment requirements.

* * * * *

(i) The following apply to **[times] timers** on the equipment:

* * * * *

COMPUTED TOMOGRAPHY X-RAY SYSTEMS

§ 221.201. Definitions.

In addition to the definitions **[in] of** §§ 215.2 and 221.2 (relating to definitions), the following words and terms, when used in this section and §§ 221.202—221.205, have the following meanings, unless the context clearly indicates otherwise:

* * * * *

***Detector*—A device that provides a signal or other indication suitable for measuring one or more quantities of incident radiation.**

* * * * *

CHAPTER 225. RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

Subchapter B. RADIATION-PRODUCING MACHINES

RADIATION-PRODUCING MACHINE REQUIREMENTS

§ 225.102. Shielded room X-ray radiography.

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(d) With the exception of the provisions **[of] in** §§ 225.4a, **225.76** and 225.84 (relating to radiation safety program; **reporting requirements;** and operating and emergency procedures), shielded room radiography is exempt from all other provisions of this chapter.

CHAPTER 230. PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

Subchapter A. SCOPE AND DEFINITIONS

§ 230.3. Incorporation by reference.

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(b) Notwithstanding the requirements incorporated by reference, 10 CFR 71.2, 71.6, **[71.13(c) and (d), 71.24] 71.14(b), 71.19**, 71.31, 71.33, 71.35, 71.37, 71.38, 71.39, 71.41, 71.43, 71.45, 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, 71.99 **[and],** 71.100**, 71.101(c)(2), (d) and (e), 71.107, 71.109, 71.111, 71.113, 71.115, 71.117, 71.119, 71.121, 71.123 and 71.125** are not incorporated by reference.

CHAPTER 240. RADON CERTIFICATION

Subchapter B. CERTIFICATION

CERTIFICATION FOR RADON TESTING

§ 240.103. Radon testing application contents.

An application for radon testing certification, by both individual and firm, shall be submitted to the Department in writing on forms provided by the Department and **[shall] must** contain:

* * * * *

(7) A verification by a responsible official of the applicant that the information contained in the application is correct to the best of the official's information and belief **[, attested by a notary public or district justice]**.

CERTIFICATION FOR RADON MITIGATION

§ 240.113. Radon mitigation application contents.

An application for mitigation certification, by both individual and firm, shall be submitted to the Department in writing on forms provided by the Department and **[shall] must** contain:

* * * * *

(6) A verification by a responsible official of the applicant that the information contained in the application is correct to the best of the official's information and belief **[, attested by a notary public or district justice]**.

CERTIFICATION FOR RADON LABORATORY

§ 240.123. Radon laboratory application contents.

An application for radon laboratory certification shall be submitted to the Department in writing on forms provided by the Department and **[shall] must** contain:

* * * * *

(6) A verification by a responsible official of the applicant that the information contained in the application is correct to the best of the official's information and belief **[, attested by a notary public or district justice]**.

CERTIFICATION FOR PERSONS CERTIFIED IN ANOTHER STATE

§ 240.133. Certification application contents.

A person who has a certification from a state with which the Department has entered into a reciprocal agreement, and who intends to conduct the radon-related activity in this Commonwealth for at least 90 days a year, shall obtain certification from the Department. The application shall be in writing and contain:

* * * * *

(6) A verification by a responsible official of the applicant that the information contained in the application is correct to the best of the official's information and belief **[, attested by a notary public or district justice]**.

Subchapter D. OPERATION REQUIREMENTS

§ 240.303. Reporting of information.

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(c) For a person performing mitigation, each building shall be tested for radon levels before and after the mitigation is performed. Each test **[shall] must** be at least **[24] 48** hours in duration and follow EPA- or DEP-approved protocols. The postmitigation test shall be conducted no sooner than **[48] 24** hours after completion of the mitigation. The results of radon testing shall be reported in accordance with this section.

§ 240.308. Testing and mitigation protocols.

A person conducting radon testing or mitigation for radon contamination shall conduct the testing and mitigation in accordance with EPA- or DEP-approved protocols and shall comply with applicable statutes, regulations, ordinances and building codes. The following protocols, **["Interim Protocols for Screening and Follow-up Radon and Radon Decay Product Measurements]" "Protocols for Radon and Radon Decay Product Measurements in Homes,"** "Indoor Radon and Radon Decay Product Measurement **Device** Protocols" and **["Guidelines for Radon Mitigation of Residential Dwellings"] "Pennsylvania Radon Mitigation Standards"** are available upon request from the following sources:

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[Pa.B. Doc. No. 06-2265. Filed for public inspection November 17, 2006, 9:00 a.m.]