

NOTICE OF FINAL RULEMAKING
DEPARTMENT OF ENVIRONMENTAL PROTECTION
ENVIRONMENTAL QUALITY BOARD
[25 Pa. Code Chs. 215, 221, 225, 230 AND 240]
Radiological Health

ORDER

The Environmental Quality Board (Board) by this order amends 25 Pa. Code, Chapters 215, 221, 225, 230 and 240 (relating to radiological health). These amendments update and correct federal citations incorporated by reference from 10 CFR Part 71 concerning the transportation and packaging of radioactive material and remove references to obsolete regulatory provisions that were deleted in previous rulemakings. The amendments update references to guidance and standards for radon testing and mitigation, restore a written reporting requirement concerning Department of Environmental Protection notification of incidents involving the malfunction of shielded room radiography equipment and remove the requirement for notarization of radon service permit applications. Additional changes are also included to clarify requirements for x-ray use in the healing arts as well as the assessment of civil penalties to recover abatement costs incurred by the department. The amendments also clarify the healing-arts screening requirements for facilities operating under the federal Mammography Quality Act Standards.

This order was adopted by the Board at its meeting of (blank) .

A. Effective Date

These amendments are effective upon publication in the *Pennsylvania Bulletin* as final rulemaking.

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. Persons with a disability may use the AT&T Relay Service by calling (800) 654-5984 (TDD users) or (800) 654-5988 (voice users). This proposal is available electronically through the Department of Environmental Protection's (Department) website <http://www.dep.state.pa.us>.

C. Statutory Authority

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

and delegates to the Board the power to adopt the regulations of the Department to implement the act.

These amendments are also made 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 and pursuant to the Radon Certification Act, 63 P.S. §§20001, et seq.

D. Background of the Amendments

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 consistent regulations that are compatible with the NRC for submission as part of its application, which is currently under review by the NRC, to become an agreement state 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 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 without issue and 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. The unchanged proposed amendments were presented to the RPAC as final-form on July 19, 2007, and August 21, 2007. At the August 21, 2007, meeting, RPAC approved the final-form rulemaking and recommended the Department submit the final rulemaking to the Environmental Quality Board for action.

No public meetings were held. The proposed regulations were published at 36 Pa.B. 7028 (November 18, 2006) with a thirty day comment period. No comments were received during the public comment period.

The regulations regarding transportation of radioactive material currently affect about 480 licensees of Naturally Occurring and Accelerator Produced Isotopes. Approximately 720 licensees of the NRC in Pennsylvania are already subject to these regulations. Failure to enact the final-form regulations may delay or prevent the NRC approving Pennsylvania's application for agreement state. This could delay overall cost savings and efficiency under state rule for NRC licensees. Without agreement state, Pennsylvania will lose its authority to regulate all radioactive material in 2009, except diffuse naturally occurring radioactive material. The final-form regulations for radon reduce regulatory burden and cost for about 600 certificate holders by removing the requirement for notarization of permit applications. This also streamlines the application process. The remaining changes to the regulations for clarity and consistency are a general benefit to some 12,000 x-ray registrants and radon service certificate holders.

E. Summary of Changes to the Proposed Rulemaking

The final-form rulemaking presented here is unchanged from proposed.

F. Summary of Comments and Responses on the Proposed Rulemaking

No comments were received to the proposed rulemaking.

G. 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 consistency; (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, reducing the net burden on the regulated community for licensing 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.

H. Sunset Review

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

I. Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on November 2, 2006, the Department submitted a copy of the proposed rulemaking, published at 36 Pa.B. 7028 (November 18, 2006) to the Independent Regulatory Review Commission (IRRC) and the Chairpersons of the House and Senate Environmental Resources and Energy Committees for review and comment.

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(c) of the Regulatory Review Act, IRRC and the Committees are to be provided with copies of the comments received during the public comment period, as well as other documents when requested. In preparing these final-form regulations, the Department has received no comments to consider.

Under section 5.1(j.2) of the Regulatory Review Act (71 P. S. § 745.5a(d)), on (blank), these final-form regulations were deemed approved by the House and Senate Committees. Under section 5.1(e) of the Regulatory Review Act, IRRC met on (blank) and approved the final-form regulations.

J. Findings of the Board

The Board finds that:

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

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

(3) These regulations do not enlarge the purpose of the proposal published at *36 Pennsylvania Bulletin* 7028 (November 18, 2006).

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

K. Order of the Board

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

(a) The regulations of the Department of Environmental Protection, *25 Pennsylvania Code*, Chapters 215, 221, 225, 230 and 240, are amended by amending the aforesaid chapters to read as set forth in Annex A.

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

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

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

(e) This order shall take effect immediately.

BY:

KATHLEEN A. MCGINTY
Chairperson
Environmental Quality Board