EXECUTIVE SUMMARY

Radiological Health Amendments

Final Rulemaking

The Final Rulemaking consists of amendments to existing regulations. The Chapters being amended are 215, General Provisions; 221, X-rays in the Healing Arts; 225, Radiation Safety Requirements for Industrial Radiographic Operations; 230, Packaging and Transportation of Radioactive Material and 240, Radon Certification.

The amendments to Chapter 215 update and correct federal NRC citations incorporated by reference from 10 CFR Part 71 concerning the transportation and packaging of radioactive material. The definition of radiation source is also clarified, and the penalties section is amended to clarify civil penalties may be assessed to recover departmental abatement costs. The amendments to Chapter 221 remove references to obsolete provisions that were deleted in previous rulemakings and clarifies the healing-arts screening requirements for facilities operating under the federal Mammography Quality Act Standards. In Chapter 225 the reporting requirement associated with the malfunction of shielded room radiography equipment is restored, as it was unintentionally deleted in a previous rulemaking. In the transportation regulations of Chapter 230, changes are made to correct federal NRC citations, as identified above. The radon regulations in Chapter 240 are amended to remove the requirement for notarization of radon service permit applications as well as to update references to guidance and standards for radon testing and mitigation.

The corrections to federal NRC radioactive material transportation regulations are necessary because Pennsylvania's application for Agreement State is currently awaiting approval by the NRC. The referenced changes to NRC transportation regulations were effective October 1, 2004. Agreement States have three years to achieve compatibility. The removal of notary requirements for radon permits is consistent with the generally accepted use of un-sworn oaths thereby reducing regulatory burden and facilitating the future application of electronic permitting. The other regulations generally improve consistency and clarity of the regulations.

Some 11,000 x-ray registrants in general are affected by the changes to the regulations for human use of x-ray equipment under Chapter 221 and about 400 of those specifically performing screening mammography. An additional few dozen are potentially subject to the reporting requirement for malfunctions of industrial radiography systems in shielded rooms. About 480 licensees possessing accelerator-produced radioisotopes are affected by changes in the transportation regulations incorporated by reference. Some 600 certificate holders are affected by the removal of notary requirements for radon service applications and the updating of approved testing and mitigation standards and guidance.

The regulations were reviewed as proposed by the Radiation Protection Advisory Committee (RPAC) on October 27, 2005, and December 6, 2005. At that time the committee made no changes to the amendments and raised few questions. The chairman of the RPAC provided a letter approving of the proposed regulations. There were no comments or issues raised during

the subsequent vetting of the proposed regulations. 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 encouraged the Department to submit the final rulemaking to the Environmental Quality Board for action.

There is no statutory deadline for final adoption. However, the NRC requires that Agreement State regulations achieve compatibility within three years of a change, in this case, October 1, 2007. Failure to adopt the transportation regulations in a timely manner may delay the effective date of Pennsylvania becoming an Agreement State.

The proposed regulations were published in the Pennsylvania Bulletin on November 18, 2006, with a 30-day comment period. No public comments were submitted to the Environmental Quality Board during the public comment period. No public hearings or meetings were held during the public comment period.