

EXECUTIVE SUMMARY

Radiation Safety Requirements for Non-Healing Arts Radiation Producing Devices 25 Pa. Code Chapters 225, 227, 227a, and 228

The Environmental Quality Board (Board) amends Chapters 225 and 228 (relating to radiation safety requirements for industrial radiographic operations; and radiation safety requirements for particle accelerators), rescinds Chapter 227 (relating to radiation safety requirements for analytical X-ray equipment, X-ray gauging equipment, electron microscopes and X-ray calibration systems) and adds new Chapter 227a to read as set forth in Annex A.

Purpose of the Final-Form Rulemaking

The Board last updated the radiological health regulations in 2019 to provide for updates and technological advances in uses of radiation sources and medical X-ray operations. However, radiological health regulations related to non-medical X-ray equipment have not been updated since 2009. Since then, advancements in X-rays and other ionizing radiation particles used for non-medical purposes have necessitated updated regulations to ensure the public, workers, and environment are protected from the potentially harmful effects of ionizing radiation.

The amendments included in this final-form rulemaking address non-medical X-ray operations and emerging technologies in the industrial field to ensure that exposure to radiation from non-medical radiation generating devices is as low as reasonably possible. Some examples of non-medical X-ray operations and emerging technologies that these amendments apply to include many recent advances in X-ray capabilities for bomb detection, contraband scanning, and advanced welding and detection capabilities.

Summary of the Final-Form Rulemaking

The amendments to Chapter 225 are intended to separate and more clearly outline requirements applicable to non-medical X-ray operations and field radiography. Chapter 227, which pertains to radiation safety requirements for analytical X-ray gauging equipment, electron microscopes and X-ray calibration systems, is rescinded and reserved. All requirements currently in Chapter 227 are moved to a new Chapter 227a, which is added to outline radiation requirements for these non-healing arts radiation-producing devices. Existing Chapter 228 is also amended to update a definition to match the U.S. Nuclear Regulatory Commission's terminology.

These amendments are based on standards for radiation-producing devices set by recognized accrediting bodies and national organizations. Specifically, the amendments incorporate the Suggested State Regulations (SSR) Part H that were developed by the Conference of Radiation Control Program Directors (CRCPD). The American National Standards Association was also consulted in developing these amendments. One of CRCPD's goals is to ensure uniformity in federal and state radiation protection laws and regulations. Typically, federal agencies develop radiation control regulations and standards, but it is left to the state to implement and enforce those regulations and standards. The CRCPD reviews draft and final federal regulations and, through various working groups, develops model state regulations called Suggested State

Regulations (SSRs). A new SSR could be developed for a given issue or problem, but more often they are updated to reflect new federal regulations. As with federal regulations, once new or revised SSRs are complete, they undergo a CRCPD Board and peer review and then are published as draft within the CRCPD Director Members for comment. The draft SSRs are also sent to federal agencies for concurrence. States may adopt a CRCPD model state SSR as is or modify them to conform to their regulatory frameworks.

Affected Parties

These regulations affect approximately 1,400 radiation-producing machine registrants in the Commonwealth. These registrants include radiographers, drug rehabilitation centers, food manufacturers, primary metal manufacturers, fabricated metal product manufacturers, machinery manufacturers, computer and electronic product manufacturers, and other miscellaneous manufacturers. In addition to these types of businesses, registrants could also be government offices such as prisons and courthouses, universities, and research laboratories. A small number of registrants (currently there are no registrants that have not obtained this training) for individual security screening devices would also be required to provide training on the use of equipment to staff that do not have formal training or knowledge in radiological sciences or radiation safety.

Outreach (Advisory Committee/Stakeholder Consultation)

The final-form rulemaking was developed in consultation with the Department's Radiation Protection Advisory Committee (RPAC). Members of RPAC represent the regulated community, including professional health physics and medical physics organizations, as well as environmental, health, science, engineering, business, or public interest groups. The final-form rulemaking was introduced to RPAC on March 3, 2022. On March 3, 2022, RPAC concurred with DEP's recommendation that the final-form rulemaking move forward in the regulatory process.

Public Comments

The Board adopted the proposed rulemaking at its meeting on May 19, 2021. The proposed rulemaking was published on August 14, 2021, opening a 30-day public comment period that closed on September 13, 2021.

The Board received comments from one public commentator and the Independent Regulatory Review Commission (IRRC), mostly requesting clarity of the amendments. Revisions were made to the final-form rulemaking to clarify the amendments based on the public comments.

Recommendation to the Board

The Department recommends the Board adopt this final-form rulemaking.