

EXECUTIVE SUMMARY

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

This proposed rulemaking 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 Propose Rulemaking

The Environmental Quality 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 proposed amendments included in this 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 proposed regulations would apply to include many recent advances in X-ray capabilities for bomb detection, contraband scanning, and advanced welding and detection capabilities.

Summary of the Proposed Rulemaking

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safety requirements for analytical X-ray gauging equipment, electron microscopes and X-ray calibration systems, be rescinded and reserved.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

These proposed amendments are based on standards for radiation-producing devices set by recognized accrediting bodies and national organizations. Specifically, the proposed amendments incorporate the Suggested State Regulations (SSR) Part H that was developed by the Conference of Radiation Control Program Directors (CRCPD). The American National Standards Association was also consulted in developing these amendments. One of the 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

The proposed regulations would 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 3 registrants) 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 proposed 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 proposed rulemaking was introduced to RPAC on October 10, 2019. An RPAC subcommittee, which was comprised of professionals in the industries potentially impacted by these proposed regulations, had further discussions on the draft proposed rulemaking on December 15, 2019, and January 15, 2020. RPAC again reviewed the package with the revisions made as a result of the recommendations of the subcommittee on March 19, 2020. On July 9, 2020, RPAC voted to concur with the Department's recommendation that the proposed rulemaking move forward in the regulatory process.

Recommendation

The Department recommends adoption of this proposed rulemaking. A 30-day public comment period with no public hearings is also recommended.