

FINAL RULEMAKING
ENVIRONMENTAL QUALITY BOARD
[25 PA. CODE CHS. 215-221, 223-228, 230, 232 AND 240]
Radiological Health

The Environmental Quality Board (Board) by this order amends Chapters 215-221, 223-228, 230, 232 and 240 to read as set forth in Annex A. This final-form rulemaking amends Article V (relating to radiological health) to include clarification and guidance regarding radiation safety, update the standards for protection against radiation and amend requirements for radon certification.

This order was adopted by the Board at its meeting on _____.

A. Effective Date

This final-form rulemaking will be effective 90 days after final-form publication in the *Pennsylvania Bulletin*.

B. Contact Persons

For further information, contact the Bureau of Radiation Protection, P.O. Box 8469, Rachel Carson State Office Building, Harrisburg, PA 17105-8469, (717) 787-2480; or Keith Salador, Assistant Counsel, Bureau of Regulatory Counsel, P.O. Box 8464, Rachel Carson State Office Building, Harrisburg, PA 17105-8464, (717) 783-8075. This final-form rulemaking is available on the Department of Environmental Protection's (Department) website at www.dep.pa.gov (Select "Public Participation," then "Environmental Quality Board (EQB)").

C. Statutory Authority

The amendments to Chapters 215-221, 223-228, 230 and 232 are authorized under Sections 301 and 302 of the Radiation Protection Act, 35 P.S. §§ 7110.301 and 7110.302, and Section 1920-A of the Administrative Code, 71 P.S. § 510-20.

The amendments to Chapter 240 are authorized under Sections 12 and 13 of the Radon Certification Act, 63 P.S. §§ 2012 and 2013, Section 302 of the Radiation Protection Act, 35 P.S. §§ 7110.302, and Section 1920-A of the Administrative Code, 71 P.S. § 510-20.

D. Background and Purpose

Significant technological advances in the use of radiation sources prompted the need to amend the radiological health regulations. This final-form rulemaking establishes and maintains appropriate radiation protection standards and oversight. The Board last updated its radiological health regulations in 2009.

This final-form rulemaking includes amendments based on standards set by recognized accrediting bodies and National organizations such as the National Council on Radiation Protection and Measurements and the Conference of Radiation Control Program Directors.

The radon certification regulations in Chapter 240 were first promulgated in 1991 and have not been significantly amended since. This final-form rulemaking amends the radon certification application requirements and the reporting requirements for certified radon service providers to add clarity to both processes. The amendments to the testing and mitigation protocol requirements and the quality assurance (QA) and quality control (QC) requirements provide greater detail regarding how these programs should be designed and what goals they should accomplish.

This final-form rulemaking was presented to and reviewed by the Radiation Protection Advisory Committee (RPAC) on October 19, 2017. The RPAC represents various stakeholders, including radioactive materials licensees, radiation-producing machine registrants, radon service providers and the general public. The RPAC endorsed moving forward with the final-form rulemaking.

E. Summary of Changes to the Proposed Rulemaking

Sections 224.11(6), 226.5(5), 230.4(5) and 232.3(4) are revised in this final-form rulemaking to delete Agreement State transition language. These deletions were inadvertently omitted in the proposed rulemaking.

The term “business days” was added throughout the final-form rulemaking for time requirements based on public comments received.

The word “individual” has been revised to “individual(s)” throughout Chapter 240 due to an amendment in the final-form rulemaking that no longer requires only one certified individual per radon testing, mitigation or laboratory firm. Other grammatical changes were also made where necessary throughout this final-form rulemaking.

The Board amended the following sections of the proposed rulemaking based on public comments, unless otherwise noted.

Chapter 215. General provisions

The title of § 215.41 (relating to address) was changed to “contact information” and the telephone number and web address were added in this final-form rulemaking.

Chapter 216. Registration of radiation-producing machines and radiation-producing machine service providers

In § 216.3 (relating to exemptions) the word “centimeter” was changed to “centimeters” in this final-form rulemaking.

Chapter 217. Licensing of Radioactive Material

In § 217.143 (relating to certain measuring, gauging or controlling devices), the units of radiation doses were reversed. For example, 37 MBq (1 mCi) in the proposed rulemaking was changed to 1 mCi (37MBq) in this final-form rulemaking, to be consistent with national standards.

Chapter 218. Fees

In 218.11(e) (relating to registration, renewal of registration and license fees), “check payable” was changed to “payment” in this final-form rulemaking to account for future payment options.

Chapter 219. Standards for protection against radiation

In § 219.3 (relating to definitions), the proposed definition of "medical reportable event for radiation-producing diagnostic or interventional X-ray procedures" contained specific dose criteria. The dose criteria for an unintended peak skin dose to the same area in a single procedure has been increased from the proposed 3 Gy (300 rad) to 1500 rad (15 Gy) in subparagraph (i) of this final-form rulemaking based on public comments. The proposed dose criteria in subparagraphs (ii) and (iii) were changed from 0.5 Gy (50 rad) to 50 rad (0.5 Gy) in this final-form rulemaking to be consistent with national standards.

The title of § 219.229 has been revised in the final-form rulemaking to “diagnostic or interventional procedure medical reports” to avoid confusion and to clarify the types of reportable events that are covered by this section.

In § 219.229(b), (b)(1), (b)(2) and (b)(4), the proposed term “medical event” was changed to “medical reportable event” in this final-form rulemaking for consistency with the definitions in § 219.3.

Chapter 220. Notices, instructions and reports to workers; inspections and investigations

In § 220.2(c) (relating to posting of notices to workers), a typographical error in a document number was corrected in this final-form rulemaking.

Chapter 221. X-rays in the healing arts

In § 221.2 (relating to definitions), a change was made in the proposed definition of “high-risk procedure” to the skin dose levels to change “200 rads” to “200 rad (2.0 Gy)” to be consistent with national standards and correct a typographical error. The term “high-risk” was added to the proposed definition of “FGI—fluoroscopic guided interventional procedures” in this final-form rulemaking in response to comments regarding the scope of this definition. The term “therapy” in subsection (iii) of the “FGI” definition was change to “the procedure” in this final-form rulemaking for clarity.

In § 221.11(b)(1) (relating to registrant responsibilities), the proposed phrase "...including certification or registration..." was changed to "...which may include certification or registration..." in this final-form rulemaking based on public comments. In subsection (c)(2), the term "film" was replaced with "image receptor" in this final-form rulemaking based on comments from the RPAC.

Proposed § 221.35a(c) (relating to fluoroscopic x-ray systems) was revised in this final-form rulemaking to improve clarity based on public comments expressing confusion with the proposed language. Subsection (c) was also revised to add "or digital acquisition" modes in paragraph (3) and separate the two types of beam evaluations into paragraphs (5) and (6) to differentiate between the two tests.

In proposed § 221.35a(d)(4) the proposed phrase "...all of the following information..." was changed to "...other information..." in this final-form rulemaking to clarify the information necessary to estimate radiation dose to the skin. Additionally, the proposed phrase "or the following, as necessary" was changed to "or one or more of the following" for clarity.

Proposed § 221.57 (relating to facilities using CR or DR) was renumbered as § 221.50 in this final-form rulemaking for proper placement in the regulation.

In proposed § 221.64(a) and (a)(2) (relating to CBCT), the phrase "or QE" was added in this final-form rulemaking along with the QMP for responsibilities outlined in the subsection and paragraph. Also in subsection (a)(2), the proposed timeframe of "12 months" was changed to "14 months" for performance evaluation intervals of CBCT units for consistency throughout the rulemaking. Subsection (c) was revised in this final-form rulemaking to clarify that CBCT systems are exempt from the requirements in § 221.202(a) (relating to equipment requirements), which relates to accreditation. Similar changes were made in this final-form rulemaking in § 221.65(1) and (3) to exempt CT systems from §§ 221.202(a) and 221.204(1)(4)(xi) (relating to performance evaluations, routine, QC and surveys).

In § 221.201 (relating to definitions), the proposed definition for $CTDI_w$ was amended in this final-form rulemaking to further clarify dose measurements.

In § 221.204(c)(1), the proposed language was amended in this final-form rulemaking to "CT X-ray systems shall have a survey performed at the time of installation..." to clarify when a survey is required.

Chapter 223. Veterinary Medicine

Proposed Section 223.31(d) (relating to registrant responsibilities) was amended in this final-form rulemaking to specify the distance within which appropriate persons required for a medical procedure or training may be during the radiographic exposure. The amendment changed "in the room" to "within 2 meters of the device."

Chapter 240. Radon certification

Section 240.2(a) (relating to scope) was amended in this final-form rulemaking to clarify that Chapter 240 applies to “a person except when the person is” performing one of the enumerated activities listed in section (a)(1)-(6). For example, if a person is conducting both commercial radon testing and testing for radon contamination in a building that the person owns or occupies, Chapter 240 would apply in the former circumstance but not in the latter circumstance. Wording was changed in Section 240.2(a)(6) to conform with those changes.

Section 240.2(a)(4) was revised in this final-form rulemaking to delete the proposed addition of “Department-approved,” and the proposed § 240.2(a)(5)(ii) was revised by adding “activated charcoal, liquid scintillation, or alpha track” to further clarify the types of radon testing devices. Section 240.2(a)(6)(iii) was added in this final-form rulemaking for clarity and specifies that radon testing must be performed in accordance with the device manufacturer’s instructions.

Section 240.3 (relating to definitions) was revised in this final-form rulemaking by removing the proposed definition of “ALARA.” The proposed term “blind study” was also removed in this final-form rulemaking and, instead, is explained in § 240.203(a)(5) (relating to conditions of certification). The method for analyzing activated charcoal has been added to the definition of “AC—activated charcoal” in this final-form rulemaking, and the method for analyzing liquid scintillation has been added to the definition of “LS—liquid scintillation.” Also, the proposed definition of “spiked measurement or spike” was revised in this final-form rulemaking to clarify that the measurement must be conducted in an approved chamber.

Sections 240.101(b) (relating to requirements for radon testing certification), 240.102(b) (relating to prerequisites for radon testing certification), 240.112(b) (relating to prerequisites for radon mitigation certification) and 240.122(b) (relating to prerequisites for radon laboratory certification) were revised in this final-form rulemaking to remove the proposed requirement that only one person in a firm can be certified. The term “person” was replaced with “individual” in this final-form rulemaking in Sections 240.101(b) and 240.111(b) for consistency.

The proposed requirement in §§ 240.102(b)(2), 240.112(b)(2) and 240.122(b)(2) that the firm’s certified individual may not also be a firm employee was removed in this final-form rulemaking and the paragraphs were renumbered accordingly.

Proposed subsections 240.102(b)(4)(ii) and 240.112(b)(4)(i) were revised in this final-form rulemaking to change the notification requirements from 5 days to 10 business days.

The proposed requirement that a testing firm in § 240.102(b)(4) and a mitigation firm in § 240.112(b)(5) may list a maximum of five firm employees at one time was removed in this final-form rulemaking.

Proposed §§ 240.102(b)(6)(iii) and 240.112(b)(6)(iii) were changed in this final-form rulemaking from requiring proof of passing the appropriate Department-approved course or exam to requiring certification that firm employees hired after the effective date of the rulemaking received initial training pursuant to new subsection (b)(6) of the respective sections. Initial

training under subsection (b)(6) may be provided by the firm's certified individual or by a third party. Proposed subsection (b)(6) was renumbered as subsection (b)(4) in each section. A new subsection (b)(6)(iv) was added to both sections in this final-form rulemaking to require each testing firm applicant to submit proof of completion of continuing education as required by new subsection (b)(7), if applicable. A new subsection (b)(6) was added to both sections in this final-form rulemaking specifying the initial training requirements for a firm employee.

Sections 240.103(a)(3), 240.113(a)(3), and 240.123(a)(3) were amended in this final-form rulemaking to remove the proposed date of birth requirement. A new paragraph in subsection (a) of each section was added in this final-form rulemaking to specify that the applying firm must submit a demonstration that the certified individual will maintain adequate span of control over the employees. These subsections were added in this final-form rulemaking because of the removal of the proposed requirements in §§ 240.102 and 240.112 that would have allowed only five firm employees. This span of control requirement will allow the Department to ensure that certified individuals in responsible charge of firm activities are adequately training firm employees.

Section 240.111(b) (relating to relating to requirements for radon mitigation certification) was amended in this final-form rulemaking to delete the proposed requirement that a certified firm may only have one certified individual in responsible charge of a firm at a time.

Section 240.121(b) was amended in this final-form rulemaking to add language to specify that there can be more than one certified individual in a laboratory firm.

Subsection 240.122(b)(4) was amended in this final-form rulemaking to clarify submittal requirements for each laboratory firm employee for individual certification for laboratory analysis. A new subsection (b)(6) was added to clarify the initial training requirements of firm employees, and a new subsection (b)(7) was added specifying the continuing education requirements for a firm employee.

Section 240.133(a)(3) (relating to certification application contents) was amended in this final-form rulemaking to remove the proposed date of birth requirement.

Proposed § 240.141 (relating to withdrawal of applications and certifications) was amended in this final-form rulemaking to allow for a withdrawn certification application to be reinstated prior to the expiration of the current certification instead of requiring a new application to be submitted along with the appropriate fee.

Proposed § 240.142 (relating to testing and mitigation identification cards) was amended in this final-form rulemaking to remove the proposed requirement for individuals identified in subsection (a) to wear the Department-issued identification card while performing radon-related activities due to the possibility of losing badges when working in tight spaces such as crawlspaces and attics.

Section 240.203(a)(5) was amended in this final-form rulemaking to explain what a blind study is.

Section 240.302(a) (relating to required client information) was amended in this final-form rulemaking to delete the phrase “for the general public” to provide clarity in the notice to clients.

Section 240.303(1)(i) (relating to reporting of information) was amended in this final-form rulemaking to add “as available” to the end of the subsection. This revision was made in response to a comment regarding the lack of control laboratories have over what information clients provide to the laboratory.

Section 240.303(2)(i) was amended in this final-form rulemaking to replace the word “of” with “after” to clarify when mitigation reporting should occur.

Section 240.303(3) was amended in this final-form rulemaking to add that the owner or occupant of the building in addition to the client is to receive test results and that the results must be reported within 10 business days. Also, the proposed phrase “secondary tester” was changed to “certified tester” and the proposed phrase “certified individual” to “certified laboratory to clarify reporting responsibility to the client.

Section 240.303(4) was amended in this final-form rulemaking to remove the proposed requirement for a test to be performed prior to a mitigation system installation. Paragraph (4) was also revised to clarify that results of the postmitigation test must be reported in accordance with this section unless the postmitigation test is performed by someone other than the mitigator and the client does not provide the postmitigation test results to the mitigator.

Section 240.305 (relating to health and safety program) was amended in this final-form rulemaking to remove the language relating to ALARA and to specify ways to protect certified individual and firm employees from exposure to radon.

Section 240.306 (relating to continuing education program) was amended in this final-form rulemaking to remove duplicative continuing education requirements that had been proposed.

Section 240.308 (relating to radon mitigation standards for detached and attached residential buildings three stories or less in height) contains several amendments in the final-form rulemaking:

- The proposed heading was amended to “Radon mitigation standards for detached and attached residential buildings three stories or less in height.”
- A new subsection (a) was added to require the certified individual to conduct a thorough visual inspection of the building prior to initiating any radon mitigation work. With this addition, the subsections were renumbered accordingly.
- Proposed subsections (a)(2) and (a)(3) were removed.
- Proposed subsection (a)(6) was renumbered as subsection (b)(5) and amended to clarify that the termination point must be at least five feet horizontally from a vertical wall that extends above the roof or higher than the vertical wall. Proposed subsection (a)(7) was renumbered as subsection (b)(6) and expanded to clarify that the termination point must be at least 12 inches above the surface of the roof for vent pipes that penetrate the roof and at least 10 feet from any openings of conditioned spaces in the structure.

- A new subsection (b)(1) was added to specify what the termination point must be, and proposed subsection (a)(1) was amended as final-form subsection (b)(2) to specify that a 45-degree elbow is permitted.
- Proposed subsection (b)(1) was renumbered as subsection (c)(1) and amended in to specify that a radon fan used in active soil or block wall depressurization may not be installed in a window well or egress window well or in the conditioned space of a building.
- Proposed subsection (c)(1)(iii) was renumbered as subsection (d)(1)(iii) and amended to change the sealing of “openings or cracks in the foundation or at...” to “expansion or control joints.” Subparagraphs (iv) and (v) were added to clarify sealing requirements for openings in the foundation and sump pits. Proposed subsection (c)(3) was renumbered as subsection (d)(3). This provision pertains to when a mitigator may leave areas unsealed and must provide written information to the homeowner. Paragraph (3) was amended in this final-form rulemaking to remove “...or that openings or cracks are inaccessible...”; paragraph (3)(i) was changed from heating and cooling “penalty” to “costs”; and paragraph (3)(ii) was changed from “decrease the efficiency” to “reduce the effectiveness.”
- Proposed subsection (d) was renumbered as subsection (e). Subsection (e)(1)(ii) and (iii) were changed in this final-form rulemaking to include reference to the firm or the certified individual on the system description label affixed to the mitigation piping system.
- Proposed Subsection (e)(1) was removed as unnecessary.
- Proposed subsection (f) was renumbered as subsection (g) and was amended to delete reference to the EPA for source material.

Proposed § 240.309 (relating to testing protocols) was renumbered in this final-form rulemaking as § 240.310 due to a recently promulgated rulemaking that added § 240.309 (relating to radon mitigation system fee). (47 Pa.B. 6482, October 21, 2017). Subsection (a)(4)(v)(G) and (a)(11)(ii) were expanded in this final-form rulemaking to clarify that the client must be notified immediately if a permanently installed radon mitigation system is not functioning during the test period. Subsection (a)(4)(vii) was amended in this final-form rulemaking to correct a grammatical error. The word “sustained” was changed to “unusually” in this final-form rulemaking in relation to describing storms and winds. Subsection (a)(6)(i), on the use of anti-tampering devices to guard against movement of test devices, was amended in this final-form rulemaking for clarity. Subsection (a)(7) was amended in this final-form rulemaking to correct a document reference number. Subsection (a)(8) was added in this final-form rulemaking to address multifamily building mitigation, and the remainder of the subsection was renumbered. Subsection (a)(11), formerly (a)(10), was amended in this final-form rulemaking to clarify the required testing timeframe applies when no unforeseen circumstance is prohibiting the test from being performed such as when an owner or occupier refuses or ignores requests to complete the postmitigation test. Subsections (b)(1) and (2) were amended in this final-form rulemaking to add “as available” with regard to the inclusion of information in the Result Report Form and to change “10 working days” to “10 business days”.

In this final-form rulemaking, § 240.604(a)(6) (relating to QA requirements for testing using primary devices), 240.605(a)(5) (relating to QA requirements for testing using secondary

devices), and 240.605(b)(3), the term “radioactive check source” was amended to “check source” to account for electronic check sources.

In this final-form rulemaking, the requirement in §§ 240.604(c)(2)(ii) and (c)(3)(v)(C) and 240.605(c)(1)(ii) and (c)(2)(v)(C) to include electret chamber serial number(s) was removed from the proposed rulemaking because including both electret and chamber serial numbers on the form tracking electret custody is unnecessary. Proposed §§ 240.604(c)(3)(iv), 240.605(c)(2)(iv) and (d)(2)(iv), and 240.606(c)(3)(iv), (d)(4)(iv) and (e)(3)(iv), pertaining to control and warning levels associated with spikes, were removed because predetermined control limits are already in place for these devices. Proposed §§ 240.604(c)(5) and 240.606(c)(5), pertaining to electret voltage drift, were removed because the manufacturer performs voltage drift checks prior to shipment of the device. All affected subsections were renumbered appropriately.

F. Summary of Major Comments and Responses on the Proposed Rulemaking

The proposed rulemaking was adopted by the Board on October 18, 2016, and published at 47 Pa.B. 2722 (May 13, 2017). Public comments on the proposed rulemaking were accepted through June 26, 2017. A webinar was presented for the proposed radiation-producing machines and radiation source regulations on May 31, 2017. A separate webinar was presented on May 31, 2017, for the proposed radon certification regulations. The Board received comments from 23 commentators during the public comment period and the Independent Regulatory Review Commission (IRRC). These comments were considered and are addressed in the comment and response document that accompanies this final-form rulemaking. All comments are available on DEP’s website at <http://www.ahs.dep.pa.gov/eComment/>. A summary of the major comments and responses is set forth below.

General IRRC Comments

IRRC noted that the Preamble to the proposed regulation did not include all amendments and did not explain why certain amendments are needed. IRRC also cited differences between the Preamble and the Regulatory Analysis Form regarding compliance costs and asked the Board to amend these sections of the two documents in the final rulemaking and include explanations that were omitted. Based on these concerns, the Board has clarified the inconsistencies in these final-form rulemaking documents.

With regard to IRRC’s comment about differences in the Preamble and the Regulatory Analysis Form, an error was made by including the cost of certification of a qualified medical professional (QMP) in the proposed rulemaking, which is not applicable to these regulations. Any costs inadvertently included in the Preamble and Regulatory Analysis Form have been corrected in this final-form rulemaking.

IRRC recommended the Board reconsider the regulatory scheme of prescriptive requirements, provide flexibility to accommodate advances in technology, and consider more reliance on the QMP, based on other comments that were submitted. In general, the Board notes that this rulemaking embodies the theory that regulatory clarity and codification of best practices can

improve the quality of services to the public, instead of ratcheting numerical standards in a command-and-control fashion. The industry had moved ahead of the Commonwealth regulations in technology and safety. The Department engaged with the business community, learned about practices that had already become standard, and is codifying them in this final-form rulemaking. This process ensures that the requirements are not an unfair surprise to the industry. Some requirements are required of operators by insurance companies (including Medicare and Medicaid), and most others are standards from national organizations, such as the Joint Commission, or are contained in technical guidance documents. The Board notes that the Department's authority in § 215.31 (relating to granting exemptions) to grant exemptions from Article V provides for flexibility to address advances in technology. Additional sections in Article V also address emerging technologies. For example, § 218.11 (relating to registration, renewal of registration, and license fees) requires Department safety review and § 221.16 (relating to training, competency, and continuing education) necessitates registrants to be knowledgeable with emerging technologies. The Department strives to write regulations as performance based; however, certain requirements, such as basic operations, are not likely to change. Regarding reliance on QMPs as technology advances, the Department anticipates that the waiver requests discussed above will necessitate QMP involvement to ensure new technologies are being implemented safely.

IRRC questioned why the answer to Question 13 of the Regulatory Analysis Form did not include citations to the Department of Health (DOH) regulations that address radiology, and how the development of this regulation was coordinated with DOH. The Board notes that DOH has regulations regarding radiation sources in 28 Pa. Code Chapters 51, 127, and 565 (relating to general information; radiology services; and laboratory and radiology services) that could be affected by this rulemaking. DOH is currently working on a regulatory update. DEP and DOH have held several meetings and have been working together to ensure DOH's regulations are consistent with DEP's regulations.

IRRC noted that several commentators identified terms that are defined but not used. IRRC recommends reviewing all proposed definitions to eliminate terms not used in the body of the regulation and ensure that defined terms are used consistently. The Board responds the defined phrase "medical reportable event for radiation-producing diagnostic or interventional X-ray procedures" remains in the final-form rulemaking to distinguish the difference between the two types of reportable events that are discussed in Chapter 219. One type is for radiation-producing machine therapy and the other is for diagnostic or interventional procedures. "Medical reportable event for radiation-producing machine therapy" is defined in existing § 219.3 and applies to sections that are not part of this final-form rulemaking. The definition of "medical reportable event for radiation-producing diagnostic or interventional X-ray procedures" clarifies § 219.229. Section 219.229 is included in this final-form rulemaking and only covers diagnostic or interventional procedures. The title of § 219.229 has been revised in the final-form rulemaking to "diagnostic or interventional procedure medical reports" to avoid confusion and to clarify the types of reportable events that are covered by this section. The proposed term "blind study" is a common term used in all types of scientific studies, but has been removed from the definitions proposed in § 240.3 and is explained in § 240.203(a)(5) in the final-form rulemaking. The proposed term "ALARA" in § 240.3 has been removed in the final-form rulemaking. Instead, the substance of how to pursue ALARA is discussed in § 240.305. The Department reviewed all of

the proposed definitions to make sure terms are used consistently in the body of the regulation and to consider which definitions should be removed from the rulemaking.

IRRC Comments and Public Comments

One commentator questioned why the rulemaking is effective upon publication. The Board acknowledges this concern and has made this final-form rulemaking effective 90 days after publication in the *Pennsylvania Bulletin*.

Chapters 215-230

Several commentators suggested that the proposed dose of 3 Gy in the definition of “Medical reportable event for radiation-producing diagnostic or interventional X-ray procedures” in § 219.3 is too low. IRRC asked the Board to explain why 3 Gy is the appropriate dose. The Board considered the comments and changed the dose to 15 Gy in this final-form rulemaking based on recommendations of The Joint Commission—a national health care accreditation body—and the Department’s discussions with the RPAC.

IRRC and the American Association of Physicists in Medicine (AAPM) commented that the proposed definition of QMP in § 221.2 is insufficient to ensure that individuals providing the designated medical physics services are qualified to do so, and they suggest using AAPM’s or CRCPD suggested state regulations’ definition. The Board notes that AAPM’s definition is a restricted definition and, further, that the individuals providing the medical physics services are already qualified to do so. The Department solicited advice from the RPAC and other organizations in determining appropriate qualifications. The Board believes it would not be reasonable to say the individuals that have already been performing these services are not qualified to do so. Therefore, the proposed definition has not been changed in this final-form rulemaking and will allow equivalent qualifications.

Two commentators questioned whether American Registry of Radiologic Technologists (ARRT) (CT) certification is required in relation to operators subject to § 221.16(a)(2), or whether other certification such as by the Nuclear Medicine Technology Certification Board (NMTCB) would be acceptable for operators of hybrid imaging devices where CT is only used for attenuation correction and localization. The Board notes that ARRT certification in Radiology is required when operating a CT that is only used for attenuation correction. Individuals certified in NMTCB must have post-primary certification in CT to perform CT procedures.

One commentator questioned whether Physician Assistants can no longer be trained to use fluoroscopy due to changes to § 221.35a(b)(1). The Board notes that Physician Assistants are licensed by the Department of State. Subchapter G (relating to medical doctor delegation of medical services) of Title 49, Chapter 18 of the Pennsylvania Code permits all duties specified in written agreements between the supervising physician and the Physician Assistant to be performed. If those duties include fluoroscopic procedures, the Physician Assistant is permitted to perform them.

Two commentators suggested that the proposed § 221.11(c), which references protocol information in the vicinity of the control panel, include an allowance for the electronic storage of pre-programmed techniques. The Board confirms that electronic storage of protocols complies with the regulation. No change has been made in this final-form rulemaking, however, because there are numerous older models in use that still print protocols and post them near the control panel.

One commentator disagrees with proposed § 221.35a(c), which states, “At a minimum, evaluations shall include all of the following.” Instead of requiring a full evaluation after any maintenance, the commentator recommended that the QMP be allowed to make a determination to evaluate components affected. The Board notes that, if the QMP determines that maintenance did not affect the exposure rate, then no further evaluation is necessary. However, a full evaluation is still required within 14 months from the date of the prior evaluation. Therefore, no change was made in this final-form rulemaking.

One commentator recommended eliminating low-risk fluoroscopic-guided interventional procedures (FGI) from proposed § 221.35a(d). The Department discussed this comment with the RPAC and amended the definition of FGI in this final-form rulemaking to only include high-risk fluoroscopic-guided interventional procedures.

One commentator is concerned that an inspector would interpret proposed § 221.63(a) as the site being expected to follow all QA procedures described in a document published by a national organization and by the device manufacturer. The commentator believes the QMP should develop QC procedures and tolerances for therapy imaging guidance systems and states that the same should apply to proposed § 221.64(a)(2) and (a)(3). The Board notes that this final-form rulemaking stipulates that it is the QMP’s responsibility to develop QC procedures, and the Department will only inspect against those procedures—not against procedures described elsewhere.

Chapter 240

IRRC and another commentator believe the proposed definition of “ALARA” in Chapter 240 is vague and unreasonable because it sets a standard of “making every reasonable effort” to limit exposure and “taking into account economic considerations and other societal concerns.” The Board has considered these comments and deleted the proposed term “ALARA” from Chapter 240 in this final-form rulemaking. Instead, the substance of how to pursue ALARA is discussed in § 240.305 in the final-form rulemaking.

Several commentators and IRRC recommended not limiting the number of firm employees in §§ 240.102(b)(4) and 240.112(b)(5). The Board agrees and has deleted this proposed requirement from the final-form rulemaking.

One commentator questioned whether, if bidding on a large job such as a school or nursing home, the proposed regulation in § 240.310 states that they cannot test the number of locations specified by the client. The Board responds that the final-form rulemaking requires testing

practices under which protocols require a certain number of tests to be placed in specific locations. The client cannot dictate how many or where the test kits will be placed.

One commentator recommended that the certification program require adherence to all Pennsylvania home improvement contractor requirements and require each certified individual to work under a certification firm. The testing reporting should include a requirement that the certified individual responsible be included in the report, and the firm should be required to have a Home Improvement Contractor license. The Board notes that requiring certified individuals to work under a certified firm is not necessary. The name, street address and telephone number of the tester is required in the report under § 240.303(1). The main purpose of a firm is to allow firm employees without certification to perform the work under the direction of a certified individual as a cost savings measure to the industry, because it is more expensive to require all employees to be certified. If a certified individual has no employees, the individual is not required to apply for firm certification. The individual can form a business entity if required by the Home Improvement Contractor program. Therefore, no change was made in this final-form rulemaking.

One commentator observed that the radon industry was not properly represented on the RPAC because none of the members are certified testers or mitigators. The Board notes that, while there is one member on the RPAC who represents the radon industry, RPAC formed a radon subcommittee and engaged that subcommittee in developing this final-form rulemaking.

Two commentators noted the proposed requirement in §§ 240.604(c)(3)(iv), 240.605(c)(2)(iv), (d)(2)(iv), 240.606(c)(3)(iv), (d)(4)(iv), and (e)(3)(iv) for "...control and warning levels identified in...shall be adjusted when the RPE of at least 20 spike results has been calculated" may be too burdensome. The Board agrees and has amended these sections in the final-form rulemaking accordingly.

One commentator noted that there is no place to report data about passive system installations and failures. The Board clarified that there are codes for reporting passive systems into Greenport, the Department's web-based method to report radon activities. The Department will consider adding a code to Greenport for failures.

Several commentators recommended eliminating an exception for new construction in § 240.2 because new construction homes should be built in accordance with radon resistant new construction (RRNC) standards. The commentators stated that data indicates a 40 percent failure rate when builder RRNC pre-pipe is activated, which occurs because builders are not certified under these regulations to install RRNC correctly. The Board will explore removing this exemption in a future rulemaking, to allow public comment from all stakeholders.

One commentator questioned whether § 240.2(a)(5) means that a real estate agent that buys and distributes but does not place or retrieve secondary devices is exempt from the regulations, and whether a home inspector placing and retrieving secondary devices and getting the lab's report is not exempt. The Board notes that § 240.2(a)(5) does not apply to a real estate agent, but it does apply to the home inspector.

One commentator and IRRC questioned why a certified individual cannot also be a firm employee in proposed §§ 240.102(b)(2) and 240.122(b)(2). The Board has deleted the proposed language that would have prohibited a certified individual from being a firm employee in this final-form rulemaking.

Several commentators questioned what training course or exam the Department requires for new radon firm employees in proposed §§ 240.102(b)(4)(iii) and 240.112(b)(4)(iii). The Board has removed the requirement for firm employees to pass a Department-approved radon course. This requirement has been replaced in this final-form rulemaking with initial training requirements that can be given by the firm's certified individual or through a Department-approved course.

Two commentators noted that the requirement for laboratories to report the status of a radon mitigation system is burdensome because it is difficult to get the required information from the consumer. The Board recognizes this concern and has added "as available" at the end of § 240.303(1) in this final-form rulemaking so that the report forms contain all information available to the lab.

One commentator and IRRC noted that the proposed provision in § 240.309(a)(4)(v)(G) states that the mitigation system must be functioning during the test period. They recommended that the final regulation address the situation in which a mitigation system is not functional. The Board notes that § 240.309 was renumbered as § 240.310 in the final-form rulemaking and subsection (a)(4)(v)(G) was amended by adding, "[i]f the system is not functioning, the client must be notified immediately."

One commentator suggested changing § 240.309(a)(7) to ANSI/AARST MAMF-2017 instead of ANSI/AARST MSMF-2010. The Board appreciates the correction and has made the suggested change in the final-form rulemaking. In the final-form rulemaking, § 240.309 is renumbered as § 240.310.

One commentator questioned why DEP does not use all of the more current ANSI/AARST Standards instead of relying on several antiquated standards. The commentator does not see how most of the proposed regulation will aid in the effort to save lives, as was the intention of the EPA and DEP in 1987. The Board believes that the standards used in this regulation are not antiquated and provide the necessary protections to test for and mitigate radon exposure. The intent of the regulations is to ensure that radon service providers are properly trained and qualified, and the standards are being followed to reduce the public's risk to radon exposure. Therefore, no change was made in this final-form rulemaking.

G. Benefits, Costs and Compliance

Benefits

As set forth in this final-form rulemaking, users of radiation sources will be required to comply with radiation protection standards that will not only protect and benefit employees but will also protect and benefit the general public. This final-form rulemaking will ensure that trained

professionals are operating these radiation sources so that both the patient and the operator are adequately protected.

The amendments to the radon certification regulations in this final-form rulemaking add clarity to the application and reporting requirements, making it easier for the regulated community to understand what is required during each process. The amendments to the testing and mitigation protocols and quality assurance and quality control requirements ensure that the radon services provided to the public will protect public health and welfare from the dangers of radon. The quality assurance and quality control requirement amendments also benefit the regulated community by eliminating certain equipment check requirements when the equipment is not used. They also remove cross-checks and duplicate tests for testers who use continuous monitors and continuous working level monitors. This final-form rulemaking will eliminate the requirement to have one year of radon testing experience prior to certification as a radon tester. This will benefit the regulated community by simplifying and shortening the process for an individual to become certified to test for radon.

All Pennsylvania residents, including those who have tested their homes for radon and subsequently taken action to reduce high levels with a certified radon mitigation contractor, will benefit from continued strong regulatory oversight of the radon industry, by assuring that testing is done properly and that mitigation systems are installed according to Department standards.

Compliance Costs

Minor costs may be experienced regarding the amendments in this final-form rulemaking to Chapters 215-221, 223-228, 230 and 232 if businesses are not following the standard industry practices codified therein. Some requirements in the final-form rulemaking are already required by insurance companies (including Medicare and Medicaid) or are contained in technical guidance documents. Therefore, because these standards are already implemented by the regulated community, the Board does not foresee increased costs resulting from this final-form rulemaking.

The amendments to Chapter 240 in this final-form rulemaking pertaining to reinstating previously withdrawn certifications will decrease costs for, and will benefit, the regulated community which will no longer need to pay certification fees to reinstate a withdrawn certification. Depending upon the type of certification, this amendment will save a firm or individual \$450 to \$1,125 when a firm or individual seeks to reinstate a withdrawn certification. See Chapter 240, Appendix A (relating to radon certification fee schedule). The standards codified in this final-form rulemaking already common practice in the radon industry. Some minor business costs may be experienced if firms are not already following these standards. Therefore, because these standards are already implemented by the regulated community, the Board does not foresee increased costs resulting from this final-form rulemaking.

Compliance Assistance Plan

Outreach and support will be provided by regional inspectors and technical staff of the Department's Radiation Control and Radon Divisions. The majority of amendments clarify

references; definitions are self-explanatory. Assistance will be offered to explain acceptable requirements for addressing new technologies.

Paperwork Requirements

The final-form rulemaking amends various records retention requirements to a 5-year period. This change was suggested by the RPAC to promote consistency throughout the radiological health regulations. These records need not be in paper format and may be stored electronically.

The final-form rulemaking adds requirements for certified radon firms and radon firm employees to document continuing education for firm employees. Continuing education records are required to be retained for 5 years. This requirement was added to this final-form rulemaking because the proposed requirement to limit certified firms to 5 employees, which was aimed at addressing span of control issues, was removed based on comments from IRRC and the public. Requiring this documentation will allow the Department to ensure that certified individuals in responsible charge of firm activities are adequately training firm employees. These records need not be in paper format and may be stored electronically.

H. Pollution Prevention

Pollution prevention is not applicable to this rulemaking.

I. Sunset Review

The Board is not establishing a sunset date for these regulations because they are needed for the Department to carry out its statutory authority. The Department will continue to closely monitor these regulations for their effectiveness and recommend updates to the Board as necessary.

J. Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), on April 21, 2017, the Department submitted a copy of the notice of proposed rulemaking, published at 47 Pa.B. 2722 (May 13, 2017), to IRRC and the Chairpersons of the House and Senate Environmental Resources and Energy Committees for review and comment.

Under section 5(c) of the Regulatory Review Act, IRRC and the Committees were provided with copies of the comments received during the public comment period, as well as other documents when requested. In preparing the final-form rulemaking, the Department has considered all comments from IRRC, the House and Senate Committees and the public.

Under section 5.1(j.2) of the Regulatory Review Act, on (blank) , the final-form rulemaking was 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 rulemaking.

K. 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 Pa. Code §§ 7.1 and 7.2.

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

(3) This final-form rulemaking does not enlarge the purpose of the proposed rulemaking published at 47 Pa.B. 2722 (May 13, 2017).

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

L. Order of the Board

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

(a) The regulations of the Department, 25 Pa. Code Chapters 215-221, 223-228, 230, 232 and 240, are amended 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 Attorney General for review and approval as to legality and form, as required by law.

(c) The Chairperson of the Board shall submit this order and Annex A to IRRC and the Senate and House Environmental Resources and Energy Committees as required by the Regulatory Review Act (71 P.S. §§ 745.1—745.14).

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

(e) This order shall take effect 90 days after publication in the Pennsylvania Bulletin.

PATRICK McDONNELL,
Chairperson