RULES AND REGULATIONS

Title 25—ENVIRONMENTAL PROTECTION

ENVIRONMENTAL QUALITY BOARD

[25 PA. CODE CHS. 215—221, 223—228, 230, 232 AND 240]

Radiological Health

The Environmental Quality Board (Board) 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 final-form rulemaking was adopted by the Board at its meeting on June 19, 2018.

A. *Effective Date*

This final-form rulemaking will be effective 90 days after 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 Robert Schena, Assistant Counsel, Bureau of Regulatory Counsel, P.O. Box 8464, Rachel Carson State Office Building, Harrisburg, PA 17105-8464, (717) 783-8072. This final-form rulemaking is available on the Department of Environmental Protection's (Department) web site 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 (relating to radon certificiation) 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 and section 1920-A of the Administrative Code.

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 this 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" is added throughout this final-form rulemaking for time requirements based on public comments received.

The word "individual" is revised to "individual(s)" throughout Chapter 240 due to an amendment in this 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 amends 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) is 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" is 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 (relating to other medical reports) is 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" is 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 is corrected in this final-form rulemaking.

Chapter 221. X-rays in the healing arts

In § 221.2 (relating to definitions), a change is 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 is changed 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. . ." is changed to ". . .which may include certification or registration. . ." in this final-form rulemaking based on public comments. In subsection (c)(2), the term "film" is 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) is revised in this final-form rulemaking to improve clarity based on public comments expressing confusion with the proposed language. Subsection (c) is 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. . ." is 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" is changed to "or one or more of the following" for clarity.

Proposed § 221.57 (relating to facilities using CR or DR) is 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" is 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" is 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 are made in this final-form rulemaking in § 221.65(1) and (3) (relating to x-ray attenuation systems) to exempt CT systems from §§ 221.202(a) and 221.204(a)(4)(xi) (relating to performance evaluations, routine QC and surveys).

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

In § 221.204(c)(1), the proposed language is 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) is 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) is 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) is revised in this final-form rulemaking to delete the proposed addition of "Department-approved," and the proposed § 240.2(a)(5)(ii) is 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) is 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) is revised in this final-form rulemaking by removing the proposed definition of "ALARA." The proposed term "blind study" is 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" is revised in this final-form rulemaking to clarify that the measurement must be conducted in an approved chamber.

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

The proposed requirement in §§ 240.102(b)(2), 240.112(b)(2) and 240.122(b)(2) (relating to prerequisites for radon testing certification; prerequisites for radon mitigation certification; and prerequisites for radon laboratory certification) that the firm's certified individual

may not also be a firm employee is removed in this final-form rulemaking and the paragraphs were renumbered accordingly.

Proposed sections 240.102(b)(4)(ii) and 240.112(b)(4)(i) are 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 is removed in this final-form rulemaking.

Proposed §§ 240.102(b)(6)(iii) and 240.112(b)(6)(iii) are 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 under 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) is renumbered as subsection (b)(4) in each section. A new subsection (b)(6)(iv) is 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) is 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) (relating to radon testing application contents; radon mitigation application contents; and radon laboratory application contents) are amended in this final-form rulemaking to remove the proposed date of birth requirement. A new paragraph in subsection (a) of each section is 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 are 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 requirements for radon mitigation certification) is 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) (relating to requirement for radon laboratory certification) is 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) (relating to prerequisites for radon laboratory certification) is 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) is amended in this final-form rulemaking to remove the proposed date of birth requirement.

Proposed § 240.141 (relating to withdrawal of applications and certifications) is 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) is 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) is amended in this final-form rulemaking to explain what a blind study is.

Section 240.302(a) (relating to required client information) is 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) is amended in this final-form rulemaking to add "as available" to the end of the subsection. This revision is 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) is amended in this final-form rulemaking to replace the word "of" with "after" to clarify when mitigation reporting should occur.

Section 240.303(3) is 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" is changed to "certified tester" and the proposed phrase "certified individual" to "certified laboratory" to clarify reporting responsibility to the client.

Section 240.303(4) is 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) is 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) is 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) is 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 this final-form rulemaking:

- The proposed heading is amended to "Radon mitigation standards for detached and attached residential buildings three stories or less in height."

- A new subsection (a) is 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 are renumbered accordingly.

• Proposed subsections (a)(2) and (a)(3) are removed.

• Proposed subsection (a)(6) is renumbered as subsection (b)(5) and is amended to clarify that the termination point must be at least 5 feet horizontally from a vertical wall that extends above the roof or higher than the vertical wall. Proposed subsection (a)(7) is 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) is added to specify what the termination point must be, and proposed subsection (a)(1) is amended as final-form subsection (b)(2) to specify that a 45-degree elbow is permitted.

• Proposed subsection (b)(1) is renumbered as subsection (c)(1) and is amended 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) is renumbered as subsection (d)(1)(iii) and is amended to change the sealing of "openings or cracks in the foundation or at. . ." to "expansion or control joints." Subparagraphs (iv) and (v) are added to clarify sealing requirements for openings in the foundation and sump pits. Proposed subsection (c)(3) is 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) is amended in this final-form rulemaking to remove ". . .or that openings or cracks are inaccessible. . ."; paragraph (3)(i) is changed from heating and cooling "penalty" to "costs"; and paragraph (3)(ii) is changed from "decrease the efficiency" to "reduce the effectiveness."

• Proposed subsection (d) is renumbered as subsection (e). Subsection (e)(1)(ii) and (iii) are 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) is removed as unnecessary.

• Proposed subsection (f) is renumbered as subsection (g) and is amended to delete reference to the EPA for source material.

Proposed § 240.309 (relating to testing protocols) is 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) are 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) is amended in this final-form rulemaking to correct a grammatical error. The word "sustained" is 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, is amended in this final-form rulemaking for clarity. Subsection (a)(7) is amended in this final-form rulemaking to correct a document reference number. Subsection (a)(8) is added in this final-form rulemaking to address multifamily building mitigation, and the remainder of the subsection is renumbered. Subsection (a)(11), formerly (a)(10), is 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) are 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" is 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) is 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) (relating to QA requirements for laboratories), (d)(4)(iv) and (e)(3)(iv), pertaining to control and warning levels associated with spikes, are 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, are 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 the Department's web site at http://www.ahs.dep.pa.gov/eComment/. A summary of the major comments and responses is set forth as follows.

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 this final-form 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 previously discussed waiver requests 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. The Department and DOH have held several meetings and have been working together to ensure DOH's regulations are consistent with the Department'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 this 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 be revised in this 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 this final-form rulemaking. The proposed term "ALARA" in § 240.3 has been removed in this 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 this final-form 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 49 Pa. Code Chapter 18 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) (relating to therapy imaging guidance systems) 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 (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 this 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 this 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 this 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 Commonwealth 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 this 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% 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, "If 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 the Department 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 QA and QC requirements ensure that the radon services provided to the public will protect public health and welfare from the dangers of radon. The QA and QC 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 1 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.

Residents of this Commonwealth; 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 are 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

This 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.

This 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 this 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 August 15, 2018, this 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 August 16, 2018, and approved this final-form rulemaking.

K. *Findings*

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 final-form rulemaking.

L. *Order*

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 by adding §§ 221.16, 221.50, 221.63, 221.64, 221.65, 223.31, 230.15, 240.141—240.143, 240.310, 240.601—240.606, Appendix B and Appendix C, deleting §§ 217.133, 218.11a, 240.304, 240.501 and 240.502, and amending §§ 215.12, 215.14, 215.22, 215.24, 215.31, 215.41, 216.1, 216.2, 216.2a, 216.2b, 216.3, 217.1, 217.131, 217.132, 217.142, 217.143, 217.152, 217.162, 217.172, 217.182, 217.202, 218.1, 218.11, 219.3, 219.6, 219.229, 220.2, 220.10, 221.1, 221.2, 221.11, 221.21, 221.25, 221.35a, 221.61, 221.71, 221.201, 221.202, 221.204, 221.205, 223.1, 223.22, 224.11, 225.3a, 225.4a, 225.81, 226.5, 227.11a, 228.11a, 228.21a, 228.35, 228.36, 228.61, 228.72, 228.73, 228.75, 230.4, 232.3, 240.1—240.3, 240.101—240.104, 240.111—240.114, 240.121—240.124, 240.132, 240.133, 240.201—240.205, 240.301—240.303, 240.305—240.308 and 240.401 to read as set forth in Annex A, with ellipses referring to the existing text of the regulations.

(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

(*Editor's Note*: Chapters 224, 226 and 232 were not part of the proposed rulemaking. Amendments to §§ 224.11, 226.5 and 232.3 are included in this final-form rulemaking.)

(*Editor's Note*: Proposed § 221.57 is renumbered as § 221.50 in this final-form rulemaking.)

(*Editor's Note*: Section 240.309 was added in the final-form rulemaking published at 47 Pa.B. 6482 (October 21, 2017). Therefore, proposed § 240.309 is renumbered as § 240.310, in this final-form rulemaking.)

(*Editor's Note*: See 48 Pa.B. 5576 (September 1, 2018) for IRRC's approval order.)

Fiscal Note: Fiscal note 7-499 remains valid for the final adoption of the subject regulation.

Annex A

TITLE 25. ENVIRONMENTAL PROTECTION

PART I. DEPARTMENT OF ENVIRONMENTAL PROTECTION

Subpart D. ENVIRONMENTAL HEALTH AND SAFETY

ARTICLE V. RADIOLOGICAL HEALTH

CHAPTER 215. GENERAL PROVISIONS

RIGHTS AND RESPONSIBILITIES OF THE DEPARTMENT

§ 215.12. Inspections and investigations.

* * * * *

(a) *Maintenance of records.* Licensees and registrants shall maintain records under this article and have these records available for inspection by the Department at permanent sites for facilities of use identified in a license or registration issued under this article.

(b) *Rights of the Department.* The Department and its agents and employees will:

(1) Have access to, and require the production of, books, papers, documents and other records and physical evidence pertinent to a matter under investigation.

(2) Require a registrant or licensee to make reports and furnish information as the Department may prescribe.

(3) Enter the premises of a licensee or registrant for the purpose of making an investigation or inspection of radiation sources and the premises and facilities where radiation sources are used or stored, necessary to ascertain the compliance or noncompliance with the act and this chapter and to protect health, safety and the environment.

(4) Secure or lock-down a device if a radiation source is abandoned or poses a threat to public health, safety or the environment.

(c) *Inspections and investigations by the Department.* The Department, its employees and agents may conduct inspections and investigations of the facilities and regulated activities of registrants of radiation-producing machines and licensees of radioactive material necessary to demonstrate compliance with the act or this article.

(d) *Additional inspections and investigations.* The Department, its employees and agents may conduct additional follow-up inspections and investigations if violations of the act or regulations promulgated thereunder were noted at the time of the original inspection, or if a person presents information, or circumstances arise which give the Department reason to believe that the health and safety of a person is threatened or that the act or this article are being violated.

§ 215.14. Availability of records.

The following Department records will not be disclosed to the public or to a litigant absent a court order unless the Department determines that disclosure is in the public interest and is necessary for the Department to carry out its duties under the act:

(1) Trade secrets or secret industrial processes customarily held in confidence.

(2) A report of investigation which would disclose the institution, progress or results of an investigation undertaken by or at the direction of the Department or other governmental agency.

(3) Personnel, medical and similar records, the disclosure of which would be reasonably likely to result in a substantial and demonstrable risk of physical harm to or the personal security of an individual.

(4) Location, identification, safeguards, security measures or other security-related information relating to a radiation source.

(5) A record designated as classified by a Federal or State authority.

(6) A record exempt from disclosure under any Federal or State law or regulation, or judicial order or decree.

(7) Any other record maintained by the Department, the disclosure of which may endanger or threaten public health, safety or preparedness.

PROHIBITIONS AND RESTRICTIONS

§ 215.22. Prohibited uses.

(a) No person may operate or maintain within this Commonwealth devices or machines which use X-ray or radiologic technology for human nonmedical use without prior written approval of the Department.

(1) A person requesting the Department to approve the nonmedical human use of radiation shall submit written information describing the proposed use to the Department for evaluation.

(2) The Department will consider efficacy of the device or procedure as a factor when evaluating the proposed nonmedical human use of radiation.

(b) Hand-held fluoroscopic screens may not be used.

§ 215.24. Human use.

* * * * *

(b) Auxiliary personnel employed by a licensed practitioner of the healing arts at the location at which the licensed practitioner practices or employed by a health care facility may use radiation sources in the healing arts provided those individuals comply with the applicable requirements of 49 Pa. Code Part I, Subpart A (relating to professional and occupational affairs), located in the following chapters:

* * * * *

(7) Chapter 33 (relating to the State Board of Dentistry).

(c) Subsection (b) notwithstanding, human use of radiation sources is permitted by individuals enrolled in clinical training programs that satisfy the related accreditation requirements of the boards in subsection (b) and who are under the supervision of a licensed practitioner of the healing arts or of auxiliary personnel authorized under subsection (b) to use radiation sources in the healing arts.

EXEMPTIONS

§ 215.31. Granting exemptions.

(a) The Department may grant exemptions from this article on its own initiative or upon application from a licensee when the Department determines that the exemptions do not result in significant risk to the health and safety of the public and safeguards that provide equivalent levels of protection in this article are implemented.

(b) The Department will not grant exemptions to the fee requirements in § 218.11 (relating to registration, renewal of registration and license fees).

COMMUNICATIONS

§ 215.41. Contact Information.

Communications and reports concerning this article and applications filed under it shall be addressed to the Bureau of Radiation Protection, Department of Environmental Protection, Post Office Box 8469, Harrisburg, Pennsylvania 17105-8469; (717) 787-2480; www.dep.pa.gov.

CHAPTER 216. REGISTRATION OF RADIATION-PRODUCING MACHINES AND RADIATION-PRODUCING MACHINE SERVICE PROVIDERS

§ 216.1. Purpose and scope.

(a) This chapter establishes requirements for the registration of radiation-producing machines and radiation-producing machine service providers. A person who possesses a radiation-producing machine or provides services described in this chapter shall comply with this chapter.

(b) A person possessing an accelerator as defined in § 228.2 (relating to definitions) or a person performing electronic brachytherapy as defined in § 221.2 (relating to definitions) is exempt from the requirements of § 216.2 (relating to registration of radiation-producing machines).

(1) Accelerators are licensed under Chapter 228 (relating to radiation safety requirements for particle accelerators).

(2) Electronic brachytherapy operations are licensed under Chapter 221 (relating to X-rays in the healing arts) and must comply with §§ 221.71—221.76 (relating to therapeutic X-ray systems with energies less than 1 MeV).

(c) License fees are specified in § 218.11(d) (relating to registration, renewal of registration and license fees).

§ 216.2. Registration of radiation-producing machines.

(a) A person possessing a radiation-producing machine shall:

(1) Register with the Department within 30 days after acquisition. Registration shall be completed on forms furnished by the Department and shall contain information required on the form and accompanying instructions.

(2) Designate on the registration form an individual to be responsible for radiation protection.

(3) Notify the Department in writing within 30 days of a change in name, address, owner or the individual designated under paragraph (2) to be responsible for radiation protection.

(4) Maintain a written inventory to include, at a minimum, the type and location of all radiation-producing devices.

(5) For registrants offering mobile services, have a current schedule, including the date and location where services are to be performed, available for inspection by the Department.

(b) The registration becomes valid upon receipt of the properly completed registration form and the fee required under Chapter 218 (relating to fees).

* * * * *

§ 216.2a. Registration of radiation-producing machine service providers.

A person who engages in the business of assembling or installing radiation-producing machines or who offers to assemble or install radiation-producing machines or who is in the business of furnishing or offering to furnish radiation-producing machine servicing or services or who is in the business of selling, leasing or lending radiation-producing machines in this Commonwealth shall apply for registration of the activities with the Department prior to furnishing or offering to furnish those services.

(1) Registration is for 12 months and is renewable.

(2) An application for registration or renewal will not be accepted unless accompanied by the appropriate fee specified in § 218.11(k) (relating to registration, renewal of registration and license fees). Fees are not refundable after issuance of a registration.

(3) An application for registration shall be submitted on forms provided by the Department. The Department will issue a certificate of registration for radiation-producing machine services to the applicant when the application is complete, contains all the information required by the Department and when the appropriate fee specified in § 218.11(k) has been paid.

(4) X-ray registrants who employ in-house service providers are exempt from this section but are subject to the requirements of 21 CFR 1020.30 (relating to diagnostic X-ray systems and their major components).

§ 216.2b. Reporting and recordkeeping requirements for registered radiation-producing machine service providers.

* * * * *

(b) Services performed that do not involve replacement or refurbishing of major X-ray system components are exempt from the reporting requirements specified in this section except subsection (d).

* * * * *

(d) A radiation-producing machine service provider who services a radiation-producing machine in a radiation installation in this Commonwealth that is not registered shall report the service to the Department. The report shall be submitted in writing within 15 days after the services and contain the following information:

(1) The date service was provided.

(2) The name, address and telephone number of the client.

(3) The type of radiation-producing machine, the manufacturer's name, model number and control panel serial number of each radiation-producing machine or major X-ray system component.

(4) The name of the individual performing the service.

(e) A radiation-producing machine service provider shall comply with the requirements of Chapter 219 (relating to standards for protection against radiation).

§ 216.3. Exemptions.

The following radiation-producing machines or equipment are exempt from registration:

(1) Electrical equipment that produces radiation incidental to its operation for other purposes, if the dose equivalent rate averaged over an area of 10 square centimeters does not exceed 0.5 mrem (0.005 mSv) per hour at 5 centimeters from an accessible surface. The production, testing or factory servicing of the equipment are not exempt. Electron beam welders and electron microscopes are not exempt.

(2) Radiation-producing machines while in transit in the possession of a transport carrier.

(3) Radiation-producing machines in the possession of vendors, installers or persons engaged in the service or repair of the machines, if applicable persons who have these machines register their activities with the Department under § 216.6 (relating to transfer and disposal obligations).

(4) Accelerators, which are licensed under Chapter 228 (relating to radiation safety requirements for particle accelerators). Accelerator service providers are not exempt from registration of services under § 216.2a (relating to registration of radiation-producing machine service providers).

(5) Electronic brachytherapy operations, which are licensed under Chapter 221 (relating to X-rays in the healing arts) and comply with §§ 221.71—221.76 (relating to therapeutic X-ray systems with energies less than 1 MeV).

CHAPTER 217. LICENSING OF RADIOACTIVE MATERIAL

Subchapter A. GENERAL

§ 217.1. Purpose and scope.

* * * * *

(c) The use of radioactive material in this Commonwealth under a license issued by the NRC is exempt from the licensing requirements of this chapter.

Subchapter B. GENERAL PROVISIONS FOR RADIOACTIVE MATERIAL

§ 217.131. Incorporation by reference.

(a) Except as provided in this subchapter, the requirements of 10 CFR Part 30 (relating to rules of general applicability to domestic licensing of byproduct material) are incorporated by reference.

(b) Notwithstanding the requirements incorporated by reference, 10 CFR 30.5, 30.6, 30.8, 30.21(c), 30.34(d), (e)(1) and (3), 30.41(b)(6), 30.55, 30.63 and 30.64 are not incorporated by reference.

§ 217.132. Effect of incorporation of 10 CFR Part 30.

To reconcile differences between this subchapter and the incorporated sections of 10 CFR Part 30 (relating to rules of general applicability to domestic licensing of byproduct material), the following words and phrases shall be substituted for the language in 10 CFR Part 30 as follows:

* * * * *

(5) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR (relating to energy) shall be directed to the Department.

§ 217.133. (Reserved).

Subchapter C. GENERAL LICENSES FOR RADIOACTIVE MATERIAL

§ 217.142. Effect of incorporation of 10 CFR Part 31.

To reconcile differences between this subchapter and the incorporated sections of 10 CFR Part 31 (relating to general domestic licenses for byproduct material), the following words and phrases shall be substituted for the language in 10 CFR Part 31 as follows:

* * * * *

(5) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR (relating to energy) shall be directed to the Department.

§ 217.143. Certain measuring, gauging or controlling devices.

In addition to the parts of 10 CFR 31.5 (relating to certain detecting measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere) incorporated by reference, general licensees subject to registration under 10 CFR 31.5(c)(13)(i) or possessing general licensed devices containing 1 mCi (37 MBq) or more of cobalt-57, cadmium-109, iron-55 or accelerator-produced material, as determined on the date of manufacture, or 0.1 mCi (3.7 MBq) or more of radium-226 shall also comply with all of the following:

* * * * *

Subchapter D. SPECIFIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING RADIOACTIVE MATERIAL

§ 217.152. Effect of incorporation of 10 CFR Part 32.

To reconcile differences between this subchapter and the incorporated sections of 10 CFR Part 32 (relating to specific domestic licenses to manufacture or transfer certain items containing byproduct material), the following words and phrases shall be substituted for the language in 10 CFR Part 32 as follows:

* * * * *

(5) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR (relating to energy) shall be directed to the Department.

Subchapter F. SPECIFIC DOMESTIC LICENSES OF BROAD SCOPE FOR RADIOACTIVE MATERIAL

§ 217.162. Effect of incorporation of 10 CFR Part 33.

To reconcile differences between this subchapter and the incorporated sections of 10 CFR Part 33 (relating to specific domestic licenses of broad scope for byproduct material), the following words and phrases shall be substituted for the language in 10 CFR Part 33 as follows:

* * * * *

(5) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR (relating to energy) shall be directed to the Department.

Subchapter G. LICENSING OF SOURCE MATERIAL

§ 217.172. Effect of incorporation of 10 CFR Part 40.

To reconcile differences between this subchapter and the incorporated sections of 10 CFR Part 40 (relating to domestic licensing of source material), the following words and phrases shall be substituted for the language in 10 CFR Part 40 as follows:

* * * * *

(5) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR (relating to energy) shall be directed to the Department.

Subchapter H. LICENSING OF SPECIAL NUCLEAR MATERIAL

§ 217.182. Effect of incorporation of 10 CFR Part 70.

To reconcile differences between this subchapter and the incorporated sections of 10 CFR Part 70 (relating to domestic licensing of special nuclear material), the following words and phrases shall be substituted for the language in 10 CFR Part 70 as follows:

* * * * *

(5) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR (relating to energy) shall be directed to the Department.

Subchapter J. RECIPROCITY

§ 217.202. Effect of incorporation of 10 CFR Part 150.

To reconcile differences between this subchapter and the incorporated sections of 10 CFR Part 150 (relating to exemptions and continued regulatory authority in agree-

ment states and in offshore waters under section 274), the following words and phrases shall be substituted for the language in 10 CFR Part 150:

* * * * *

(5) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR (relating to energy) shall be directed to the Department.

CHAPTER 218. FEES

GENERAL

§ 218.1. Purpose and scope.

(a) This chapter establishes fees for registration and licensing and provides for their payment. For the purpose of this chapter, radiation-producing machines under the same administrative control in a single building are registered or licensed as a single facility. Radiation-producing machines under the same administrative control at the same address or in a contiguous group of buildings may be registered or licensed as a single facility if the Department determines that it is appropriate.

(b) Except as otherwise specifically provided, this chapter applies to a person who:

(1) Is required to register or renew registration for radiation-producing machines or radiation-producing machine service providers under Chapter 216 (relating to registration of radiation-producing machines and radiation-producing machine service providers).

(2) Is an applicant for or holder of a radioactive material license issued under Chapter 217 (relating to licensing of radioactive material).

(3) Is an applicant for or holder of an accelerator license issued under Chapter 228 (relating to radiation safety requirements for particle accelerators).

(4) Is an applicant for or holder of an electronic brachytherapy license issued under Chapter 221 (relating to X-rays in the healing arts).

PAYMENT OF FEES

§ 218.11. Registration, renewal of registration and license fees.

(a) Annual registration fees for radiation-producing machines are the sum of an annual administrative fee and an annual fee for each X-ray tube or radiation generating device and shall be paid as follows:

* * * * *

(c) Annual license fees for radioactive material shall be paid as set forth in Appendix A (relating to fees for radioactive material licenses).

* * * * *

(e) An initial application for a license or reciprocity shall be accompanied by a payment to the Department in accordance with the fee schedules in subsections (c) and (d). Thereafter, the Department will issue an annual fee invoice in accordance with the appropriate fee schedule at least 2 months prior to the license expiration. Fees shall be paid by the last day of the license expiration month as shown on the license fee invoice. This provision is not applicable to full cost recovery licenses specified in Appendix A.

(f) The Department will not accept an initial application for a license prior to payment of the fees required by subsections (c) and (d).

(g) If the registration involves more than one of the facilities in subsection (a), or if a license involves more than one of the categories in subsection (c), the highest applicable fee applies.

(h) The fee schedule in subsection (a) is not applicable to accelerators, emerging technology devices or electronic brachytherapy.

(i) Electronic brachytherapy devices are licensed under Chapter 221 (relating to X-rays in the healing arts). The annual fee is $1,000 for the first unit (controller) at the facility plus $100 for each additional unit at that facility.

(j) Emerging technology devices require Department safety review and approval prior to use. The registrant shall pay a fee equal to the full cost of Department staff time, as specified in Appendix A, for the review and approval process.

(k) A radiation-producing machine service provider shall pay an annual registration fee of $140.

(l) The Department will review the adequacy of the fees established in this section at least once every 3 years and provide a written report to the EQB. The report must identify any disparity between the amount of program income generated by the fees and the costs to administer these programs, and must contain recommendations to increase fees to eliminate the disparity, including recommendations for regulatory amendments to increase program fees.

§ 218.11a. (Reserved).

CHAPTER 219. STANDARDS FOR PROTECTION AGAINST RADIATION

Subchapter A. GENERAL PROVISIONS

§ 219.3. Definitions.

The following terms, when used in this subchapter, have the following meanings, unless the context clearly indicates otherwise:

Medical reportable event for radiation-producing diagnostic or interventional X-ray procedures—The administration to a human being, except for an administration resulting from a direct intervention of a patient that could not have been reasonably prevented by the licensee or registrant, that results in one of the following:

(i) An unintended peak skin dose to the same area in a single procedure greater than 1500 rad (15 Gy).

(ii) An unintended dose, other than skin dose, in a single procedure exceeding five times the facility's established protocol and 50 rad (0.5 Gy) to any organ.

(iii) A dose to the wrong patient, or wrong site for the entire procedure, and exceeding 50 rad (0.5 Gy) to any organ.

Medical reportable event for radiation-producing machine therapy—The administration to a human being, except for an administration resulting from a direct intervention of a patient that could not have been reasonably prevented by the licensee or registrant, that results in one of the following:

(i) An administration of a therapeutic radiation dose to the wrong individual, wrong treatment site or using a treatment delivery intended for another individual.

(ii) An administration of a dose for therapy identified in a written directive that differs from the prescribed dose for the treatment site or any other organ from the intended prescribed dose, by one of the following:

(A) More than 20% of the total prescribed dose.

(B) Exceeds 30% of the weekly prescribed dose.

(C) Exceeds 50% of a single fraction dose of a multifraction plan.

§ 219.6. Effect of incorporation of 10 CFR Part 20.

To reconcile differences between this chapter and the incorporated sections of 10 CFR Part 20 (relating to standards for protection against radiation), the following words and phrases shall be substituted for the language in 10 CFR Part 20 as follows:

* * * * *

(7) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR (relating to energy) shall be directed to the Department, except as required under 10 CFR 20.2206 (relating to reports of individual monitoring).

(8) 10 CFR Part 20, notwithstanding, exposures involving the use of X-rays may be weighted, in a manner specified by the Department, so that, with Department approval, the effective dose equivalent may be substituted for the deep dose equivalent in determining compliance with occupational exposure limits for specified groups of individuals.

Subchapter M. REPORTS

§ 219.229. Diagnostic or interventional procedure medical reports.

(a) Within 30 days of the determination by a physician of either actual or suspected acute or long-term functional damage to an organ or a physiological system of a patient exposed to radiation from a diagnostic or interventional procedure from a radiation-producing machine, the registrant or licensee shall document the finding and provide a report to the Department and provide a clinical summary to the prescribing physician and the patient. The report shall be retained for at least 5 years. Exempt from this reporting requirement are any events already reported under § 219.228 (relating to reports of medical reportable events for radiation-producing machine therapy) and any functional damage to a patient organ or a physiological system that was an expected outcome when the causative procedures were prescribed.

(b) Upon discovery of a medical reportable event, the registrant or licensee shall:

(1) Notify the Department regarding the medical reportable event within 1 business day.

(2) Provide a written report, including the analysis of the medical reportable event, by the qualified medical physicist, as defined in § 221.2 (relating to definitions), to the Department within 15 business days.

(3) Provide a clinical summary to the prescribing physician and patient within 15 business days.

(4) Maintain a record of the medical reportable event as part of the patient's permanent medical record.

CHAPTER 220. NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS; INSPECTIONS AND INVESTIGATIONS

§ 220.2. Posting of notices to workers.

(a) A licensee or registrant shall post current copies of the following documents:

(1) This chapter and Chapter 219 (relating to standards for protection against radiation).

(2) The license, certificate of registration, conditions or documents incorporated into the license by reference and amendments thereto.

(3) The operating procedures applicable to activities under the license or registration.

(4) A notice of violation involving radiological working conditions, proposed imposition of civil penalty or order issued under Chapter 215 (relating to general provisions) and response from the licensee or registrant.

(b) If posting of a document specified in subsection (a)(1), (2) or (3) is not practicable, the licensee or registrant may post a notice which describes the document and states where it may be examined.

(c) Department Form 2900-FM-BRP0003, "Notice to Employees," shall be posted by a licensee or registrant as required by this article.

* * * * *

§ 220.10. Effect of incorporation of 10 CFR Part 19.

To reconcile differences between this chapter and the incorporated sections of 10 CFR Part 19 (relating to notices, instructions and reports to workers; inspection and investigations), the following words and phrases shall be substituted for the language in 10 CFR Part 19 as follows:

* * * * *

(4) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR (relating to energy) shall be directed to the Department.

CHAPTER 221. X-RAYS IN THE HEALING ARTS

GENERAL PROVISIONS

§ 221.1. Purpose and scope.

This chapter establishes requirements for the use of X-ray equipment by or under the supervision of a licensed practitioner of the healing arts. A registrant or licensee who uses X-rays in the healing arts shall comply with this chapter. This chapter is in addition to, and not in substitution for, other applicable provisions of this article.

§ 221.2. Definitions.

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

AAPM—American Association of Physicists in Medicine.

Air kerma—Kerma in air.

Air kerma rate—Air kerma per unit time.

Aluminum equivalent—The thickness of type 1100 aluminum alloy—the nominal chemical composition of type 1100 aluminum alloy is 99% minimum aluminum, 0.12% copper—affording the same attenuation, under specified conditions, as the material in question.

Automatic exposure control—A device which automatically controls one or more technique factors to obtain at preselected locations a desired quantity of radiation.

Beam axis—A line from the source through the centers of the X-ray fields.

Beam-limiting device—A device providing a means to restrict the dimensions of the X-ray field.

CBCT—Cone beam computed tomography—A digital volume tomography method used in some imaging applications using two-dimensional digital detector arrays and a cone-shaped X-ray beam, instead of fan-shaped, that

rotates around to generate a high-resolution 3D image with high geometric accuracy. Reconstruction algorithms can be used to generate images of any desired plane.

CINE—Cineradiography—A motion picture record of successive images appearing on a fluoroscopic screen.

CR—Computed radiography—A digital X-ray imaging method in which a photo-stimulable phosphor is used to capture and store a latent image. The latent image is read out by stimulating the phosphor with a laser. CR systems may use cassettes to house the phosphor or it may be integrated into a DR system.

CT—Computed tomography—The production of a tomogram by the acquisition and computer processing of X-ray transmission data.

Cephalometric device—A device intended for the radiographic visualization and measurement of the dimensions of the human head.

* * * * *

Control panel—The part of the X-ray control upon which are mounted the switches, knobs, pushbuttons and other hardware necessary for manually setting the technique factors.

DDR—Direct digital radiography—An X-ray imaging method in which a digital sensor, usually incorporating a thin-film transistor, is used to capture an X-ray image. Some DDR systems use a scintillator to convert X-rays to light and a photodiode array to convert light to charge, while others use a photoconductor to convert X-rays directly to charge, which is stored on the thin-film transistor.

DR—Digital radiography—

(i) An X-ray imaging method (or radiography) which produces a digital rather than film projection image.

(ii) The term includes CR and DDR.

DRL—Diagnostic reference level—An investigational level, set as a standard by a recognized body (for example, the American College of Radiology, the American Association of Physicists in Medicine, the National Council on Radiation Protection and Measurements or similar), used to identify unusually high radiation doses for common diagnostic medical X-ray imaging procedures. DRLs are suggested action levels above which a facility should review its methods and determine if acceptable image quality can be achieved at lower doses. DRLs should not be applied to an individual patient.

Dead-man switch—A switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

Dental panoramic system—A device intended to produce a radiographic image of both dental arches on one film.

Diagnostic source assembly—The tube housing assembly with a beam-limiting device attached.

Diagnostic X-ray system—An X-ray system designed for irradiation of a part of the human body for the purpose of diagnosis or visualization.

Direct supervision—A licensed practitioner of the healing arts who exercises general supervision and is present in the facility and immediately available to furnish assistance and direction throughout the performance of the procedure. The licensed practitioner does not have to be present in the room when the procedure is being performed.

Dose length product—The indicator of the integrated radiation dose from a complete CT examination. It addresses the total scan length by the following formula:

$$\text{DLP (mGy} - \text{cm)} = \text{CTDI}_{\text{vol}} \text{ (mGy)} \times \text{scan length (cm)}$$

Electronic brachytherapy—A modality of radiation therapy where an electrically generated source of ionizing radiation is placed in or near the tumor or target tissue to deliver therapeutic radiation dosage. X-ray devices specifically designed and solely used to treat skin cancer lesions are not considered electronic brachytherapy devices under this definition and must meet the applicable parts of this title pertaining to registration and use.

Emerging technology—An innovative medical technology that uses an ionizing radiation source.

Entrance exposure rate—The exposure in air per unit time at the point where the center of the useful beam enters the patient.

FGI—Fluoroscopic-guided interventional procedures—An interventional diagnostic or therapeutic HIGH-RISK procedure performed by means of percutaneous or other access routes, usually with local anesthesia or intravenous sedation, which uses external ionizing radiation in the form of fluoroscopy to do all of the following:

(i) Localize or characterize a lesion, diagnostic site or treatment site.

(ii) Monitor the procedure.

(iii) Control and document the procedure.

Field emission equipment—Equipment using an X-ray tube in which electrons are emitted from the cathode solely by the force between an electric field and the electrons.

Filter—Material placed in the useful beam to modify the spectral energy distribution and flux of the transmitted radiation and preferentially absorb selected radiation.

Filtration—The amount of material placed in the useful beam to modify the radiation's characteristics, typically expressed in terms of millimeters of aluminum or copper equivalent.

Fluoroscopic imaging assembly—A subsystem in which X-ray photons produce a fluoroscopic image. The term includes the image receptors such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

Fluoroscopic system—See fluoroscopic imaging assembly.

Focal spot—The area projected on the anode of the X-ray tube by the electrons accelerated from the cathode and from which the useful beam originates.

General supervision—The overall direction and control of a licensed practitioner of the healing arts. The licensed practitioner is not required to be present during the performance of the procedure.

HVL—Half-value layer—

(i) The thickness of specified material which attenuates the exposure rate by 1/2 when introduced into the path of a given beam of radiation. In this definition, the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

(ii) The term is used to describe the penetrating ability of the radiation.

Healing arts screening—The testing of human beings using X-ray machines for the detection or evaluation of health indications when the tests are not specifically and individually ordered for the purpose of diagnosis or treatment by a licensed practitioner of the healing arts legally authorized to prescribe the X-ray tests.

Health physics—An application of physics concerned with protection of people and the environment from the biological effects of radiation.

High-risk procedure—Any radiologic procedure that uses energies of less than 1 million electron volts that could exceed skin doses of 200 rad (2.0 Gy).

IORT—Intraoperative radiation therapy—A modality of therapy in which therapeutic levels of ionizing radiation are applied to a target area, such as a cancer tumor, while the area is exposed during surgery.

Image intensifier—An image receptor with electronic amplification, installed in its housing, which instantaneously converts an X-ray pattern into a corresponding light image of higher energy density.

Image receptor—A device, such as a fluorescent screen or radiographic film, which transforms incident X-ray photons either into a visible image or into another form which can be made into a visible image by further transformations.

Intensifying screen—A fluorescent screen which transforms incident X-ray photons into a visible image.

Intraoral dental radiography—A modality of dental radiography in which the image receptor is placed inside a patient's oral cavity.

kV—Kilovolts

kVp—Peak tube potential (see kilovolts peak).

Kerma—A measure of energy transferred from radiation to matter and means kinetic energy released per unit mass. It is related to, but not the same as, absorbed dose. Unit of measure is gray.

Kilovolts peak (kVp)—The maximum value of the potential difference across the X-ray tube during an exposure.

* * * * *

Line-voltage regulation—The difference between the no-load and the load line potentials expressed as a percent of the load line potential calculated using the following equation:

Percent line-voltage regulation = $100\ (V_n - V_1)/V_1$

where

V_n = No-load line potential and

V_1 = Load line potential.

Low-risk procedure—Any radiologic procedure that is not a high-risk procedure.

mA—Milliampere.

mAs—Milliampere second.

mR—Milliroentgen.

Maximum line current—The root-mean-square current in the supply line of an X-ray machine operating at its maximum rating.

Medical physics—An application of physics that addresses the needs of medicine or health care. Subfields of medical physics include the following:

(i) Therapeutic medical physics.

(ii) Diagnostic medical physics or imaging.

(iii) Nuclear medical diagnostic or molecular imaging and therapy.

(iv) Medical health physics or radiation protection.

Mobile X-ray system—See X-ray equipment.

Patient—An individual subjected to healing arts examination, diagnosis or treatment.

Peak tube potential—The maximum value of the potential difference across the X-ray tube during an exposure.

Performance phantom—A device specifically approved by the QMP or QE for evaluation of operational conformance with tolerances established by the QMP, QE or manufacturer.

Personal supervision—A licensed practitioner of the healing arts who exercises general supervision and is present in the room or adjacent control area during the performance of the procedure.

Phototimer—A method for controlling the radiation exposures to an image receptor by measuring the radiation which reaches a radiation monitoring device. The radiation monitoring device is part of an electronic circuit which controls the duration of time the tube is activated.

* * * * *

Protective barrier—A barrier of radiation absorbing material used to reduce radiation exposure. The term includes the following types:

(i) *Primary protective barrier*—Material used to reduce radiation exposure from the useful beam.

(ii) *Secondary protective barrier*—Material used to reduce exposure from stray, leakage or scattered radiation.

QE—Qualified expert—The term as defined in § 215.2 (relating to definitions).

QMP—Qualified medical physicist—An individual who is competent to independently provide clinical professional services and practices only in health or radiological physics, or in the subfields of medical physics.

(i) A QMP meets all of the following credentials:

(A) Certified in the field of medical physics, radiological physics, medical health physics or health physics by an appropriate national certifying body recognized by the Department.

(B) Complies with the certifying body's requirements for continuing education and recertification.

(C) Provides clinical professional services and practices only in health/radiological physics or in one or more of the subfields of medical physics, consistent with the individual's training and experience, and in accordance with the individual's respective certifying body's code of ethics.

(ii) An individual who does not meet the requirements of subparagraph (i) shall meet each of the following credentials to qualify as a QMP:

(A) Has earned a master's or doctoral degree, or both, in physics, medical physics, biophysics, radiological physics, health physics or equivalent disciplines from an accredited college or university.

(B) Has 3 years of documented relevant clinical training and experience in each of the subfields in the definition of "medical physics," under the supervision of a

QMP who is qualified to practice in the same subfield, for each of the areas in which the individual intends to practice.

(C) Completes the continuing education requirements of an applicable certifying body of health/radiological physics or in one or more of the subfields of medical physics in which the individual practices.

(iii) An individual who has been practicing as a QMP in health/radiological physics or in one or more of subfields of medical physics for at least 5 years prior to January 24, 2019, is exempt from the requirements of subparagraphs (i) and (ii). Documentation of at least 5 years of practicing as a QMP in health/radiological physics or in one or more of the subfields of medical physics must be maintained for each of the fields or subfields, or both, in which the individual practices. As of January 24, 2019, an individual who qualifies as a QMP under this subparagraph shall meet the continuing education requirements in subparagraph (ii)(C).

Radiation therapy simulation system—A radiographic or fluoroscopic X-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

Radiograph—An image receptor on which an image is created directly or indirectly by an X-ray pattern and results in a permanent record.

Radiographic imaging system—A system whereby an image is produced on an image receptor by the action of ionizing radiation.

Radiological physics—See health physics.

Rating—The operating limits specified by the component manufacturer.

Registrant—A person who is legally obligated to register with the Department under this article and the act.

Research—One of the following:

(i) Theoretical analysis, exploration or experimentation.

(ii) The extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental testing of models, devices, equipment, materials and processes. The term includes the external administration of X-ray radiation to human beings for diagnostic or therapeutic purposes or in an equivalent manner as a diagnostic or therapeutic procedure.

SID—Source-image receptor distance—The distance from the source to the center of the input surface of the image receptor.

SRDL—Substantial radiation dose level—An appropriately selected dose used to trigger additional dose-management actions during a procedure and medical follow-up for a radiation level that might produce a clinically relevant injury in an average patient.

SSD—The distance between the source and the skin of the patient.

Scattered radiation—Radiation that, during passage through matter, has been deviated in direction.

* * * * *

Tube housing assembly—The tube housing with the X-ray tube installed. The term includes high-voltage or filament transformers, or both, and other appropriate elements when contained within the tube housing.

Unintended dose—A radiation dose in diagnostic or interventional X-ray resulting from an error in procedure or equipment malfunction.

Useful beam—The radiation which passes through the tube housing port and the aperture of the beam-limiting device when the exposure switch or timer is activated.

* * * * *

ADMINISTRATIVE CONTROLS

§ 221.11. Registrant responsibilities.

(a) The registrant is responsible for directing the operation of X-ray systems under his administrative control and shall assure that the requirements of this article are met in the operation of the X-ray systems.

(b) An individual who operates an X-ray system shall be instructed adequately in the safe operating procedures and be competent in the safe use of the equipment. The instructions shall include items included in Appendix A (relating to determination of competence) and there shall be continuing education in radiation safety, biological effects of radiation, quality assurance and quality control.

(1) The operator or the individual who supervises the operation of a high-risk procedure shall have additional instruction, which may include certification or registration in the applicable specialty by a professional organization recognized by the Department. Continuing education for high-risk procedures shall occur, at a minimum, every 2 years.

(2) Continuing education for all other (low-risk) procedures shall occur, at a minimum, every 4 years.

(c) Protocol information, which specifies the techniques for examinations performed with the system, shall be provided in the vicinity of each diagnostic X-ray system's control panel. The protocol shall include information pertinent to the particular examination, such as:

(1) The patient's body part and anatomical size, or body part thickness, or age (for pediatrics), versus technique factors to be utilized.

(2) The type and size of the image receptor or film-screen combination.

(3) The type of grid, if any.

(4) The type and location of placement of patient shielding, for example, gonad, and the like.

(5) For mammography, indication of kVp/target/filter combination.

(6) Source to image receptor distance to be used, except for dental intraoral radiography.

* * * * *

(l) The registrant shall have a quality assurance program. This quality assurance program shall be documented and be in accordance with guidelines established by the Department or by another appropriate organization recognized by the Department. At a minimum, the quality assurance program shall address repeat rate, DRLs, image recording, processing and viewing, image quality and artifacts, and maintenance and modifications to the quality assurance program. For CT, each study shall be checked. If an artifact is present, the registrant shall take corrective action as appropriate. Records shall be maintained by the registrant for inspection by the Department for 5 years. The Department's guidelines and a list of recognized organizations will be maintained and made available on the Department's website and on request.

(m) Neither the X-ray tube housing nor the collimating device may be handheld during the exposure unless specifically designed to be handheld.

(n) Functional damage to a patient organ or a physiological system that results from a prescribed causative procedure shall be reported to the Department as outlined in § 219.229 (relating to diagnostic or interventional procedure medical reports).

(o) The registrant shall maintain records documenting the QMP's qualifications and compliance with continuing education requirements.

§ 221.16. Training, competency and continuing education.

(a) *Training and competency.* The registrant shall ensure that:

(1) An individual who operates X-ray equipment during diagnostic or interventional procedures or supervises the operation of X-ray equipment during a procedure is trained and competent in all of the following subject areas, as applicable to the procedures performed and the specific equipment utilized:

(i) Basic properties of radiation.

(ii) Units of measurement.

(iii) Sources of radiation exposure.

(iv) Methods of radiation protection for patients and others.

(v) Biological effects of radiation exposure.

(vi) Facility-specific and modality-specific X-ray equipment.

(vii) Facility-specific and modality-specific image recording and processing.

(viii) Patient exposure and positioning.

(ix) Facility-specific and modality-specific procedures.

(x) Facility-specific and modality-specific quality assurance.

(xi) Facility-specific and modality-specific dose reduction, monitoring and recording procedures.

(xii) Units of measurement and dose, such as dose-area product values, CT dose index and air kerma.

(xiii) Factors affecting fluoroscopic outputs.

(xiv) High-level control options.

(xv) Dose management including dose reduction techniques, monitoring and recording.

(xvi) Principles and operation of the specific fluoroscopic X-ray system to be used.

(xvii) Fluoroscopic and fluorographic outputs of each mode of operation on the system to be used clinically.

(xviii) Applicable State and Federal regulations.

(2) An individual who operates X-ray equipment during potentially high-risk diagnostic or interventional procedures or supervises the operation of X-ray equipment during these procedures is registered or credentialed and privileged in the applicable specialty by a professional organization recognized by the Department.

(3) Documentation demonstrating compliance with this section is maintained for inspection by the Department.

(b) *Continuing education.*

(1) The registrant shall ensure that individuals who operate X-ray equipment during diagnostic or interventional procedures or supervise the operation of X-ray equipment during a procedure complete continuing education in biological effects of radiation, quality assurance and quality control, and radiation safety, including concepts for minimizing patient and occupational dose and emerging technologies.

(i) An individual who performs low-risk procedures shall complete continuing education every 4 years.

(ii) An individual who performs high-risk procedures shall complete continuing education every 2 years. In addition to the topics in this paragraph, the continuing education must include facility and X-ray unit-specific methods to manage patient dose.

(2) Documentation of continuing education must be maintained for inspection by the Department for 5 years.

DIAGNOSTIC INSTALLATIONS GENERAL REQUIREMENTS

§ 221.21. Diagnostic equipment requirements.

(a) Diagnostic systems incorporating one or more certified components shall comply with 21 CFR 1020.30—1020.33.

(b) Equipment registered after _____, (*Editor's Note*: The blank refers to the effective date of adoption of this final rulemaking.) must comply with 21 CFR 1010.2 (relating to certification).

§ 221.25. Beam quality.

(a) Diagnostic X-ray systems shall have filtration that satisfies the requirements of Table I. The requirements of this section shall be considered to have been met if it can be demonstrated that the half value layer of the primary beam is not less than that shown in Table II.

TABLE I

Filtration Required vs. Operating Voltage

Operating Voltage (kVp)	*Total Filtration (inherent plus added) (millimeters aluminum equivalent)*
Below 50	0.5 millimeters
50—70	1.5 millimeters
Above 70	2.5 millimeters

TABLE II

X-Ray Tube Voltage (kilovolt peak)

Design Operating Range	*Measured Operating Potential*	*Minimum HVL (mm of Aluminum)*		
		Specified Dental Systems[1]	*Other X-Ray Systems*[2]	*Other X-Ray Systems*[3]
Below 51	30	1.5	0.3	0.3
	40	1.5	0.4	0.4
	50	1.5	0.5	0.5
51 to 70	51	1.5	1.2	1.3
	60	1.5	1.3	1.5
	70	1.5	1.5	1.8
Above 70	71	2.1	2.1	2.5
	80	2.3	2.3	2.9
	90	2.5	2.5	3.2
	100	2.7	2.7	3.6
	110	3.0	3.0	3.9
	120	3.2	3.2	4.3
	130	3.5	3.5	4.7
	140	3.8	3.8	5.0
	150	4.1	4.1	5.4

[1] Dental X-ray systems designed for use with intraoral image receptors and manufactured after December 1, 1980.

[2] Dental X-ray systems designed for use with intraoral image receptors and manufactured before or on December 1, 1980, and all other X-ray systems subject to this section and manufactured before June 10, 2006.

[3] All X-ray systems, except dental X-ray systems designed for use with intraoral image receptors, subject to this section and manufactured on or after June 10, 2006.

Note: Half-value layers for kilovoltages not listed in Table II may be determined by interpolation or extrapolation.

(b) Beryllium window tubes shall have a minimum of 0.5 millimeter aluminum equivalent filtration permanently installed in the useful beam.

* * * * *

§ 221.35a. Fluoroscopic X-ray systems.

(a) *General requirements.* Fluoroscopic X-ray systems shall use an image intensifier and, in addition to the requirements of §§ 221.1—221.34a, shall meet the requirements of §§ 221.36a—221.38a (relating to limitation of useful beam of fluoroscopic equipment; activation of fluoroscopic tube; and entrance exposure rate).

(b) *Operator qualifications.* In addition to the applicable sections of these regulations, the operation of a fluoroscopic X-ray system for clinical purposes is limited to:

(1) A licensed practitioner working within his scope of practice.

(2) A Department-recognized radiologist assistant working within his scope of practice and under the direct supervision of a licensed practitioner working within his scope of practice.

(3) An individual who passed the American Registry of Radiologic Technologists exam or equivalent, holds a valid certification and is under the personal supervision of a licensed practitioner working within his scope of practice.

(4) A medical resident, radiologist assistant or radiologic technology student in training who is under the personal supervision of a licensed practitioner working within his scope of practice.

(c) *QMP evaluations.* Fluoroscopic equipment shall be evaluated by or under the direction of a QMP within 30 days after installation and after any maintenance of the system that may affect the exposure rate. Thereafter, evaluations shall be made at intervals not to exceed 14 months from the date of the prior evaluation by or under the direction of a QMP. At a minimum, evaluations shall include all of the following:

(1) A measurement of entrance exposure rates over a representative range of attenuating materials in all modes clinically used, including fluoroscopy, high-level control, acquisition and CINE, when available. Measurements shall be performed with a dosimetry system calibrated within 2 years preceding the measurements. Records of these output measurements shall be maintained for 5 years for inspection by the Department. Measurements shall be made as follows:

(i) For systems without automatic exposure control, by utilizing an mA and kVp typical of the clinical use of the fluoroscopic system.

(ii) For systems with automatic exposure control, by utilizing sufficient attenuating material in the useful beam to produce an mA and kVp typical of the clinical use of the fluoroscopic system.

(2) A measurement and verification of compliance with maximum air kerma rate for fluoroscopy and high-level control, if available.

(3) An evaluation of high-contrast resolution and low-contrast resolution in both fluoroscopic and spot-film or digital acquisition modes.

(4) An evaluation of the operation of the 5-minute timer, warning lights, interlocks and collision sensors.

(5) An evaluation of the beam quality.

(6) An evaluation of the collimation in the fluoroscopy and spot-film or digital acquisition modes.

(7) An evaluation of the availability and accuracy of technique indicators and integrated radiation dose displays.

(8) An evaluation of any changes that may impact patient and personnel exposure.

(d) *Additional requirements for facilities performing FGI.*

(1) The registrant utilizing FGI studies shall establish and implement written procedures, or procedures documented in an electronic reporting system, that include all of the following:

(i) Identification of individuals who are authorized to use fluoroscopic systems for interventional purposes.

(ii) A method to be used to monitor patient radiation dose during FGI.

(iii) Dose notification levels, as appropriate, at which the physician is notified for actions that may be taken for patient safety.

(iv) SRDL values referencing or consistent with nationally-recognized standards.

(v) Actions to be taken for cases when an SRDL is exceeded, which may include patient follow-up.

(vi) A review of the established procedures at an interval not to exceed 12 months.

(2) Records of policies and procedures shall be maintained for inspection by the Department. If the registrant revises a policy or procedure, documentation shall be maintained that includes the justification for the revision.

(3) A record of radiation output information shall be maintained so the radiation dose to the skin may be estimated in accordance with established protocols. The record must include all of the following:

(i) Patient identification.

(ii) Type and date of examination.

(iii) Identification of the fluoroscopic system used.

(iv) Peak skin dose, cumulative air kerma or dose area product used if the information is available on the fluoroscopic system.

(4) If the peak skin dose, cumulative air kerma or dose area product is not displayed on the fluoroscopic system, records must include other information necessary to estimate the radiation dose to the skin in accordance with established protocol or one or more of the following:

(i) Fluoroscopic mode, such as high-level or pulsed mode of operation.

(ii) Cumulative fluoroscopic exposure time.

(iii) Number of films or recorded exposures.

(5) The registrant shall maintain records for 5 years for inspection by the Department.

§ 221.50. Facilities using CR or DR.

(a) When exposure indicators are available, the facility shall establish, document and post an acceptable range for the exposure values for examinations routinely performed at the facility. The indicated exposure values for each image shall be compared to the established range. Consistent deviations from established ranges shall be investigated, corrective actions taken as necessary and results documented.

(b) Facilities shall establish and follow an image QC program in accordance with the recommendations of a QMP, the system manufacturer or a nationally-recognized organization.

(c) Facilities other than dental, podiatric and veterinary shall complete phantom image evaluation using a phantom approved by a QMP, system manufacturer or the Department. The evaluation shall be completed on a quarterly basis and include, at a minimum, all of the following:

(1) Artifacts.

(2) Spatial resolution.

(3) Contrast/noise.

(4) Workstation monitors.

(5) Exposure indicator constancy.

(d) In addition to subsections (a)—(c), CR facilities shall erase all CR cassettes, at a minimum, on a weekly basis.

(e) Dental and podiatric facilities shall maintain and operate photostimulable storage phosphor and DDR systems in accordance with manufacturer specifications.

(f) The facility shall maintain records for 5 years for inspection by the Department.

OTHER SYSTEMS

§ 221.61. Radiation therapy simulation systems.

(a) Fluoroscopic systems used solely for radiation therapy simulations shall only comply with §§ 221.35a(a) and (b), 221.37a, 221.40a and 221.41a. The requirements in § 221.41a (relating to fluoroscopic timer) may also be satisfied if a means is provided to indicate the cumulative time that an individual patient has been exposed to X-rays. In this case, procedures shall require that the timer be reset between examinations.

(b) CT units used solely for therapy simulations shall comply with §§ 221.202(h)(1), (7) and (8) and 221.203 (relating to equipment requirements; and facility design requirements).

§ 221.63. Therapy imaging guidance systems.

(a) The QMP shall develop QC procedures and tolerances for therapy imaging guidance systems following nationally-recognized standards or those recommended by the manufacturer.

(b) If a system is a CBCT, it must conform to the requirements of § 221.64 (relating to CBCT).

§ 221.64. CBCT.

(a) The following radiation measurements shall be evaluated annually and as soon as practical after a component repair or change which, in the opinion of the QMP or QE, may affect the performance of the CBCT unit:

(1) *Beam alignment.* The X-ray field in the plane of the image receptor may not exceed beyond the edge of the image receptor by more than 2% of the SID, when the axis of the X-ray beam is perpendicular to the plane of the image receptor. In addition, the center of the X-ray field must be aligned with the center of the image receptor to within 2% of the SID.

(2) A performance evaluation shall be performed by or under the direct supervision of a QMP or QE. The evaluation shall follow nationally-recognized standards and tolerances or those recommended by the manufacturer. The evaluation shall be performed within 30 days of initial installation, at intervals not to exceed 14 months, and within 30 days after any change or replacement of components which could cause a change in the radiation output or image quality.

(3) The registrant shall document and implement QC guidelines in accordance with nationally-recognized guidelines.

(4) The registrant shall document and implement a policy addressing deviations from established protocols.

(5) In addition to the requirements of § 221.16 (relating to training, competency and continuing education), the CBCT X-ray system shall only be operated by an individual who has been specifically trained in its operation.

(6) The facility shall maintain documentation of the established standards and tolerances and testing results for 5 years for inspection by the Department.

(b) The CBCT operator shall have instructions on all of the following:

(1) Performing routine QC, including the use of the CBCT phantom.

(2) A schedule of routine QC appropriate for the system.

(3) Allowable variations set by the QMP, if required, for the indicated parameters.

(4) The results of at least the most recent routine QC completed on the system.

(c) CBCT systems are exempt from § 221.202(a) (relating to equipment requirements).

§ 221.65. X-ray attenuation systems.

CT systems solely used to calculate attenuation coefficients or for image registration in nuclear medicine studies must meet the requirements in §§ 221.202—221.205 unless otherwise exempted as follows:

(1) CT systems identified in this section are exempt from §§ 221.202(a) and 221.204(a)(4)(xi) (relating to equipment requirements; and performance evaluations, routine QC and surveys).

(2) Instead of § 221.204(a) (relating to performance evaluations, routine QC and surveys), the registrant shall complete a performance evaluation on the CT system following the recommendations of a QMP, the system manufacturer or a nationally-recognized organization at intervals not to exceed 14 months.

(3) Instead of § 221.204(b), checks shall be established and documented by the registrant following nationally-recognized guidelines or those recommended by the manufacturer.

THERAPEUTIC X-RAY SYSTEMS WITH ENERGIES LESS THAN 1 MEV

§ 221.71. Equipment requirements.

* * * * *

(m) Unless it is possible to bring the X-ray output to the prescribed exposure parameters within 5 seconds, the entire useful beam shall be automatically attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly.

(1) After the unit is at operating parameters, the shutter shall be controlled electrically by the operator from the control panel.

(2) An indication of shutter position must appear at the control panel.

(n) Electronic brachytherapy devices are exempt from the requirements in subsections (k)—(m).

COMPUTED TOMOGRAPHY X-RAY SYSTEMS

§ 221.201. Definitions.

In addition to the definitions in §§ 215.2 and 221.2 (relating to definitions), the following words and terms, when used in this section and §§ 221.202—221.205, have the following meanings, unless the context clearly indicates otherwise:

Alert value—A dose index value (for example, $CTDI_{vol}$ (mGy) or of DLP (mGy-cm)) that is set by the registrant or licensee, or both, to trigger an alert to the operator prior to scanning within an ongoing examination. The alert value represents a value well above the registrant's or licensee's established range for the examination that warrants more stringent review and consideration before proceeding.

CS—Contrast scale—The change in the linear attenuation coefficient per CT number relative to water; that is:

$CS = (U_x - U_w)/((CT)_x - (CT)_w)$

Where:

U_x = Linear attenuation coefficient of the material of interest

U_w = Linear attenuation coefficient of water

$(CT)_x$ = CT number of the material of interest

$(CT)_w$ = CT number of water

CT—Computed tomography—The production of a tomogram by the acquisition and computer processing of X-ray transmission data.

CT conditions of operation—The selectable parameters governing the operation of a CT X-ray system including, but not limited to, nominal tomographic section thickness, filtration and the technique factors as defined in this chapter.

CT dosimetry phantom—The phantom used for determination of the dose delivered by a CT X-ray system.

CT number—The number used to represent the X-ray attenuation associated with each elemental area of the CT image:

$$\overline{CTN} = \frac{k(\mu_x - \mu_w)}{\mu_w}$$

where:

k = A constant, a normal value of 1,000 when the Hounsfield scale of CTN is used.

μ_x = Linear attenuation coefficient of the material of interest.

μ_w = Linear attenuation coefficient of water.

CTDI—Computed tomography dose index—

(i) The integral of the dose profile along a line perpendicular to the tomographic plane divided by the product of

the nominal tomographic section thickness and the number of tomograms produced in a single scan.

$$CTDI = \frac{1}{NT}\int_{-\infty}^{\infty} D(z)dz\ ,$$

where:

z = Position along a line perpendicular to the tomographic plane.

D(z) = Dose at position z.

T = Nominal tomographic section thickness (cm).

N = Number of tomograms produced in a single scan.

(ii) This definition assumes that the dose profile is centered around z = 0 and that, for a multiple tomogram system, the scan increment between adjacent scans is NT.

$CTDI_{100}$—An accumulated multiple scan dose at the center of a 100-mm scan that requires integration of the radiation dose profile from a single axial scan over specific integration limits. In the case of $CTDI_{100}$, the integration limits are +50 mm, which corresponds to the 100-mm length of the commercially available "pencil" ionization chamber. $CTDI_{100}$ is acquired using a 100-mm long, 3-cc active volume CT "pencil" ionization chamber, one of the two standard CTDI acrylic phantoms (16 and 32 cm diameter) and a stationary patient table.

$CTDI_{vol}$—Volume Computed Tomography Dose Index—A radiation dose parameter derived from the $CTDI_w$ (weighted or average CTDI given across the field of view), that is:

$CTDI_{vol} = (N)(T)(CTDI_w)/I$,

where:

N = number of simultaneous axial scans per X-ray source rotation,

T = thickness of one axial scan (mm), and

I = table increment per axial scan (mm).

Thus,

$CTDI_{vol} = (1 / pitch) \times CTDI_w$

$CTDI_w$—Weighted Computed Tomography Dose Index—The estimated average $CTDI_{100}$ across the field of view. The equation is:

$CTDI_w = 1/3\ CTDI_{100}.center + 2/3\ CTDI_{100}.edge$

Where 1/3 and 2/3 approximate the relative areas represented by the center and edge values derived using the 16 cm or 32 cm acrylic phantom. $CTDI_w$ uses $CTDI_{100}$ and an f-factor for air (0.87 rad/R for exposure or 1.0 mGy/mGy for air kerma measurements).

Detector—A device that provides a signal or other indication suitable for measuring one or more quantities of incident radiation.

Dose profile—The dose as a function of position along a line.

Elemental area—The smallest area within a tomogram for which the X-ray attenuation properties of a body are depicted.

Gantry—The tube housing assemblies, beam-limiting devices, detectors, transformers, if applicable, and the supporting structures and frames which hold these components.

Lux—A unit illumination equivalent to 1 lumen per square centimeter or 0.0929 foot-candles.

Modulation transfer function—The modulus of the Fourier transform of the impulse response of the system.

Multiple tomogram system—A CT X-ray system which obtains X-ray transmission data simultaneously during a single scan to produce more than one tomogram.

Noise—The standard deviation of the fluctuations in the CT number expressed as a percentage of the attenuation coefficient of water. Its estimate (S_n) is calculated using the following expression:

$S_n = 100 \times CS \times S/U_w$

Where:

CS = Contrast scale

U_w = Linear attenuation coefficient of water.

S = Estimated standard deviation of the CT number of picture elements in a specified area of the CT image.

Nominal tomographic section thickness—The full-width at half-maximum of the sensitivity profile taken at the center of the cross-sectional volume over which X-ray transmission data are collected.

Notification value—A dose index value (for example, $CTDI_{vol}$ (mGy) or DLP (mGy-cm)) that is set by the registrant to trigger a notification to the operator prior to scanning when the dose index exceeds the established range for the examination.

Performance phantom—A phantom which has a capability of providing an indication of CS, noise, nominal tomographic section thickness, the resolution capability of the CT system for low and high contrast objects, and measuring the mean CT number for water or other reference materials.

* * * * *

§ 221.202. Equipment requirements.

(a) *Accreditation.* All diagnostic CT X-ray systems must be accredited by an accrediting organization recognized by the Department within 1 year from first patient use.

(b) *Technical and safety information.* The technical and safety information relating to the conditions of operation, dose information and imaging performance provided by the CT manufacturer shall be maintained by the facility and readily accessible to the operators.

(c) *Termination of exposure.* The operator shall be able to terminate the X-ray exposure at any time during a scan, or series of scans under X-ray system control, of greater than 0.5 second duration. Termination of the X-ray exposure shall necessitate resetting of the conditions of operation prior to initiation of another scan.

(d) *Tomographic plane indication and alignment.*

(1) For any single tomogram system, a means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.

(2) For any multiple tomogram system, a means shall be provided to permit visual determination of the location of a reference plane. This reference plane may be offset from the location of the tomographic plane.

(e) *Status indicators and control switches.*

(1) The CT X-ray control and gantry shall provide visual indication whenever X-rays are produced and, if applicable, whether the shutter is open or closed.

(2) The emergency buttons or switches shall be clearly labeled as to their function.

(3) Each individual scan or series of scans shall require initiation by the operator.

(f) *Indication of CT conditions of operation.* The CT X-ray system shall be designed so that the CT conditions of operation to be used during a scan or a scan sequence are indicated prior to the initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.

(g) *Leakage radiation.* The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source may not exceed 100 milliroentgens (25.8 μC/kg) in 1 hour when the X-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(h) *Additional requirements applicable to CT X-ray systems containing a gantry manufactured after September 3, 1985.*

(1) The total error in the indicated location of the tomographic plane or reference plane by the light field or laser indicator may not exceed 5 millimeters.

(2) If the X-ray production period is less than 0.5 second, the indication of X-ray production shall be actuated for at least 0.5 second. Beam-on and shutter status indicators at or near the gantry shall be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible.

(3) The CT X-ray system shall be normalized to water.

(4) The CT number for water for a region of interest, not exceeding 100 square millimeters, shall be 0 ± 7.0 CT number units. The facility's performance phantom shall be utilized, with the technique factors specified by the QMP, to confirm compliance. In instances when a CTN of 0 for water is inappropriate, as in 3D treatment planning, the QMP may establish and maintain an equivalent value.

(5) With the performance phantom, the mean CT number of water of one group of pixels may not differ from the mean CT number of water of a second group of pixels equal size within the same image by more than the manufacturer's published specifications, or those established by the QMP.

(6) The noise, utilizing the facility's performance phantom, may not exceed the manufacturer's published specifications.

(7) The total error between the indicated and actual slice thickness may not exceed 2.0 millimeters.

(8) A distance of at least 100 millimeters measured in a CT image shall agree with the actual distance to within ± 5%.

(9) Premature termination of the X-ray exposure by the operator shall necessitate resetting the CT conditions of operation prior to the initiation of another scan.

§ 221.204. Performance evaluations, routine QC and surveys.

(a) *Performance evaluations.*

(1) The performance evaluation of the CT X-ray system shall be performed by or under the direction of a QMP.

(2) Evaluation standards and tolerances shall be established by a QMP and maintained by the facility. These standards and tolerances must meet nationally-recognized standards and tolerances for the CT X-ray system.

(3) The performance evaluation of a CT X-ray system shall be performed after initial installation and before use on human patients. Thereafter, the evaluation shall be made at intervals not to exceed 14 months.

(4) The performance evaluation must include all of the following:

(i) Geometric factors and alignment, including alignment light accuracy and table incrementation accuracy.

(ii) Slice localization from scanned projection radiograph (localization image).

(iii) Slice thickness.

(iv) Image quality including high-contrast (spatial) resolution, low-contrast resolution, image uniformity, noise and artifact evaluation.

(v) CT number accuracy.

(vi) Image quality for acquisition workstation display devices (video and hard copy when applicable).

(vii) A review of the results of the routine QC required under subsection (b).

(viii) A safety evaluation of audible and visual signals and posting requirements.

(ix) A review of commonly used CT protocols along with the evaluation for appropriateness of dose and image quality, in comparison with the older protocols. The review should be by the QMP along with the radiologist and lead CT technologist.

(x) For dosimetry, a review of the protocols deemed appropriate by the QMP which could result in significant doses. This review must include acquisition and reconstruction parameters, and radiation dose. At a minimum, the QMP shall review the following clinical protocols, if performed, at intervals not to exceed 14 months:

(A) Pediatric head (1 year of age).

(B) Pediatric abdomen (5 years of age; 40—50 lbs. (about 20 kg)).

(C) Adult head.

(D) Adult abdomen (70 kg).

(E) Brain perfusion.

(xi) Review DRL, notification values and alert values for the procedures reviewed under subparagraph (x).

(xii) Review actions to be taken when a dose alert value is exceeded including patient follow-up.

(xiii) Review the process determining who has access and authority to make changes to the protocol management systems, including a policy or procedure to prevent inadvertent or unauthorized modifications to a CT protocol.

(5) A performance evaluation shall be made within 30 days after any change or replacement of components which, in the opinion of the QMP, could cause a change in the radiation output or image quality.

(6) Dose measurements of a CT unit shall be performed with a calibrated dosimetry system. The calibration of the system shall be traceable to a national standard. The dosimetry system must have been calibrated within the preceding 2 years.

(b) *Routine QC.*

(1) Written routine QC procedures shall be developed by a QMP. These procedures shall be available for review by the Department.

(2) The routine QC procedures must include, at a minimum, all of the following using the facility's performance phantom:

(i) Noise.

(ii) Mean CT number for water.

(iii) Artifact evaluation.

(3) The routine QC shall be performed at intervals not to exceed 1 week.

(4) The QMP need not be present during the routine QC.

(5) Routine QC shall include acquisition of images obtained with the performance phantom using the same processing mode and CT conditions of operation as are used to perform the measurements required by subsection (a).

(c) *Radiation protection surveys.*

(1) CT X-ray systems shall have a survey performed at the time of installation by or under the direction of a QMP. In addition, a survey shall be performed after a change in the facility or equipment which might cause a significant increase in radiation hazard.

(2) The registrant shall obtain a written report of the survey from the QMP, and a copy of the report shall be made available to the Department upon request.

(d) *Records.* Records of the performance evaluations and surveys shall be maintained for inspection by the Department for at least 5 years. Routine QC records shall be maintained for at least 1 year.

§ 221.205. Operating procedures.

(a) In addition to the training requirements in § 221.16 (relating to training, competency and continuing education), a CT X-ray system shall be operated only by an individual who has been specifically trained in its operation.

(b) All of the following information must be readily available to the CT operator:

(1) Instructions on the use of the CT phantoms and a process for reporting deviations in protocols including a schedule of routine QC appropriate for the system, allowable variations for the indicated parameters and the results of at least the most recent performance evaluation conducted on the system.

(2) Current protocol information available at the control panel which specifies for each routine examination the CT conditions of operation.

(c) If the radiation measurements and performance evaluation of the CT X-ray system indicates that a system operating parameter has exceeded a tolerance established by the QMP, the use of the CT X-ray system on patients shall be limited to those uses permitted by established written instructions of the QMP.

CHAPTER 223. VETERINARY MEDICINE

GENERAL PROVISIONS

§ 223.1. Purpose and scope.

This chapter establishes radiation safety requirements for persons utilizing radiation sources in veterinary medicine. Persons who use radiation sources for veterinary medicine or research on animals shall comply with this chapter. The requirements of this chapter are in addition to and not in substitution for other applicable requirements of this article.

RADIOACTIVE MATERIAL

§ 223.22. Sealed and unsealed sources.

A veterinarian who uses sealed or unsealed sources for therapeutic treatment of animals shall comply with 10 CFR Parts 30 and 31.11 (relating to rules of general applicability to domestic licensing of byproduct material; and general license for use of byproduct material for certain in vitro clinical or laboratory testing).

ADMINISTRATIVE CONTROLS

§ 223.31. Registrant responsibilities.

(a) The registrant is responsible for directing the operation of X-ray systems under the registrant's administrative control and shall assure that the requirements of this article are met for the operation of the X-ray systems.

(b) A person who operates an X-ray system shall be instructed adequately about safe X-ray operating procedures and be competent in the safe use of X-ray equipment. The instructions must include the subjects listed in Chapter 221, Appendix A (relating to determination of competence). The person shall receive continuing education at least every 4 years in radiation safety, biological effects of radiation, species-specific positioning techniques, QA and QC.

(c) Written safety procedures and rules shall be available at the facility and include restrictions of the operating technique required for the safe operation of the particular X-ray system. The operator shall be able to demonstrate familiarity with these procedures and rules.

(d) Only the staff, ancillary facility personnel or other persons required for the medical procedure or training may be within 2 meters of the device during the radiographic exposure. All of the following requirements apply to persons involved with the examination:

(1) An individual or extremity may not be positioned in the useful beam unless required to conduct the procedure.

(2) Individuals shall be positioned so that no part of the body will be struck by the useful beam unless protected by at least 0.5 millimeter lead equivalent material. The lead equivalent of the material is to be determined at 60 kV.

(3) Each person shall be protected from stray radiation by protective aprons or whole protective barriers of at least 0.25 millimeter lead equivalent or shall be positioned so that no person is in the direct line of the useful beam and the nearest portion of the body is at least 2 meters from both the tube head and the nearest edge of the image receptor.

(e) If an animal or image receptor requires auxiliary support during a radiation exposure, all of the following requirements apply:

(1) Mechanical holding devices or chemical restraint shall be used when the technique permits.

(2) An individual may not be used routinely to hold image receptors or subjects. Procedures and auxiliary equipment designed to minimize personnel exposure commensurate with the needed diagnostic information shall be used.

(3) An individual who holds the animal or image receptor shall be protected as required under subsection (d).

(f) The registrant shall have a QA program. The QA program must be documented and be in accordance with guidelines established by the Department or by another appropriate organization recognized by the Department. At a minimum, the QA program must address radiation safety to personnel and modifications to the QA program.

(g) Neither the X-ray tube housing nor the collimating device may be handheld during the exposure unless specifically designed and shielded to be handheld.

(h) CT systems used solely for nonhuman imaging are exempt from §§ 221.202—221.205.

CHAPTER 224. MEDICAL USE OF RADIOACTIVE MATERIAL

Subchapter A. GENERAL

§ 224.11. Effect of incorporation of 10 CFR Part 35.

To reconcile differences between this chapter and the incorporated sections of 10 CFR Part 35 (relating to medical use of byproduct material), the following words and phrases shall be substituted for the language in 10 CFR Part 35 as follows:

(1) A reference to "NRC" or "Commission" means Department.

(2) A reference to "NRC or agreement state" means Department, NRC or agreement state.

(3) A reference to "byproduct material" includes NARM.

(4) The definition of "sealed source" includes NARM.

(5) A reference to the Advisory Committee on the Medical Uses of Isotopes is synonymous with the Department's Radiation Protection Advisory Committee.

(6) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR shall be directed to the Department.

CHAPTER 225. RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

Subchapter A. GENERAL PROVISIONS

§ 225.3a. Effect of incorporation of 10 CFR Part 34.

To reconcile differences between this chapter and the incorporated sections of 10 CFR Part 34 (relating to licenses for industrial radiography and radiation safety requirements for industrial radiographic operations), the following words and phrases shall be substituted for the language in 10 CFR Part 34 as follows:

* * * * *

(5) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR (relating to energy) shall be directed to the Department.

§ 225.4a. Radiation safety program.

(a) A person who intends to use radiation-producing machines for industrial radiography shall have a program for training personnel, written operating procedures and emergency procedures, individual monitoring reports required under 10 CFR 20.2206(a)(2) (relating to reports of individual monitoring), an internal review system and an organizational structure for radiographic operations which includes specified delegations of authority and responsibility for operation of the program. This program shall be approved by the Department before beginning industrial radiographic operations.

(b) The registrant shall notify the Department of intended changes to the registrant's radiation safety program and obtain Departmental approval.

Subchapter B. RADIATION-PRODUCING MACHINES

GENERAL TECHNICAL REQUIREMENTS

§ 225.81. Permanent radiographic installations.

(a) Permanent radiographic installations having high radiation area entrance controls of the types described in 10 CFR 20.1601 and 20.1902 (relating to control of access to high radiation areas; and posting requirements) shall also meet all of the following requirements:

(1) Each entrance that is used for personnel access to the high radiation area in a permanent radiographic installation shall have both visible and audible warning signals to warn of the presence of radiation. The visible signal shall be activated by radiation whenever the X-ray source is energized. The audible signal shall be actuated when an attempt is made to enter the installation while the X-ray source is energized.

(2) The entrance control device or alarm system shall be tested for proper function prior to beginning operations on each day of use.

(3) The radiographic exposure system may not be used if an entrance control device or alarm system is not operating properly. If an entrance control device or alarm system is not functioning properly, it shall be removed from service and repaired or replaced immediately. If no replacement is available, the facility may continue to be used provided that the registrant implements the continuous surveillance under 10 CFR 34.51 and 34.53 (relating to surveillance; and posting), § 225.83 (relating to records required at field radiography sites) and uses an alarming ratemeter. Before the entrance control device or alarm system is returned to service, the radiation safety officer or an individual designated by the radiation safety officer shall validate the repair.

(b) Records of the tests performed under subsection (a) shall be maintained for inspection by the Department for 5 years.

CHAPTER 226. LICENSES AND RADIATION SAFETY REQUIREMENTS FOR WELL LOGGING

GENERAL

§ 226.5. Effect of incorporation of 10 CFR Part 39.

To reconcile differences between this chapter and the incorporated sections of 10 CFR Part 39 (relating to licenses and radiation safety requirements for well logging), the following words and phrases shall be substituted for the language in 10 CFR Part 39 as follows:

(1) A reference to "NRC" or "Commission" means Department.

(2) A reference to "NRC or agreement state" means Department, NRC or agreement state.

(3) The definition of "sealed source" includes NARM.

(4) The definition of "licensed material" includes NARM.

(5) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR (relating to energy) shall be directed to the Department.

CHAPTER 227. RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL X-RAY EQUIPMENT, X-RAY GAUGING EQUIPMENT, ELECTRON MICROSCOPES AND X-RAY CALIBRATION SYSTEMS

ANALYTICAL X-RAY EQUIPMENT

§ 227.11a. Equipment requirements.

* * * * *

(h) Equipment exclusively designed and exclusively used for vacuum spectroscopy where the tube housing and sample chamber is located behind all external surfaces of the unit shall be exempt from the requirements of this section, §§ 227.12a and 227.13a (relating to area requirements; and operating requirements), but shall meet the requirements of § 227.14 (relating to personnel requirements) and the following:

* * * * *

(6) A sign bearing the radiation symbol and the words "CAUTION—RADIATION," or words of similar intent shall be placed next to the opening of the sample chamber.

(i) Analytical X-ray equipment operating at less than or equal to 50 kV tube voltage and designed to be held by an operator during use are exempt from the requirements of this section and § 227.12a(b), but shall meet the requirements of subsection (f)(2) and §§ 227.13a(a) and 227.14(a).

CHAPTER 228. RADIATION SAFETY REQUIREMENTS FOR PARTICLE ACCELERATORS

ADMINISTRATIVE CONTROLS

§ 228.11a. Licensee responsibilities.

(a) A person may not possess, operate or permit the operation of an accelerator unless the accelerator and installation meet the applicable requirements of this article.

(b) Written safety procedures and rules shall be available at a facility, including restrictions of the operating technique required for the safe operation of the particular accelerator. The operator shall be able to demonstrate familiarity with the rules. The operator of an accelerator used for healing arts shall have additional instruction, including certification in the applicable specialty by a professional organization recognized by the Department.

(c) An individual may not be exposed to the useful beam except for healing arts purposes. An exposure shall be authorized by a licensed practitioner of the healing arts.

NOTIFICATION AND LICENSING PROCEDURES

§ 228.21a. Notification and license requirements.

(a) A person who intends to purchase, construct or acquire an accelerator shall notify the Department of this intent by filing an application for a specific license within 90 days after the initial order is issued to obtain any or all parts of the accelerator.

(1) The application shall be filed in duplicate on a form prescribed by the Department and shall be accompanied by the required fee as described in § 218.11(d) (relating to registration, renewal of registration and license fees).

(2) The application shall contain pertinent information to permit the Department to evaluate the accelerator facility for compliance with the act and this article.

(b) In addition to the notification requirement in subsection (a), a person who intends to install an accelerator shall notify the Department within 30 days after the initial construction or installation begins.

(c) The Department may, after the filing of an original application, and before the expiration of the license, require further information to enable the Department to determine whether the application will be granted or denied or whether a license will be modified or revoked.

(d) The application shall be signed by the applicant or licensee, or an individual authorized by the applicant or licensee.

(e) A license issued under this chapter may not be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, to any person except through submission of a written request by the licensee to the Department for approval.

GENERAL RADIATION SAFETY REQUIREMENTS

§ 228.35. Operating procedures.

* * * * *

(c) Each safety and warning device, except interlocks, shall be checked at least every 3 months for proper functioning and shall be repaired as necessary. Interlocks shall be checked at least annually. Results of these checks and records of repairs shall be maintained for 5 years at the accelerator facility for inspection by the Department.

* * * * *

(g) For accelerators used in the healing arts, operating procedures shall meet the following requirements:

* * * * *

(h) An individual who operates an accelerator system shall be instructed adequately in the safe operating procedures and be competent in the safe use of the equipment. The instructions must include items included in Appendix A (relating to determination of competence) for medical accelerator operations, as well as basic radiation protection for nonmedical accelerator operations. There shall be continuing education in radiation safety, biological effects of radiation, quality assurance and quality control.

§ 228.36. Radiation monitoring requirements.

An independent radiation monitoring system shall be provided so that the individuals entering or present in a potential very high radiation area become aware of the existence of the hazard. Independent radiation monitors shall be tested for response daily and after each servicing or repair.

RADIATION SAFETY REQUIREMENTS FOR ACCELERATORS USED IN THE HEALING ARTS

§ 228.61. Leakage radiation to the patient area.

(a) Equipment must meet all of the following requirements:

(1) For operating conditions producing maximum leakage radiation, the dose due to leakage radiation, including X-rays, electrons and neutrons, at any point on a circle of 2 meters radius centered on and perpendicular to the central axis of the beam at the isocenter or normal treatment distance and outside the maximum useful beam size, may not exceed 0.1% of the maximum dose of

the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the plane surface. Measurements, excluding those for neutrons, shall be averaged over an area up to, but not exceeding, 100 square centimeters at the position specified. Measurements of the portion of the leakage radiation dose contributed by neutrons shall be averaged over an area up to, but not exceeding, 200 square centimeters.

(2) For each system, the licensee shall determine or obtain from the manufacturer the leakage radiation existing at the positions specified in paragraph (1) for the specified operating conditions. The licensee shall maintain records for 5 years on leakage radiation measurements for inspection by the Department.

(b) Equipment manufactured or installed prior to July 17, 2004, must meet all of the following requirements:

(1) For operating conditions producing maximum leakage radiation, the absorbed dose due to leakage radiation, including neutrons, at any point on a circle of 2 meters radius centered on and perpendicular to the central axis of the beam 1 meter from the virtual source, may not exceed 0.1% of the maximum absorbed dose of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the surface of the circular plane. Measurements shall be averaged over an area up to but not exceeding 100 square centimeters at the positions specified.

(2) For each system, the licensee shall have available the leakage radiation data existing at the positions specified in paragraph (1) for the specified operating conditions. The licensee shall maintain records on radiation leakage for 5 years for inspection by the Department.

§ 228.72. Selection of radiation type.

Equipment capable of X-ray therapy or electron therapy, or both, must meet all of the following additional requirements:

* * * * *

§ 228.73. Selection of stationary beam therapy or moving beam therapy.

Equipment capable of stationary beam therapy or moving beam therapy, or both, must meet all of the following additional requirements:

* * * * *

§ 228.75. Calibrations.

* * * * *

(e) The calibration of the therapy beam shall include, but is not limited to, the following determinations:

(1) Verification that the equipment is operating in compliance with the design specifications concerning the light localizer, the side light and back-pointer alignment with the isocenter when applicable, variation in the axis of rotation for the table, gantry and beam limiting device (collimator) system.

(2) The absorbed dose rate at various depths (depth dose) and beam profile measured in water and the beam flatness and symmetry for the range of field sizes used, for each beam energy, and if applicable, for each flattening filter free mode.

* * * * *

CHAPTER 230. PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

Subchapter A. SCOPE AND DEFINITIONS

§ 230.4. Effect of incorporation of 10 CFR Part 71.

To reconcile differences between this chapter and the incorporated sections of 10 CFR Part 71 (relating to packaging and transportation of radioactive material), the following words and phrases shall be substituted for the language in 10 CFR Part 71 as follows:

(1) A reference to "NRC" or "Commission" means Department.

(2) A reference to "NRC or agreement state" means Department, NRC or agreement state.

(3) The definition of "sealed source" includes NARM.

(4) The definition of "licensed material" includes NARM.

(5) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR (relating to energy) shall be directed to the Department.

Subchapter B. GENERAL

§ 230.15. Packaging and transportation of unlicensed material.

Radioactive material not licensed by the Department or under the specific regulatory control of another state or Federal agency that meets the definition of radioactive material in 49 CFR 173.403 (relating to definitions) must be packaged and transported in compliance with the standards and requirements of 49 CFR 173.401—173.477 (relating to class 7 (radioactive) materials).

CHAPTER 232. LICENSES AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS

§ 232.3. Effect of incorporation of 10 CFR Part 36.

To reconcile differences between this chapter and the incorporated sections of 10 CFR Part 36 (relating to licenses and radiation safety requirements for irradiators), the following words and phrases shall be substituted for the language in 10 CFR Part 36 as follows:

(1) A reference to "NRC" or "Commission" means Department.

(2) A reference to "NRC or agreement state" means Department, NRC or Agreement State.

(3) The definition of "sealed source" includes NARM.

(4) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR (relating to energy) shall be directed to the Department.

CHAPTER 240. RADON CERTIFICATION

Subchapter A. GENERAL PROVISIONS

GENERAL

§ 240.1. Description of regulatory structure.

* * * * *

(e) Subchapter E (relating to enforcement and decertification) contains the enforcement provisions, including inspection, decertification and assessment of civil penalties. Other enforcement actions are available under sections 308 and 309 of the Radiation Protection Act (35 P.S. §§ 7110.308 and 7110.309) and section 14 of the act (63 P.S. § 2014).

(f) This section is for descriptive purposes only. This section does not limit the authority of the Department under the acts or this chapter.

§ 240.2. Scope.

(a) This chapter applies to a person except when the person is:

(1) Testing for or mitigating against radon contamination in a building that the person owns or in which the person resides.

(2) Using measures designed to prevent radon contamination in newly constructed buildings. This exemption does not apply to radon testing or installation of radon mitigating devices in these buildings following occupancy.

(3) Performing testing or mitigation in the course of the person's normal duties as an employee or contractor of the Department or the Federal government.

(4) Performing scientific research if the person discloses the information obtained to the Department under § 240.303 (relating to reporting of information) and the person informs the owner or occupant of the affected building of all of the following:

(i) That the person is not certified by the Department to test for or mitigate against radon contamination.

(ii) That the test results are not valid.

(iii) That the mitigation methods are for experimental purposes and may be unsuccessful.

(5) Purveying secondary devices supplied by a certified laboratory, if radon concentrations determined by the laboratory are only reported directly to the owner or resident of the building tested.

(i) Test results may also be reported to the certified mitigator who installed a mitigation system at the property.

(ii) Purveying does not include the activities of either placing or retrieving activated charcoal, liquid scintillation, or alpha track radon testing devices.

(6) Employed by a local government or a school and performing testing for that local government or school if all of the following criteria are met:

(i) The practice is limited to the employee's official duties and no fee is charged for the testing except for the employee's salary.

(ii) Radon testing is limited to the buildings owned or occupied by the local government or school.

(iii) The radon testing is performed in accordance with the device manufacturer's instructions.

(b) This chapter is in addition to, and not in substitution for, other applicable provisions of this article.

§ 240.3. Definitions.

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

AC—Activated charcoal—A device used to measure radon by exposing activated charcoal to air in the area to be tested and analyzed by gamma ray spectroscopy.

AT—Alpha track—A device used to measure radon by recording alpha particle tracks on a plastic chip.

Act—The Radon Certification Act (63 P.S. §§ 2001—2014).

Active radon mitigation system—A radon mitigation system with an electric vent fan.

Acts—The Radon Certification Act and the Radiation Protection Act (35 P.S. §§ 7110.101—7110.703).

Alteration—A change to the original mitigation system design, including fan size, number or placement of suction points, or pipe diameter.

CRM—Continuous radon monitor—An active device used to measure radon with solid state silicon surface barrier detectors, scintillation cells or ion chambers, usually on an hourly basis.

CWLM—Continuous working level monitor—An active device used to measure radon decay products, usually on an hourly basis.

Calibration—The process of determining the response of an instrument (or measurement system) to a series of known values over the range of the instrument (or measurement system).

Certification year—Each 12-month period beginning with the most recent certification date of the certified individual.

Certified individual—An individual with a Department certification to perform radon testing, mitigation or laboratory analysis in this Commonwealth.

Client—A receiver of services that are regulated under the Act or this chapter.

Control limit—A QC value set at ±3 sigma.

Diagnostic test—A test performed to determine specific radon entry points and sources, the result of which is not reported to the Department or in writing to the client.

Duplicate measurements—Two measurements made concurrently, for the same time period and in the same location, approximately 4 inches from one another.

Electret ion chamber—A radon measurement device that consists of a small plastic container with an electrostatically charged disk inside to serve as a detector.

Electret reader—A radon measurement device that consists of a voltmeter used to measure the voltage on the electrostatically charged disk of an electret ion chamber testing device at the beginning and end of a test period.

Electret voltage drift—A QC process which evaluates the voltage drift of each new batch of electrets received from the manufacturer of the electrets.

Field blank—A QC measurement made by analyzing unexposed (closed) detectors that have been maintained in a low-radon environment to assess radon exposure to the detector from a source other than the concentration in the environment to be measured.

Firm—A Department-certified entity that has at least one certified individual in responsible charge of the entity's testing, mitigation or laboratory radon activities. A business, such as a corporation or limited liability company, may contain more than one firm.

Firm employee—A Department-listed radon testing, mitigation or laboratory employee under the responsible charge of a certified individual.

Firm owner—A person or business entity which owns and is responsible for the radon firm.

LS—Liquid scintillation—A device used to measure radon by exposing a small amount of activated charcoal contained within a small vial and placed in the area to be sampled and analyzed in a liquid scintillation counter.

Laboratory—A Department-certified individual or firm.

Laboratory analysis—The act of analyzing a radon test device and calculating a radon concentration in air or water.

Lowest livable level—The lowest level of a building that may be used as a living space without requiring any major structural changes.

MV—Measured value—The radon concentration reported by the analyst, in units of picocuries per liter or WLs.

Measurement—A radon or radon decay product test result used for the performance of quality assurance, including a spike, blank, duplicate, intercomparison or cross check.

Mitigate—To repair or alter a building or building design for the purpose in whole or in part of reducing the concentration of radon in the indoor atmosphere.

Mitigator—A Department-certified individual or a Department-listed mitigation employee of a Department-certified mitigation firm.

Multifamily building—A building with more than three attached dwellings.

Nonreported test—A test conducted for reasons other than reporting valid, written results to the client, such as a diagnostic test.

pCi/L—Picocurie per liter—2.22 disintegrations per minute of radioactive material per liter of air.

Passive radon mitigation system—A radon mitigation system without an electric vent fan.

Person—An individual, corporation, partnership, business entity, association, trust, estate, public or private institution, group, agency or political subdivision of this Commonwealth, another state or political subdivision or agency thereof, and a legal successor, representative, agency or agency of the entities in this definition.

Primary device—Continuous monitors or electret ion chambers, or both, read or analyzed, or both, by a primary tester.

Primary tester—A tester who reads or analyzes, or both, a primary device that the tester places or retrieves, or both.

QA—Quality assurance—The activities required to provide the evidences needed to establish confidence that radon test data are of the required precision and accuracy.

QC—Quality control—The process through which a person measures performance, compares performance with standards and acts on any differences.

RPD—Relative percent difference—The absolute value of the difference between two measurements divided by their average, multiplied by 100. The equation is:

$$RPD=\{(|MV_1-MV_2|)/(MV_1+MV_2)/2\} \times 100.$$

RPE—Relative percent error—The measured value (pCi/L) minus the RV (pCi/L), divided by the RV, multiplied by 100. The equation is:

$$RPE = \{(MV—RV)/RV\} \times 100.$$

RV—Reference value—The known radon concentration value, in units of picocuries per liter or WL, to which a test device is exposed.

Radon—The radioactive noble gas radon-222 and the short-lived radionuclides which are products of radon-222 decay, including polonium-218, lead-214, bismuth-214 and polonium-214.

Secondary device—A radon test device that is analyzed by a Department-certified laboratory.

Secondary tester—A tester who places or retrieves, or both, a radon test device that is analyzed by a Department-certified laboratory.

Sigma level—A sample standard deviation around a mean, which is a measure of the scatter of data around a mean. The term is often described as 1, 2 or 3 sigma, corresponding to one, two or three standard deviations around the mean.

Spiked measurement or spike—A quality control measurement conducted in an approved chamber to evaluate accuracy by exposing the detector or device to a known concentration and submitted for analysis.

Test—The act of measuring for the presence of radon in a building's air or water supply.

Tester—A Department-certified individual or a Department-listed testing employee of a Department-certified testing firm.

WL—Working level—Any combination of short-lived radon progeny (for radon-222: polonium-218, lead-214, bismuth-214 and polonium-214; and for radon-220: polonium-216, lead-212, bismuth-212 and polonium-212) in 1 liter of air that will result in the ultimate emission of 1.3×10^5 MeV of alpha particle energy.

WLM—Working level month—The cumulative exposure from breathing in an atmosphere at a concentration of 1 WL for a working month of 170 hours.

WLM/yr—Working level month per year—The cumulative exposure incurred over 1 year (2,040 hours) from breathing in an atmosphere at a concentration of 1 WL for a working month of 170 hours.

Warning level—A QC value set at ±2 sigma.

Subchapter B. CERTIFICATION

CERTIFICATION FOR RADON TESTING

§ 240.101. Requirements for radon testing certification.

(a) A person may not test for radon or represent or advertise that he may so test in a building in this Commonwealth unless the person has first applied for and obtained certification from the Department to test or is a firm employee of a certified testing firm.

(b) For a firm to perform radon testing it shall employ at least one individual certified to test who is in responsible charge of the firm's testing activities, and the firm shall submit an application for certification and receive certification from the Department.

(c) A certified primary tester does not also have to be certified in radon laboratory analysis to read or analyze continuous monitors or electret ion chambers that he places and retrieves.

(d) A person using secondary radon testing devices, such as AC, from a certified radon laboratory does not also have to be certified in radon laboratory analysis.

§ 240.102. Prerequisites for radon testing certification.

(a) *Individual certification for radon testing.* An individual will not be certified to test unless the individual has:

(1) Completed a Department-approved course on radon.

(2) Passed a Department-approved written exam on radon testing within 2 years before the postmark date of the individual's application submittal. The applicant shall forward a copy of exam results to the Department.

(3) Submitted a complete and accurate application to the Department, including applicable fees.

(b) *Firm certification for radon testing.* If the applicant for testing certification is a firm, it shall employ at least one individual who is certified to test and who is in responsible charge of the firm's testing activities.

(1) If the firm loses its certified individual, all of the following apply:

(i) The firm owner shall notify the Department in writing within 5 business days of losing that individual.

(ii) The firm's certification automatically lapses and is void until the Department approves in writing the firm owner's written and signed request for a certified individual to be in responsible charge of that firm's radon testing activities.

(2) If a testing firm employee is no longer under the responsible charge of the firm's certified individual, all of the following apply:

(i) The firm's certified individual shall notify the Department within 10 business days of this change.

(ii) The firm employee's Department listing becomes invalid.

(3) Each testing firm employee shall conduct activities in accordance with the signed testing firm employee application.

(4) Each testing firm employee applicant shall submit all of the following:

(i) A nonrefundable fee as set forth in Appendix A (relating to radon certification fee schedule).

(ii) A completed firm employee application as provided by the Department within 10 business days of performing radon testing activities.

(iii) For firm employees hired after January 24, 2019, a certification that the firm employee received initial training pursuant to subsection (b)(6).

(iv) A document signed by the certified individual that the firm employee completed continuing education as required by subsection (b)(7), if applicable.

(v) The applicant's current photograph, in a format specified by the Department, to be used on the identification card as required under § 240.142 (relating to testing and mitigation identification cards).

(5) The firm's certified individual shall receive written approval from the Department of a testing firm employee.

(6) For firm employees hired after January 24, 2019, the firm's certified individual shall ensure that each firm employee receives initial training before participating in radon testing activities. Initial training may be given by the firm's certified individual or through a department-approved training program. The firm's certified individual shall document that each firm employee has received initial training that includes, at a minimum, the following:

(i) General information regarding radon and the risks associated with radon exposure.

(ii) A tutorial on how to properly use the testing device(s) employed by the certified firm including:

(A) The strengths and weaknesses of the specific device(s) including any limitations of the device(s).

(B) Device handling precautions, if any.

(C) Short-term versus long-term testing.

(D) Device sampling times.

(E) When to invalidate a measurement.

(iii) Information regarding the appropriate radon testing protocol(s) including:

(A) Closed building conditions.

(B) Heating and air conditioning system considerations.

(C) Unusual weather conditions.

(D) Tampering precautions.

(E) Measurement documentation.

(F) Brief QA/QC overview.

(G) Real estate and non-real estate testing.

(H) Device placement locations within the building.

(7) The firm's certified individual shall ensure that each firm employee receives continuing education every two years. Continuing education may be given by the firm's certified individual or through a Department-approved training program. The firm's certified individual shall document that each firm employee has received continuing education. Continuing education records shall be retained for 5 years. Continuing education shall include, at a minimum, the requirements set forth in subsection (b)(6)(ii) and (iii).

(c) *Additional requirements.* If the applicant for testing certification is a firm, or an individual performing testing and not working for a certified radon testing firm, the applicant shall also have a QA program and a continuing education program as required under §§ 240.306 and 240.604 (relating to continuing education program; and QA requirements for testing using primary devices). In addition, the applicant shall be successfully enrolled in a Department-approved radon measurement proficiency program as required under § 240.307 (relating to radon measurement proficiency program).

§ 240.103. Radon testing application contents.

(a) An application for radon testing certification, by an individual or a firm, shall be submitted to the Department in writing on forms provided by the Department and must contain all of the following:

(1) Evidence that the applicant has the certification prerequisites in § 240.102 (relating to prerequisites for radon testing certification). The application must include the duties assigned to the certified individual in responsible charge of the testing activities.

(2) A nonrefundable fee as set forth in Appendix A (relating to radon certification fee schedule).

(3) The applicant's name, address, and telephone number. It must also indicate if the applicant is an individual, partnership, limited partnership, corporation or other entity. The application must include, when appropriate,

the name and address of every officer, general and limited partner, director, principal shareholder, parent corporation and certified person within the applicant's organization.

(4) Compliance information, including descriptions of notices of violation, administrative orders, civil penalty assessments and actions for violations of the act, this chapter or a term or condition of a certification.

(5) Copies of reporting forms, information distributed to potential clients and recent or proposed advertisements.

(6) The applicant's current photograph, in a format specified by the Department, to be used on the identification card as required under § 240.142 (relating to testing and mitigation identification cards).

(7) Other information the Department may require related to an applicant's qualifications or technical or administrative information related to radon testing.

(8) A verification by the applicant that the information contained in the application is correct to the best of the applicant's information and belief. This verification is subject to the penalties of 18 Pa.C.S. § 4904 (relating to unsworn falsification to authorities).

(9) If the applicant for testing certification is a firm, the application shall include a demonstration that the firm's certified individual will maintain adequate span of control over the firm's employees. This demonstration shall include, at a minimum, the following:

(i) Information regarding the initial training and continuing education given to firm employees that is required by § 240.102(b)(6) and (b)(7) (relating to prerequisites for radon testing certification).

(ii) The firm's protocol for ensuring that firm employees are adequately supervised by the firm's certified individual.

(b) Within 10 business days of a change to the information submitted in the certified individual application or firm certification application, the certified individual shall submit to the Department a written and signed notification listing each change. The change will not take effect until the Department provides written approval of the change.

§ 240.104. Application filing deadline.

(a) A person who expects to conduct radon testing shall file a complete application for certification a minimum of 30 days prior to the anticipated starting date of testing activity.

(b) A testing individual certification renewal application postmarked after the previous testing individual certification expiration date will be charged a late application fee as set forth in Appendix A (relating to radon certification fee schedule).

CERTIFICATION FOR RADON MITIGATION

§ 240.111. Requirements for radon mitigation certification.

(a) A person may not mitigate radon contamination in a building or represent or advertise that he may so mitigate in a building in this Commonwealth unless the person has first applied for and obtained certification from the Department to mitigate or is a firm employee of a certified mitigation firm.

(b) For a firm to perform radon mitigation it shall employ at least one individual certified to mitigate who is in responsible charge of the firm's mitigation activities, and the firm shall submit an application for certification and receive certification from the Department prior to performing mitigation of radon contamination.

§ 240.112. Prerequisites for radon mitigation certification.

(a) *Individual certification for radon mitigation.* An individual will not be certified to mitigate unless the individual has:

(1) Completed a Department-approved course on radon mitigation.

(2) Passed a Department-approved written exam on radon mitigation within 2 years before the postmark date of the individual's application submittal. The applicant shall forward a copy of exam results to the Department.

(3) Had 1 year professional experience in radon mitigation system installation or 3 years experience in architecture, engineering, electrical contracting, plumbing, carpentry, masonry or related trades.

(4) Submitted a complete and accurate application to the Department including applicable fees.

(b) *Firm certification for radon mitigation.* If the applicant for mitigation certification is a firm, it shall employ at least one individual who is certified to mitigate and who is in responsible charge of the firm's mitigation activities.

(1) If the firm loses its certified mitigation individual, all of the following apply:

(i) The mitigation firm owner shall notify the Department in writing within 5 business days of losing that individual.

(ii) The firm's certification automatically lapses and is void until the Department approves in writing the mitigation firm owner's written and signed request for a certified individual to be in responsible charge of that firm's radon mitigation activities.

(2) If the mitigation firm employee is no longer under the responsible charge of the firm's certified individual, all of the following apply:

(i) The firm's certified individual shall notify the Department within 10 business days of this change.

(ii) The firm employee's Department listing becomes invalid.

(3) The mitigation firm employee shall conduct activities in accordance with the signed mitigation firm employee application.

(4) Each mitigation firm employee applicant shall submit all of the following:

(i) A completed firm employee application as provided by the Department within 10 business days of performing radon mitigation activities.

(ii) The applicant's current photograph, in a format specified by the Department, to be used on the identification card as required under § 240.142 (relating to testing and mitigation identification cards).

(iii) For firm employees hired after January 24, 2019, a certification that the firm employee received initial training pursuant to subsection (b)(6).

(iv) A document signed by the certified individual that the firm employee completed continuing education as required by subsection (b)(7), if applicable.

(5) The firm's certified individual shall receive written approval from the Department of a mitigation firm employee.

(6) For firm employees hired after January 24, 2019, the firm's certified individual shall ensure that each firm employee receives initial training before participating in radon mitigation activities. Initial training may be given by the firm's certified individual or through a Department-approved training program. The firm's certified individual shall document that each firm employee has received initial training that includes, at a minimum, the following:

(i) Information regarding radon and the risks associated with radon exposure.

(ii) Information regarding radon mitigation health and safety topics such as fall protection, mold hazards, and ventilation.

(iii) Information regarding radon mitigation protocols and standards.

(iv) Information regarding electrical wiring and electrical issues as they relate to radon mitigation installations.

(7) The firm's certified individual shall ensure that each firm employee receives continuing education every two years. Continuing education may be given by the firm's certified individual or through a Department-approved training program. The firm's certified individual shall document that each firm employee has received continuing education. Continuing education records shall be retained for 5 years. Continuing education shall include at least the requirements set forth in subsection (b)(6)(ii)-(iv).

(c) *Additional requirements.* If the applicant for mitigation certification is a firm, or an individual performing mitigation and not working for a certified mitigation firm, he shall also have a health and safety program, and a continuing education program, as required in §§ 240.305 and 240.306 (relating to health and safety program; and continuing education program).

§ 240.113. Radon mitigation application contents.

(a) An application for radon mitigation certification, by an individual or a firm, shall be submitted to the Department in writing on forms provided by the Department and must contain all of the following:

(1) Evidence that the applicant has the certification prerequisites contained in § 240.112 (relating to prerequisites for radon mitigation certification). The application must include the duties assigned to the certified individual in responsible charge of the mitigation activities.

(2) A nonrefundable fee as set forth in Appendix A (relating to radon certification fee schedule).

(3) The applicant's name, address, and telephone number. It must also indicate if the applicant is an individual, partnership, limited partnership, corporation or other entity. The application must include, when appropriate, the name and address of every officer, general and limited partner, director, principal shareholder, parent corporation and certified person within the applicant's organization.

(4) Compliance information, including descriptions of notices of violation, administrative orders, civil penalty assessments and actions for violations of the act, this chapter or a term or condition of a certification.

(5) Copies of reporting forms, information distributed to potential clients and recent or proposed advertisements.

(6) The applicant's current photograph, in a format specified by the Department, to be used on the identification card as required under § 240.142 (relating to testing and mitigation identification cards).

(7) Other information the Department may require related to an applicant's qualifications or technical or administrative information related to radon mitigation.

(8) A verification by the applicant that the information contained in the application is correct to the best of the applicant's information and belief. This verification is subject to the penalties of 18 Pa.C.S. § 4904 (relating to unsworn falsification to authorities).

(9) If the applicant for mitigation certification is a firm, the application shall include a demonstration that the firm's certified individual will maintain adequate span of control over the firm's employees. This demonstration shall at least include:

(i) Information regarding the initial training and continuing education given to firm employees that is required by § 240.112(b)(6) and (b)(7).

(ii) The firm's protocol for ensuring that firm employees are adequately supervised by the firm's certified individual.

(b) Within 10 business days of a change to the information submitted in the mitigation certification application, the certified individual shall submit to the Department a written and signed notification listing each change. The change will not take effect until the Department provides written approval of the change.

§ 240.114. Application filing deadline.

(a) A person who anticipates conducting radon mitigation services shall file a complete application for certification a minimum of 30 days prior to the anticipated starting date of mitigation activities.

(b) A certified individual renewal application postmarked after the previous certified individual certification expiration date will be charged a late application fee as set forth in Appendix A (relating to radon certification fee schedule).

CERTIFICATION FOR RADON LABORATORY

§ 240.121. Requirements for radon laboratory certification.

(a) A person in this Commonwealth or a person analyzing devices placed or retrieved in this Commonwealth may not perform laboratory analysis or represent or advertise that the person may perform laboratory analysis of radon testing devices supplied to the public or of samples or devices received from the public or from other certified persons, unless that person has first applied for and obtained radon laboratory analysis certification from the Department or is a firm employee of a certified laboratory firm.

(b) For a firm to perform radon laboratory analysis it shall employ at least one individual certified to perform laboratory analysis who is in responsible charge of the firm's laboratory radon analytical activities, and the firm shall submit an application for certification and receive certification from the Department.

§ 240.122. Prerequisites for radon laboratory certification.

(a) *Individual certification for laboratory analysis.* A person will not be certified to perform radon laboratory analysis unless the person has:

(1) Completed a Department-approved course on radon.

(2) Had 1 year professional experience in performing laboratory analysis of radon measurement devices or samples or is certified in Health Physics by the American Board of Health Physics, or equivalent certification or professional work experience, or both, as determined by the Department.

(3) Received a bachelors degree in the physical sciences or engineering or related fields as approved by the Department, or the education or professional work experience equivalent to a degree, as determined by the Department.

(4) Submitted a complete and accurate application to the Department, including applicable fees.

(b) *Firm certification for laboratory analysis.* If the applicant for radon laboratory certification is a firm, it shall employ at least one individual who is certified to perform radon laboratory analysis and who is in responsible charge of the laboratory radon analytical activities.

(1) If the firm loses its certified individual, all of the following apply:

(i) The firm owner shall notify the Department in writing within 5 business days of losing its certified individual.

(ii) The firm's certification automatically lapses and is void until the Department approves in writing the firm owner's written and signed request for a certified individual to be in responsible charge of that firm's radon laboratory activities.

(2) If a laboratory firm employee is no longer under the responsible charge of the firm's certified individual, the following apply:

(i) The firm's certified individual shall notify the Department within 10 business days of this change.

(ii) The firm employee's Department listing becomes invalid.

(3) Activities of the laboratory firm employee shall be conducted in accordance with the signed laboratory firm employee application.

(4) Each laboratory firm employee applicant shall submit all of the following:

(i) A completed and signed laboratory firm employee application as provided by the Department.

(ii) For firm employees hired after January 24, 2019, a document signed by the certified individual that the firm employee received initial training pursuant to subsection (b)(6).

(5) Each laboratory firm employee shall receive written approval from the Department prior to conducting radon laboratory activities as a laboratory firm employee.

(6) For firm employees hired after January 24, 2019, the firm's certified individual shall ensure that each firm employee receives initial training before participating in radon laboratory activities. Initial training may be given by the firm's certified individual or through a Department-approved training program. The firm's certified individual shall document that each firm employee has received initial training that includes, at a minimum, the following:

(i) General information regarding radon and the risks associated with radon exposure.

(ii) Information regarding radon laboratory analysis methods, protocols and standards.

(iii) Information regarding QA/QC for the laboratory device(s).

(iv) Information regarding necessary record keeping.

(7) The firm's certified individual shall ensure that each firm employee receives continuing education every two years. Continuing education may be given by the firm's certified individual or through a Department-approved training program. The firm's certified individual shall document that each firm employee has received continuing education. Continuing education records shall be retained for 5 years and include, at a minimum, the requirements set forth in subsection (b)(6)(ii)—(iv).

(c) *Additional requirements.* If the applicant for radon laboratory certification is a firm, or an individual performing laboratory analysis and not working for a certified laboratory, the applicant shall also have a QA program and a continuing education program as required under §§ 240.306 and 240.604 (relating to continuing education program; and QA requirements for testing using primary devices). In addition, the applicant shall be successfully enrolled in a Department-approved radon measurement proficiency program as required under § 240.307 (relating to radon measurement proficiency program).

§ 240.123. Radon laboratory application contents.

(a) An application for radon laboratory certification, by an individual or a firm, shall be submitted to the Department in writing on forms provided by the Department and must contain all of the following:

(1) Evidence that the applicant has the certification prerequisites contained in § 240.122 (relating to prerequisites for radon laboratory certification). The application must include the duties assigned to the certified individual in responsible charge of the laboratory analysis activities.

(2) A nonrefundable fee as set forth in Appendix A (relating to radon certification fee schedule).

(3) The applicant's name, address, and telephone number. It must also indicate if the applicant is an individual, partnership, limited partnership, corporation or other entity. The application must include, when appropriate, the name and address of every officer, general and limited partner, director, principal shareholder, parent corporation and certified person within the applicant's organization.

(4) Compliance information, including descriptions of notices of violation, administrative orders, civil penalty assessments and actions for violations of the act, this chapter or a term or condition of a certification.

(5) Other information the Department may require related to an applicant's qualifications or technical or administrative information related to laboratory analysis of radon samples.

(6) A verification by the applicant that the information contained in the application is correct to the best of the applicant's information and belief. This verification is

subject to the penalties of 18 Pa.C.S. § 4904 (relating to unsworn falsification to authorities).

(7) If the applicant for laboratory certification is a firm, the application shall include a demonstration that the firm's certified individual will maintain adequate span of control over the firm's employees. This demonstration shall at least include:

(i) Information regarding the initial training and continuing education given to firm employees that is required by § 240.122(b)(6) and (b)(7) (relating to prerequisites for radon laboratory certification).

(ii) The firm's protocol for ensuring that firm employees are adequately supervised by the firm's certified individual.

(b) Within 10 business days of a change to the information submitted in the laboratory certification application, the laboratory certified individual shall submit to the Department a written and signed notification listing each change.

§ 240.124. Application filing deadline.

(a) A person who anticipates performing laboratory analysis of samples to determine radon concentrations shall file a complete application for laboratory analysis certification a minimum of 30 days prior to the anticipated starting date of laboratory analysis.

(b) A laboratory individual certification application postmarked after the previous laboratory individual certification expiration date will be charged a late application fee as set forth in Appendix A (relating to radon certification fee schedule).

CERTIFICATION FOR PERSONS CERTIFIED IN ANOTHER STATE

§ 240.132. Limited radon practice in this Commonwealth.

A person may test, mitigate or perform laboratory analysis without first obtaining certification from the Department if the person does all of the following:

(1) Obtains certification to do so from a state with which the Department has entered into a reciprocal agreement.

(2) Conducts that activity in this Commonwealth fewer than 90 days each calendar year.

§ 240.133. Certification application contents.

(a) A person who has a certification from a state with which the Department has entered into a reciprocal agreement, and who intends to conduct the radon-related activity in this Commonwealth for 90 days or more a year, shall first obtain certification from the Department. The application must be in writing and contain all of the following:

(1) A copy of the certification from the foreign state.

(2) A nonrefundable fee as set forth in Appendix A (relating to radon certification fee schedule).

(3) The applicant's name, address, and telephone number. It must also indicate if the applicant is an individual, partnership, limited partnership, corporation or other entity. The application must include, when appropriate, the name and address of every officer, general and limited partner, director, principal shareholder, parent corporation and certified person within the applicant's organization.

(4) Compliance information, including descriptions of notices of violation, administrative orders, civil penalty assessments and actions for violations of the act, this chapter or a term or condition of a certification.

(5) Other information the Department may require related to an applicant's qualifications, or technical or administrative information related to radon testing, mitigation of radon contamination or laboratory analysis of radon samples.

(6) A verification by the applicant that the information contained in the application is correct to the best of the applicant's information and belief.

(b) Within 10 business days of a change to the information submitted in the certification application, the certified individual shall submit to the Department a written and signed notification listing each change.

OTHER CERTIFICATION PROCEDURES

§ 240.141. Withdrawal of applications and certifications.

(a) *Withdrawal of applications.*

(1) An application may be withdrawn before Department approval is granted.

(2) Fees will not be refunded.

(3) After an application for certification is withdrawn, a person may request to have the application reinstated prior to expiration of current certification.

(4) The withdrawal is complete when all of the following conditions have been met:

(i) The request for an application withdrawal has been submitted to the Department in writing and signed by the applicant.

(ii) The Department has confirmed the withdrawal in writing.

(b) *Withdrawal of certifications.*

(1) A certified testing, mitigation or laboratory individual may request that the Department withdraw the individual's own certification or a firm certification. The withdrawal is complete when the request has been submitted in writing, signed by the certified individual and the Department has provided written confirmation of the withdrawal.

(2) A firm owner may request that the Department withdraw the firm's certification. The withdrawal is complete when the request has been submitted in writing, signed by the firm owner and the Department has provided written confirmation of the withdrawal.

(c) *Withdrawal of a testing or laboratory individual certification by the Department.*

(1) The Department may withdraw a testing or laboratory individual certification when that individual no longer has Department-listed testing devices.

(2) The Department will confirm the withdrawal in writing.

(d) *Reinstatement of withdrawn certifications.*

(1) The previously certified individual may submit a written, signed request to reinstate the individual's testing, mitigation or laboratory individual certification or the firm owner may request to reinstate the testing, mitigation or laboratory firm certification prior to the withdrawn certification's expiration date.

(2) The Department will approve or disapprove this request in writing.

(3) A person who wishes to reapply for certification after the expiration of the person's previous certification shall submit a new application along with appropriate fees as set forth in Appendix A.

§ 240.142. Testing and mitigation identification cards.

(a) All of the following persons shall obtain Department identification cards:

(1) Individuals for testing certification.

(2) Individuals for mitigation certification.

(3) Each testing firm employee.

(4) Each mitigation firm employee.

(b) Each applicant referenced in subsection (a) shall submit the applicant's current photograph, in a format specified by the Department, to the Department with the application.

(c) Each person listed in subsection (a) shall present the Department-issued identification card to a client upon request.

§ 240.143. Adding or removing devices from certification.

(a) To add or remove a device from laboratory or testing certification, the certified individual shall submit a written and signed request to the Department.

(b) The certified individual who analyzes each continuous monitor and electret reader shall provide in the request the specific serial number and proof of current calibration of each device to be added.

(c) The certified individual who analyzes each continuous monitor and electret reader shall provide in the request the specific serial number of each device to be removed.

(d) The device will be considered Department-listed or removed on the effective date stated in the Department's confirmation letter to the certified individual.

(e) After the effective removal date of the device, the device may no longer be used to conduct radon testing activities or laboratory analysis.

(f) The certified individual shall receive written approval from the Department to add a specific device prior to performing radon testing activities or laboratory analysis with the device.

Subchapter C. CERTIFICATION REVIEW PROCEDURES AND STANDARDS

§ 240.201. Criteria for issuance or denial of certifications or course provider applications.

(a) A certification or course provider application will not be approved unless the applicant affirmatively demonstrates to the Department's satisfaction that all of the following conditions are met:

(1) Neither the applicant nor a person identified in the application or involved with the course or its development is in violation of the act or this chapter or has been decertified under § 240.403 (relating to decertification).

(2) The application is accurate and complete and the applicant is in compliance with the requirements of the act and this chapter.

(3) The applicant has the qualifications required in this chapter and is capable of performing the activities for which he is seeking certification as required by the act and this chapter.

(b) The Department may deny the certification or course provider application of a person who has shown a lack of ability or intention to comply with the acts or this chapter, as indicated by past or continuous conduct. A certification lapse under § 240.203(b) (relating to conditions of certification) may be considered evidence of a lack of ability or intention to comply with the acts or this chapter.

§ 240.202. Terms of certification.

(a) A certification will be valid for 2 years following issuance.

(b) Testing, mitigating or laboratory analysis may not be conducted after the expiration of the term of certification.

§ 240.203. Conditions of certification.

(a) Persons certified under this chapter shall, at a minimum, comply with all of the following conditions:

(1) The certified person shall conduct all activities as described in the approved application.

(2) The certified person shall allow the Department, its agents and employees, without advance notice or a search warrant, upon presentation of appropriate credentials, and without delay, to have access to the person's facilities, offices and files for inspection and examination of records. The certified person shall also allow the Department, its agents and employees to accompany him while performing radon-related activities for the purpose of inspection of those activities.

(3) The certified person shall remain in compliance with the acts and this chapter.

(4) For certification of a firm, the certified individual shall remain in responsible charge of the radon-related activities. The certified individual shall have his duties and responsibilities listed in the firm's certification application.

(5) Certified testing and laboratory individuals shall pass blind studies conducted by the Department. The individual measurement results of the blind study must achieve an individual relative percent error of less than or equal to ±25% of the reference value. The blind study is conducted without the knowledge of the certified individual so that no special precaution is taken during the measurement device analysis. Blind studies are designed to assess the performance of the measurement device to ensure that clients are receiving accurate and precise results.

(b) The Department may suspend certification if a condition of certification is violated. The Department will publish notice of the suspension in the *Pennsylvania Bulletin*.

§ 240.204. Certification renewal.

(a) An application for certification renewal must contain the contents required in an initial certification application, except that the Department may permit an applicant to rely on information previously submitted if the information remains the same. A certification renewal application shall be issued or denied according to the criteria in § 240.201 (relating to criteria for issuance or denial of certifications or course provider applications).

(b) Prior to the expiration of radon certification, a person who intends to continue to provide radon-related services in this Commonwealth shall submit an application for certification renewal. To avoid a lapse in certification, an applicant for certification renewal shall file an application at least 30 days prior to the expiration of the current certification. Submitting a renewal application does not extend the previous certification period. The certified person is responsible to make a timely application for certification renewal.

(c) For an application from a radon service provider postmarked after the expiration of the certification, the following criteria will determine application requirements:

(1) An individual certification application postmarked prior to 1 year after the expiration of the certification is a renewal application subject to the late application fee in Appendix A (relating to radon certification fee schedule).

(2) An individual certification application postmarked 1 year or more after expiration of certification is an initial application subject to the initial application fee in Appendix A. The application is not subject to the late application fee set forth in Appendix A.

§ 240.205. Certification modification.

The terms and conditions of a certification are subject to amendment, revision or modification by the Department for a violation of the acts, this chapter or a term or condition of the certification, or for a false statement made to the Department by the certified party, or for a change of condition which would warrant the issuance or denial of a certification on the basis of an original application.

Subchapter D. OPERATION REQUIREMENTS

§ 240.301. Advertising.

A person may not advertise a radon-related service or product with false or misleading statements regarding the services or products offered, health effects or property value. A person required to obtain certification may not advertise a service or product unless the person currently holds a valid certification from the Department to perform that service or provide that product. Advertising for a radon-related service or product must include the valid Department certification number of the certified individual providing that service.

§ 240.302. Required client information.

(a) A person may not test, mitigate against radon or provide a radon-related service or product without first offering the potential client a price list of services offered, and providing evidence of certification and a notice that only persons certified under the act and this chapter may provide the services or products. For mitigators, a written estimate for services shall constitute a price list. The notice must read substantially as follows:

NOTICE TO CLIENTS:

Pennsylvania law requires that anyone who performs radon testing, mitigation or laboratory analysis activities must be currently certified by the Pennsylvania Department of Environmental Protection (DEP). Any person providing these radon services shall present to the client a current Department-issued photo identification card upon request. If you have questions, you may contact DEP at the Bureau of Radiation Protection, Department of Environmental Protection, P.O. Box 8469, Harrisburg, Pa. 17105-8469, (717) 783-3594.

(b) For a person performing mitigation, warranty information, if offered, and information on the proper method of checking and servicing of mitigation equipment to maintain its function shall be provided in writing to the client.

§ 240.303. Reporting of information.

This section specifies reporting requirements for testing, mitigation and other radon-related services.

(1) *Laboratory reporting and primary tester reporting.*

(i) A primary tester performing analyses or a certified individual performing laboratory analyses shall report test results to the Department within 45 days of the analysis date. If a radon-related analysis is not provided during a 45-day period, the certified individual shall inform the Department by the end of that 45-day period in a format approved by the Department. Radon tests used for diagnostic purposes must be identified as "diagnostic" when submitted to the laboratory. The information must include all of the following as available:

(A) The name and certification number of the person certified to provide the testing or laboratory analysis service.

(B) The address of the building tested, including street and number, post office, full zip code and county.

(C) The begin and end date of each measurement, measurement method and locations in the building.

(D) The type of house or building, the types of measurement devices used, the locations within the building of specific measurements and the results in picocuries per liter.

(E) The operational status of the mitigation system at the test site.

(F) The date the analysis was performed.

(G) The serial number of the CRM or electret reader.

(ii) The primary certified individual shall retain for 5 years the test result documentation identified in subparagraph (i).

(iii) The following test results should not be reported to the Department:

(A) An invalid test.

(B) A diagnostic test.

(C) A measurement performed only for QA.

(2) *Mitigation reporting.*

(i) A mitigation certified individual shall report the mitigation activity results to the Department within 45 days after the mitigation system initial fan activation or the alteration to an existing mitigation system. If mitigation activity is not performed during a 45-day period, the certified individual shall inform the Department by the end of that 45-day period in a format approved by the Department. The reported information must include all of the following:

(A) The name and certification number of the person providing the service.

(B) The address of the building involved, including street and number, post office, full zip code and county.

(C) The date of the initial fan activation or the alteration to an existing mitigation system.

(D) The type of house or building.

(E) The type of mitigation installation or alteration.

(F) The cost to the client.

(G) The postmitigation result.

(ii) The mitigation certified individual shall retain for 5 years the mitigation activity result documentation identified in subparagraph (i).

(3) *Reporting to client.* Within 10 business days after testing or laboratory analysis is provided, the person providing radon-related services shall report in writing to the client and to the owner or occupant the results in picocuries per liter and, when appropriate, in WLs of radon measurements taken in the building. If a certified tester provides the service through a certified laboratory, it is the responsibility of the certified laboratory to report the results to the client and to the owner or occupant of the building.

(4) *Postmitigation testing and reporting.* For a person performing mitigation, each building shall be tested for radon levels after the mitigation is performed. Each test must be at least 48 hours in duration and follow Department-approved protocols in § 240.310 (relating to testing protocols). The postmitigation test shall be conducted no sooner than 24 hours after completion of the mitigation. The results of the postmitigation test shall 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.

§ 240.304. (Reserved).

§ 240.305. Health and safety program.

A certified individual shall have a radon health and safety program to protect himself and firm employees from exposure to radon that, at a minimum, includes minimizing one's time in the building and providing fresh air intake from outside air, when appropriate. The program must include records of each mitigator's exposure to radon during the course of employment. The certified individual shall record the items on the form in Appendix C (relating to radon exposure tracking record) and retain the records for a period of 5 years. Testers and mitigators may not exceed 4 WLM/yr in radon exposure.

§ 240.306. Continuing education program.

Upon certification renewal, the certified individual shall submit to the Department proof of having satisfactorily completed 16 credit hours of Department-approved continuing education courses or Department-approved equivalent.

§ 240.307. Radon measurement proficiency program.

An initial laboratory individual applicant, initial primary testing individual applicant, or an applicant applying to add a new primary testing or laboratory device shall provide written evidence of successful participation in a Department-approved radon measurement proficiency program for each model type.

§ 240.308. Radon mitigation standards for detached and attached residential buildings three stories or less in height.

(a) The certified individual shall conduct a thorough visual inspection of the building prior to initiating any radon mitigation work.

(b) *Terminal discharge.* To prevent re-entrainment of radon, discharges of depressurization systems, whether fan-powered or passive, must meet all of the following requirements:

(1) The termination point shall be above the immediate edge of the roof for vent pipes attached to the side of the building.

(2) The termination point must be vertical, upward, outside the structure and discharging to the atmosphere. A 45-degree elbow is permitted. Rain caps may not be used.

(3) The termination point must be 10 feet or more above the ground level nearest to the point of discharge.

(4) The termination point must be 10 feet or more from an operable window unit, door or other opening into conditioned spaces unless it is 2 feet above the top of the openings. The 10-foot distance may be measured directly between the opening and the exhaust point or with a flexible tape following the shortest path possible around intervening solid objects. A chimney is not considered an opening into conditioned spaces.

(5) The termination point must be at least 5 feet horizontally from a vertical wall that extends above the roof or higher than the vertical wall.

(6) The termination point must be 10 feet or more from an opening into an adjacent structure and be:

(i) At least 12 inches above the surface of the roof for vent pipes that penetrate the roof.

(ii) At least 10 feet from any openings of conditioned spaces in the structure.

(c) *Fan location.* A radon fan used in active soil depressurization or a block wall depressurization system may not be installed:

(1) Below grade, in a window well or egress window well, or in the conditioned space of a building.

(2) In a basement, crawl space or other interior location directly beneath the heated or cooled spaces of a building.

(d) *Sealing.*

(1) When accessible, the following are required to be adequately sealed with urethane caulk or equivalent material using methods and materials that are permanent and durable when installing a mitigation system:

(i) Perimeter channel drains.

(ii) Cracks that exist where the slab meets the foundation wall (floor wall joint).

(iii) Expansion or control joints.

(iv) Openings around utility penetrations of the foundation walls.

(v) Sump pits that allow entry of soil gas or that allow conditioned air to be drawn into a sub-slab depressurization system.

(2) When the opening or channel is greater than 1/2 inch in width, a foam backer rod or other equivalent filler material shall be inserted into the channel before application of the sealant. Materials inserted into the channel must leave adequate space below the filler material to allow subsurface drainage from the channel into the subslab material.

(3) If the mitigator and homeowner determine that the perimeter channel drain cannot be sealed for water control reasons, then the mitigator may leave those areas unsealed and shall provide the following written statements to the homeowner:

(i) This technique may contribute to increased heating and cooling costs.

(ii) This technique may reduce the effectiveness of the radon mitigation system.

(iii) This technique may increase the potential for backdrafting natural draft combustion appliances.

(e) *Labeling.*

(1) If the mitigation system is accessible and visible, a system description label shall be prominently and permanently affixed to the mitigation system piping. If the mitigation system is concealed or not accessible, then the label shall be placed in another prominent location. The label must be legible from a distance of at least 3 feet and include all of the following information:

(i) "Radon Reduction System."

(ii) The name and certification number of the mitigation certified individual or firm.

(iii) The contact telephone number of the mitigation certified individual or firm.

(iv) The date of installation.

(v) "Building should be tested for radon at least every two years."

(2) Each exposed and visible interior radon mitigation system vent pipe section shall be identified with at least one label on each floor level. The label must read "Radon Reduction System."

(f) *Required client information.* Upon completion of the mitigation project, the mitigator shall attach an information package to the mitigation system in a secure and permanent manner, visible location and labeled "Radon Mitigation Information." The information package must include all of the following:

(1) A copy of contracts and warranties for the mitigation system.

(2) A description of the installed mitigation system and its basic operating principles.

(3) A description of the proper operating procedures of installed mechanical or electrical systems, including the manufacturer's operation and maintenance instructions, drain-filling instructions and warning device interpretations.

(4) A list of appropriate actions for the client to take if the system failure warning device indicates system degradation or failure.

(5) A recommendation to retest at least every 2 years.

(6) A recommendation to have an electrical inspection performed on the applicable components of the installed system.

(g) *Compliance.* A person conducting radon mitigation activities shall conduct the mitigation in accordance with Department-approved mitigation standards and shall comply with applicable statutes, regulations, ordinances and building codes. The following protocols, "Protocols for Radon and Radon Decay Product Measurements in Homes," "Indoor Radon and Radon Decay Product Measurement Device Protocols" and "Pennsylvania Radon Mitigation Standards" are available upon request from the following source:

Department of Environmental Protection
Bureau of Radiation Protection
Rachel Carson State Office Building, 13th Floor
400 Market Street
Post Office Box 8469
Harrisburg, Pennsylvania 17105-8469

§ 240.310. Testing protocols.

(a) *Radon testing protocols.* The certified individual shall ensure that the requirements in this section are completed. For testing that is required to be reported to the Department under § 240.303 (relating to reporting of information), radon testing shall be performed in accordance with all of the following testing protocols:

(1) *Placement of testing devices.* Testing devices shall be placed as follows:

(i) At least 3 feet from exterior doors, windows or ventilation ducts.

(ii) Out of the direct flow of air.

(iii) At least 1 foot from ceilings and exterior walls.

(iv) At least 20 inches but not more than 6 feet from the floor.

(v) At least 4 inches from other objects horizontally or vertically above the detector.

(vi) At least 4 feet from heat sources including fireplaces, furnaces and direct sunlight.

(vii) At least 7 feet from sump pits.

(viii) Where the device will remain undisturbed during the test period.

(2) *Improper placement of testing devices.* Testing devices may not be placed in the following locations:

(i) Bathrooms.

(ii) Kitchens.

(iii) Within 10 feet of washer/dryer unit.

(iv) Spa rooms or other areas of high humidity.

(v) Closets.

(vi) Cupboards.

(vii) Sump pits.

(viii) Crawlspaces or nooks within the foundation.

(3) *Short-term tests.* Short-term tests shall be taken in the lowest livable level of each structural zone that contacts the soil.

(4) *Conditions of testing.* Testing shall be conducted under the following conditions:

(i) Testing devices must remain undisturbed during the testing period.

(ii) A short-term test must range in duration from 48 hours to 90 days.

(iii) Short-term tests must be conducted under closed-building conditions.

(iv) Closed-building conditions must begin at least 12 hours prior to the beginning of the test period for tests lasting less than 96 hours.

(v) Closed-building conditions consist of all of the following criteria:

(A) All windows must be closed.

(B) All external doors must be closed except for normal entry and exit. Structural openings due to disrepair or structural defects shall be repaired to correct their condition prior to initiation of testing.

(C) Normal operation of permanently installed HVAC systems must continue during closed-building conditions.

(D) Fireplaces, wood stoves and coal stoves may not be operated unless they are normal sources of heat for the building.

(E) Air conditioning systems that recycle interior air may be operated during closed-building conditions.

(F) Whole-house fans may not be operated during the test period. Portable window fans shall be removed from windows or sealed in place. Window air conditioning units may only be operated in a recirculation mode. If the building contains an air handling system, the air handling system may not be set for continuous operation unless the air handling equipment is specifically used for radon control and is labeled accordingly.

(G) In buildings with permanently installed radon mitigation systems, the mitigation system must be functioning during the test period. If the system is not functioning, the client must be notified immediately.

(H) Operation of fans, portable dehumidifiers, portable humidifiers, portable air filters and window air conditioners may not create a direct flow of air on the radon testing device.

(vi) All closed-building conditions shall be inspected and documented at the time of placement and retrieval of the detectors.

(vii) Short-term tests of fewer than 96 hours may not be conducted during unusually severe storms or periods of high winds of 30 miles per hour or greater. Local weather forecasts shall be checked and documented prior to placing short-term test devices when the test period is less than 96 hours.

(viii) Instructions describing closed-building conditions required in this section shall be provided to the persons who control the building.

(ix) Only co-located duplicate tests may be averaged.

(5) *Minimum requirements for short-term testing.*

(i) *Simultaneous testing using short-term passive devices.*

(A) Simultaneous testing must comprise at least two short-term indoor radon tests conducted simultaneously with identical test devices.

(B) Simultaneous testing devices shall be:

(I) Co-located and the near edges spaced 4 to 5 inches apart.

(II) Exposed for the same test period.

(C) Both tests and the average of the simultaneous tests shall be reported to the client, except as indicated in subclause (II):

(I) If the RPD is greater than 67% for simultaneous test results that are both between 2.0 and 3.9 pCi/L, the tests shall be reported to the client and the cause investigated, documented and corrected.

(II) If the RPD is greater than 36% for simultaneous test results that are both equal to or greater than 4.0 pCi/L, the tests may not be reported to the client, and the cause shall be investigated, documented and corrected.

(D) If one test is equal to or greater than 4.0 pCi/L and one test is less than 4.0 pCi/L, and the higher test is more than twice the amount of the lower test, the tests may not be reported to the client.

(ii) *CRM testing.*

(A) A CRM must have the capability to integrate and record a new result at least hourly.

(B) The minimum test period is 48 hours, with 44 contiguous hours of usable data to produce a valid average. The first 4 hours of data from a CRM may be discarded.

(C) The contiguous results shall be averaged to produce a result that is reported to the client.

(D) A copy of the hourly printout shall be provided to the client as part of the test results.

(6) *Real estate testing.* Real estate testing shall be conducted using all of the following anti-tampering procedures:

(i) Anti-tampering devices shall be employed to indicate if a test device was moved during the testing period.

(ii) The buyer, seller, occupant, real estate professional or other individual in control of the property shall sign a Conditions for Short-Term Radon Testing Agreement, which must contain the information in Appendix B (relating to non-interference agreement for real estate radon testing).

(iii) If the Conditions for Short-Term Radon Testing Agreement cannot be signed by the buyer, seller, occupant, real estate professional or other individual in control of the property, the reason shall be documented on the completed agreement.

(iv) A Radon Testing in Progress Notice shall be posted and in a conspicuous indoor location. The notice shall be posted upon initiation of a radon test and include all of the following statements:

(A) "Radon Testing in Progress."

(B) "Keep all windows closed."

(C) "Keep all exterior doors closed, except for normal entry and exit."

(D) "Do not move or touch the radon testing device."

(7) *Multifamily building tests.* Multifamily building tests shall be performed in accordance with ANSI/AARST MAMF-2017, "Protocol for Conducting Radon and Radon Decay Product Measurements in Multifamily Buildings," or its equivalent as determined by the Department.

(8) *Multifamily building mitigation.* Multifamily building mitigation shall be performed in accordance with ANSI/AARST RMS-MF 2014, "Radon Mitigation Standards for Multifamily Buildings," or its equivalent as determined by the Department.

(9) *School and commercial building tests.* School and commercial building tests shall be performed in accordance with *Radon Measurement in Schools* (EPA 402-R-92-014) or its equivalent as determined by the Department.

(10) *New construction and buildings under renovation.* This paragraph provides the testing requirements for new construction and buildings under renovation. A newly constructed building or existing building under renovation may not be tested for radon or radon progeny unless all of the following items have been installed:

(i) Insulation.

(ii) Exterior doors with associated hardware.

(iii) Windows.

(iv) Fireplaces and fireplace dampers, if they are or will be installed.

(v) Heating, air conditioning and plumbing appliances.

(vi) Ceilings.

(vii) Interior trim and coverings for the exterior walls.

(viii) Exterior siding, weatherproofing and caulking.

(ix) Interior and exterior structural components.

(x) Interior or exterior work that may adversely affect the test validity.

(11) *Postmitigation testing.*

(i) Testing conducted while temporary radon reduction systems are in use may not be used as the postmitigation test.

(ii) The mitigation system must be operated continuously during the entire test period. If the system is not functioning, the client must be notified immediately.

(iii) The postmitigation test may not be performed sooner than 24 hours or later than 30 days following the completion and activation of the mitigation system or an alteration to an existing system unless unforeseen circumstances prohibit the testing being performed within this timeframe, such as the owner or occupier refusing or ignoring requests to complete the postmitigation test.

(iv) Postmitigation testing shall be conducted in accordance with this subsection.

(b) *Result Report Form.*

(1) A tester shall have a Department-approved Result Report Form. Testers shall provide the client with a completed Result Report Form within 10 business days from the completion of the test or the receipt of the test results from the laboratory. The Result Report Form must contain all of the following as available:

(i) Each test result in pCi/L and rounded to one decimal place. Standard mathematical rules for rounding shall be followed.

(ii) Notification of an invalid radon test with an explanation and without a test result given.

(iii) The average of co-located test device results as well as the individual results.

(iv) The exact start and stop dates and times of the test period.

(v) The complete street address of the test location, including, when applicable, the apartment, suite or building number.

(vi) The test device used and its manufacturer, model and serial number.

(vii) The complete name, street address and telephone number of the tester.

(viii) The name and Department certification number of each tester placing and retrieving each testing device.

(ix) The name and certification number of the laboratory analyzing the testing device, if applicable.

(x) A statement whether a mitigation system was observed in the building during placement or retrieval of the testing device, including whether the mitigation system was operating.

(xi) A statement describing if tampering, interference or deviations from the required test conditions was observed.

(xii) A description of the condition (open, closed or not applicable) of permanent vents that allow outdoor air into the building, such as crawlspace vents or combustion air supply to combustive appliances.

(xiii) A description of unusually severe storms or periods of high winds during the test period.

(xiv) The location within the building of each testing device.

(xv) The Pennsylvania "Notice to Clients" statement as indicated in § 240.302 (relating to required client information).

(xvi) If using a CRM, a copy of the device printout.

(xvii) If using a CRM or electret reader, the calibration expiration date.

(xviii) If using a CRM or electret reader, the device serial number.

(xix) The following radon health risk information:

Radon is the second leading cause of lung cancer, after smoking. The U.S. Environmental Protection Agency (EPA) and the Surgeon General strongly recommend taking further action when the home's radon test results are 4.0 pCi/L or greater. The National average indoor radon level is about 1.3 pCi/L. The higher the home's radon level the greater the health risk to you and your family. Reducing your radon levels can be done easily, effectively and fairly inexpensively. Even homes with very high radon levels can be reduced below 4.0 pCi/L. For further information about reducing elevated radon levels, please refer to the "Pennsylvania Consumers Guide to Reduction."

(2) A laboratory shall use a Department-approved Result Report Form. Laboratories shall provide the client with a completed Result Report Form within 10 business days after completion of test analysis. The Result Report Form must contain all of the following as available:

(i) Each test result in pCi/L and rounded to one decimal place. Standard mathematical rules for rounding shall be followed.

(ii) Notification of invalid radon tests with an explanation and without a test result given.

(iii) The average of co-located testing devices as well as the individual results.

(iv) The exact start and stop dates and times of the test period.

(v) The complete street address of the test location, including, when applicable, the apartment, suite or building number, as available.

(vi) The test device used and its manufacturer, model and serial numbers.

(vii) The name and certification number of the laboratory analyzing the testing device.

(viii) The location within the building of each test device, as available.

(ix) The Pennsylvania "Notice to Clients" statement as indicated in § 240.302.

(x) If using a CRM, a copy of the device printout.

(xi) The calibration expiration date of the electret reader or continuous monitor.

(xii) The following radon health risk information:

Radon is the second leading cause of lung cancer, after smoking. The U.S. Environmental Protection Agency (EPA) and the Surgeon General strongly recommend taking further action when the home's radon test results are 4.0 pCi/L or greater. The national average indoor radon level is about 1.3 pCi/L. The higher the home's radon level the greater the health risk to you and your family. Reducing your radon levels can be done easily, effectively and fairly inexpensively. Even homes with very

high radon levels can be reduced below 4.0 pCi/L. For further information about reducing elevated radon levels, please refer to the "Pennsylvania Consumers Guide to Reduction."

Subchapter E. ENFORCEMENT AND DECERTIFICATION

§ 240.401. Inspection.

(a) The Department and its agents and employees will:

* * * * *

(b) The Department, its agents and employees may conduct inspections of a building, property, premises or place of business of a person who conducts radon-related activities if a person presents information to the Department or the Department has access to information which gives it reason to believe that one of the following exists:

* * * * *

(c) An agent or employee of the Department may not enter a private residence for the purpose of conducting an inspection under this section without a search warrant or without the consent of the occupant.

* * * * *

Subchapter F. (Reserved)

§ 240.501. (Reserved).

§ 240.502. (Reserved).

Subchapter G. QA REQUIREMENTS

Sec.
240.601. Scope.
240.602. General requirements.
240.603. QA program.
240.604. QA requirements for testing using primary devices.
240.605. QA requirements for testing using secondary devices.
240.606. QA requirements for laboratories.

§ 240.601. Scope.

(a) This subchapter applies to QA requirements for:

(1) Persons conducting radon testing and radon laboratory analysis activities.

(2) Testing devices listed with the Department on the individual's certification.

(b) The subchapter does not apply to tests performed for the sole purpose of diagnostic testing.

§ 240.602. General requirements.

(a) The certified individual is responsible for all requirements in this subchapter, including when QA activities are performed by others.

(b) QA requirements and corrective actions in this section shall be documented and the records retained for a minimum of 5 years.

§ 240.603. QA program.

A person conducting radon testing or radon laboratory analysis activities shall have a QA program to ensure the measurements are accurate and errors are controlled. The program must ensure that testing devices are routinely and properly calibrated. The program shall provide the information related to all of the following activities:

(1) Organization and responsibilities.

(2) Sampling procedures.

(3) Detector custody.

(4) Analytical procedures.

(5) Data reduction, validation and reporting.

(6) Corrective action.

(7) QA reports to management.

§ 240.604. QA requirements for testing using primary devices.

(a) *CRMs for primary testers.*

(1) *Calibration.* Each Department-listed CRM must have a current calibration. To have a current calibration, the CRM shall be calibrated in a Department-approved calibration facility within 1 year from the date of the previous calibration and when alterations or repairs are made to the CRM.

(2) *Background measurements.* Background measurements shall be performed and documented after every 1,000 hours of operation of scintillation cell-type CRM. These background measurements shall be checked by purging the unit with clean, aged air or nitrogen in accordance with the manufacturer's instructions. For all CRMs, the background shall be monitored in accordance with the manufacturer's instructions.

(3) *Check source counting.* For a CRM with a check source, check source counting shall be documented and completed with that check source prior to each test.

(4) *Routine instrument checks.* Before and after each measurement, the CRM shall be checked according to the manufacturer's instructions. For each check, all of the following shall be verified:

(i) The correct input parameters and the unit's clock or timer are set properly.

(ii) The pump's flow rates are within the range of the manufacturer's specifications.

(5) *Data collection log.*

(i) CRM data shall be tracked on a form that contains all of the following:

(A) The CRM serial number.

(B) The exposure dates and times.

(C) The test result.

(D) The address of the building tested.

(E) The test location in the building.

(F) The name of the tester who placed the CRM.

(G) The name of the tester who retrieved the CRM.

(H) The calibration, repair and Department listing dates.

(ii) For a CRM without a check source, the data collection log must also contain all of the following intercomparison measurement information:

(A) The intercomparison devices' serial numbers.

(B) The RPD value.

(C) The intercomparison measurements results.

(6) *Intercomparison measurements.* An intercomparison measurement shall be performed for each CRM without a check source.

(i) Intercomparison measurements shall be made at least every tenth test with another Department-listed passive device that is analyzed by a Department-certified laboratory or with another CRM with a hard copy printout. The intercomparison measurements shall be distributed systematically throughout the entire population of test locations. Original printouts or Department-certified laboratory results, or both, shall be kept for each

intercomparison. Each intercomparison measurement must be performed with the devices side by side for the measurement for at least 48 hours.

(ii) For intercomparison measurements, the RPD shall be used to track performance. The RPD value shall be tracked using control charts from "Protocols for Radon and Radon Decay Product Measurements in Homes," EPA 402-R-92-003, May 1993, Appendix B, Exhibits B-2 and B-3.

(iii) If the RPD value exceeds the control limit, the CRM may not be used for radon measurements until the problem is identified and corrected. If the RPD value exceeds the warning level, the criteria in "Protocols for Radon and Radon Decay Product Measurements in Homes," EPA 402-R-92-003, May 1993, Appendix B, Exhibit B-5, shall be followed.

(iv) In addition to the control charts, intercomparison measurements shall be documented on the CRM data collection log.

(b) *CWLMs for primary testers.*

(1) *Calibration.* Each Department-listed CWLM must have a current calibration. To have a current calibration, the CWLM shall be calibrated in a Department-approved calibration facility within 1 year from the date of the previous calibration and when alterations or repairs are made to the CWLM.

(2) *Background measurements.* CWLM background measurements shall be performed and documented at least every 168 hours of operation and when the unit is calibrated.

(3) *Routine instrument checks.* Routine instrument checks for each CWLM shall be documented and performed before and after each test by using an Am-241 or similar energy check source. Pumps and flow meters shall be checked in accordance with the manufacturer's instructions and documented. The pump and flow meter check shall be performed with a dry-gas meter or other flow measurement device of traceable accuracy.

(4) *Data collection log.*

(i) CWLM data shall be tracked on a form that contains all of the following:

(A) The CWLM serial number.

(B) The exposure dates and times.

(C) The test result.

(D) The address of the building tested.

(E) The test location in the building.

(F) The name of the tester who placed the CWLM.

(G) The name of the tester who retrieved the CWLM.

(H) The calibration, repair and Department listing dates.

(ii) For CWLMs without a check source, the data collection log must also contain all of the following intercomparison measurement information:

(A) The intercomparison devices' serial numbers.

(B) The RPE value or RPD value.

(C) The intercomparison measurement results.

(5) *Intercomparison measurements.* An intercomparison measurement shall be performed for each CWLM monitor without a check source.

(i) A CWLM without check source capability must have an informal intercomparison measurement made with another CWLM with a hard copy printout at least every tenth test. This printout shall be retained for each intercomparison. The intercomparison measurements shall be distributed systematically throughout the entire population of test locations. Each intercomparison measurement must be performed with the devices side by side for the measurement for at least 48 hours.

(ii) Each intercomparison shall be documented on the data collection log.

(iii) For intercomparison measurements the RPD shall be used to track performance. The RPD value shall be tracked using control charts from "Protocols for Radon and Radon Decay Product Measurements in Homes," EPA 402-R-92-003, May 1993, Appendix B, Exhibits B-2 and B-3.

(iv) If the RPD value exceeds the control limit, the CWLM may not be used for radon measurements until the problem is identified and corrected. If the RPD value exceeds the warning level, the criteria in "Protocols for Radon and Radon Decay Product Measurements in Homes," EPA 402-R-92-003, May 1993, Appendix B, Exhibit B-5, shall be followed.

(c) *Electret ion chambers for primary testers.*

(1) *Calibration.* Each Department-listed electret reader must have a current calibration. To have a current calibration, the electret reader shall be calibrated in a Department-approved calibration facility within 1 year from the date of the previous calibration and when alterations or repairs are made to the electret reader. Each electret reader shall be calibrated simultaneously with its corresponding reference electret's recertification.

(2) *Data collection log.* Electret custody shall be tracked on a form that contains all of the following:

(i) The electret serial number.

(ii) The initial voltage reading.

(iii) The final voltage reading.

(iv) The exposure dates and times.

(v) The test result.

(vi) The serial number of duplicate electret.

(vii) The RPD value.

(viii) The address of the building tested.

(ix) The test location in the building.

(x) The name of the tester who placed the electret.

(xi) The name of the tester who retrieved the electret.

(3) *Known exposure measurements (spikes).*

(i) Spikes shall be conducted at a rate of 3 for each 100 test devices deployed, with a minimum of 3 spikes for each certification year when tests were conducted in the certification year, and with a maximum of 6 spikes each month.

(ii) Spikes shall be analyzed in the same manner as all other testing.

(iii) Spikes shall be monitored using a means control chart. The means control chart must be established as follows:

(A) Using an RPE value of plus and minus 10%, which corresponds to the 1 sigma level.

(B) A warning level of the RPE of plus and minus 20%, which corresponds to the 2 sigma warning level.

(C) Control limits of the RPE of plus and minus 30%, which corresponds to the 3 sigma control level.

(iv) Each RPE value shall be plotted on the means control chart within 1 week of return of the device from the chamber. If the RPE value is outside the 3 sigma control level, all measurements shall cease until the problem is evaluated and corrected. All evaluations shall be documented.

(v) In addition to the means control chart, all spikes shall be documented on a form that contains all of the following:

(A) The radon chamber name.

(B) The electret serial numbers.

(C) The RV from radon chamber.

(D) The measured spike value or values.

(E) The individual RPE results.

(F) The certification year beginning date and end date.

(G) The exposure dates.

(4) *Duplicate measurements.*

(i) Duplicates shall be made in at least 10% of the total number of test devices deployed each month, or 50 each month, whichever is smaller.

(ii) The RPD shall be calculated for all duplicate results with an average of greater than or equal to 2.0 pCi/L. Two control charts shall be constructed to monitor duplicate precision:

(A) One for duplicates when the average is greater than or equal to 4.0 pCi/L.

(B) One for duplicates when the average is greater than or equal to 2.0 pCi/L and less than 4.0 pCi/L.

(iii) Each RPD value shall be plotted on the control chart within 1 week of performing the duplicate measurement.

(iv) The RPD shall be tracked using control charts from "Protocols for Radon and Radon Decay Product Measurements in Homes," EPA 402-R-92-003, May 1993, Appendix B, Exhibits B-2 and B-3.

(v) For duplicates when the average is greater than or equal to 4.0 pCi/L, all of the following apply:

(A) The control level shall be set at an RPD of 14%.

(B) The warning level shall be set at an RPD of 28%.

(C) The control limit shall be set at an RPD of 36%.

(vi) For duplicates when the average is greater than or equal to 2.0 pCi/L and less than 4.0 pCi/L, all of the following apply:

(A) The control level shall be set at an RPD of 25%.

(B) The warning level shall be set at an RPD of 50%.

(C) The control limit shall be set at an RPD of 67%.

(vii) If the plotted RPD result falls outside of the control limit, the measurements shall cease until the problem is identified and corrected.

(viii) If the plotted RPD result falls outside of the warning level, "Protocols for Radon and Radon Decay Product Measurements in Homes," EPA 402-R-92-003, May 1993, Appendix B, Exhibit B-5, shall be used to determine the action to be taken.

(ix) Documentation of duplicates must include all of the following:

(A) The device serial numbers.

(B) The exposure dates.

(C) Each duplicate measurement result.

(D) The RPD results.

(5) *Voltmeter routine instrument checks.*

(i) Proper operation of the surface voltmeter shall be monitored following the manufacturer's procedures for analyzing the reference electrets and zeroing the voltmeter.

(ii) A voltage reading of a reference electret difference of more than 2 volts from the reference electret specified value shall be considered a wrong reading. The second reference electret in the set shall be read to determine whether the wrong reading is in the first reference electret or in the reader. Corrective action shall be taken in consultation with the manufacturer.

(iii) When zeroing the reader, if the voltmeter displays more than (±) 3 volts, corrective action shall be taken in consultation with the manufacturer.

(iv) Voltmeter checks shall be conducted at least once each week while the voltmeter is in use and shall be documented. Documentation of routine instrument checks must include all of the following:

(A) The reader serial number.

(B) The date of analysis.

(C) Zero value.

(D) The reference electret values.

(E) Corrective actions performed.

§ 240.605. QA requirements for testing using secondary devices.

(a) *CRMs for secondary testers.*

(1) *Calibration.* Each Department-listed CRM must have a current calibration. To have a current calibration, the CRM shall be calibrated in a Department-approved calibration facility within 1 year from the date of the previous calibration and when alterations or repairs are made to the CRM. A current calibration certificate shall be retained for each monitor.

(2) *Check source counting.* For a CRM with a check source, check source counting shall be documented and completed with that check source prior to each test.

(3) *Routine instrument checks.* Before and after each measurement, the CRM shall be checked according to the manufacturer's instructions. For each check, all of the following shall be verified:

(i) The correct input parameters and the unit's clock or timer are set properly.

(ii) The pump's flow rates are within the range of the manufacturer's specifications.

(4) *Data collection log.*

(i) CRM data shall be tracked on a form that contains all of the following:

(A) The CRM serial number.

(B) The exposure dates and times.

(C) The test result.

(D) The address of the building tested.

(E) The test location in the building.

(F) The name of the tester who placed the CRM.

(G) The name of the tester who retrieved the CRM.

(H) The calibration, repair and Department listing dates.

(ii) For a CRM without a check source, the data collection log must also contain all of the following intercomparison measurement information:

(A) The intercomparison device serial number.

(B) The RPE value or RPD value.

(C) The intercomparison measurement result.

(5) *Intercomparison measurements.* An intercomparison measurement shall be performed for each CRM without a check source.

(i) Intercomparison measurements shall be made at least every tenth test with another Department-listed passive device that is analyzed by a Department-certified laboratory or with another CRM with a hard copy printout. The intercomparison measurements shall be distributed systematically throughout the entire population of test locations. Original printouts or Department-certified laboratory results, or both, shall be kept for each intercomparison. Each intercomparison measurement must be performed with the devices side by side for the measurement for at least 48 hours.

(ii) When performing intercomparison measurements, the RPD shall be used to track performance. The RPD value shall be tracked using control charts from "Protocols for Radon and Radon Decay Product Measurements in Homes," EPA 402-R-92-003, May 1993, Appendix B, Exhibits B-2 and B-3.

(iii) If the RPD value exceeds the control limit, the CRM may not be used for radon measurements until the problem is identified and corrected. If the RPD value exceeds the warning level, the criteria in the "Protocols for Radon and Radon Decay Product Measurements in Homes," EPA 402-R-92-003, May 1993, Appendix B, Exhibit B-5, shall be followed.

(iv) In addition to the control charts, intercomparison measurements shall be documented on the CRM data collection log.

(b) *CWLM for secondary testers.*

(1) *Calibration.* Each Department-listed CWLM must have a current calibration. To have a current calibration, the CWLM shall be calibrated in a Department-approved calibration facility within 1 year from the date of the previous calibration and when alterations or repairs are made to the CWLM. A current calibration certificate shall be retained for each monitor.

(2) *Data collection log.*

(i) CWLM data shall be tracked on a form that contains all of the following:

(A) The CWLM serial number.

(B) The exposure dates and times.

(C) The test result.

(D) The address of the building tested.

(E) The test location in the building.

(F) The name of the tester who placed the CWLM.

(G) The name of the tester who retrieved the CWLM.

(H) The calibration, repair and Department listing dates.

(ii) For CWLMs without a check source, the data collection log must also contain all of the following intercomparison measurement information:

(A) The intercomparison device serial number.

(B) The RPD value.

(C) The intercomparison measurement result.

(3) *Intercomparison measurements.* An intercomparison measurement shall be performed for all CWLM monitors without a check source.

(i) A CWLM without check source capability shall have an informal intercomparison measurement made with another CWLM with a hard copy printout at least every tenth test. This printout shall be retained for each intercomparison. The intercomparison measurements shall be distributed systematically throughout the entire population of test locations. Each intercomparison measurement must be performed with the devices side by side for the measurement for at least 48 hours.

(ii) Each intercomparison shall be documented on the data collection log.

(iii) When performing intercomparison measurements, the RPD shall be used to track performance. The RPD value shall be tracked using control charts from "Protocols for Radon and Radon Decay product measurements in Homes," EPA 402-R-92-003, May 1993, Appendix B, Exhibits B-2 and B-3.

(iv) If the RPD value exceeds the control limit, the CWLM may not be used for radon measurements until the problem is identified and corrected. If the RPD value exceeds the warning level, the criteria in the "Protocols for Radon and Radon Decay Product Measurements in Homes," EPA 402-R-92-003, May 1993, Appendix B, Exhibit B-5, shall be followed.

(c) *Electret ion chambers for secondary testers.*

(1) *Data collection log.* Electret data shall be tracked on a form that contains all of the following:

(i) The electret serial number.

(ii) The initial voltage reading.

(iii) The final voltage reading.

(iv) The exposure dates and times.

(v) The test results.

(vi) The serial number of duplicate electret.

(vii) The RPD value.

(viii) The address of the building tested.

(ix) The test location in the building.

(x) The name of the tester who placed the electret.

(xi) The name of the tester who retrieved the electret.

(2) *Known exposure measurements (spikes).*

(i) Spikes shall be conducted at a rate of 3 for each 100 test devices deployed, with a minimum of 3 spikes for each certification year when tests were conducted in the certification year, and with a maximum of 6 spikes each month.

(ii) Spikes shall be submitted to a Department-certified laboratory labeled as QA. The RV of the spiked device may not be revealed to the laboratory prior to analysis.

(iii) Spikes shall be monitored using a means control chart. The means control chart must be established as follows:

(A) Using an RPE value of plus and minus 10%, which corresponds to the 1 sigma level.

(B) A warning level of the RPE of plus and minus 20%, which corresponds to the 2 sigma warning level.

(C) Control limits of the RPE of plus and minus 30%, which correspond to the 3 sigma control level.

(iv) Each RPE value shall be plotted on the means control chart within 1 week of return of the device from the chamber. If the RPE value is outside the 3 sigma control level, all measurements shall cease until the problem is evaluated and corrected. All evaluations shall be documented.

(v) In addition to the means control chart, all spikes shall be documented on a form that contains all of the following:

(A) The radon chamber name.

(B) The electret serial numbers.

(C) The RV from radon chamber.

(D) The measured spike value or values.

(E) The individual RPE results.

(F) The certification year beginning date and end date.

(G) The exposure dates.

(3) *Duplicate measurements.*

(i) Duplicates shall be made in at least 10% of the total number of test devices deployed each month, or 50 each month, whichever is smaller.

(ii) The RPD shall be calculated for all duplicate results with an average of greater than or equal to 2.0 pCi/L. Two control charts shall be constructed to monitor duplicate precision:

(A) One for duplicates when the average is greater than or equal to 4.0 pCi/L.

(B) One for duplicates when the average is greater than or equal to 2.0 pCi/L and less than 4.0 pCi/L.

(iii) Each RPD value shall be plotted on the control chart within 1 week of performing the duplicate measurement.

(iv) The RPD shall be tracked using control charts from "Protocols for Radon and Radon Decay Product Measurements in Homes," EPA 402-R-92-003, May 1993, Appendix B, Exhibits B-2 and B-3.

(v) For duplicates when the average is greater than or equal to 4.0 pCi/L, all of the following apply:

(A) The control level shall be set at an RPD of 14%.

(B) The warning level shall be set at an RPD of 28%.

(C) The control limit shall be set at an RPD of 36%.

(vi) For duplicates when the average is greater than or equal to 2.0 pCi/L and less than 4.0 pCi/L, all of the following apply:

(A) The control level shall be set at an RPD of 25%.

(B) The warning level shall be set at an RPD of 50%.

(C) The control limit shall be set at an RPD of 67%.

(vii) If the plotted RPD result falls outside of the control limit, the measurements shall cease until the problem is identified and corrected.

(viii) If the plotted RPD result falls outside of the warning level, "Protocols for Radon and Radon Decay Product Measurements in Homes," EPA 402-R-92-003, May 1993, Appendix B, Exhibit B-5, shall be used to determine the action to be taken.

(ix) Documentation of duplicates must include all of the following:

(A) The device serial numbers.

(B) The exposure dates.

(C) Each duplicate measurement result.

(D) The RPD results.

(d) *LS, AC and ATs for secondary testers.*

(1) *Data collection log.* Detector data shall be tracked on a form that contains all of the following:

(i) The device serial number.

(ii) The serial number of duplicate devices.

(iii) The serial number of spiked devices.

(iv) The exposure dates and times.

(v) The test results.

(vi) The RPE value or RPD value.

(vii) The address of the building tested.

(viii) The test location in the building.

(ix) The name of the tester who placed the device.

(x) The name of the tester who retrieved the device.

(xi) The name of the laboratory to which device was sent.

(2) *Known exposure measurements (spikes).*

(i) Spikes shall be conducted at a rate of 3 for each 100 test devices deployed, with a minimum of 3 spikes for each certification year when tests were conducted in the certification year, and with a maximum of 6 spikes each month.

(ii) Spikes shall be submitted to a Department-certified laboratory labeled as QA. The RV of the spiked device may not be revealed to the laboratory prior to analysis.

(iii) Spikes shall be monitored using a means control chart. The means control chart must be established as follows:

(A) Using an RPE value of plus and minus 10%, which corresponds to the 1 sigma level.

(B) A warning level of the RPE of plus and minus 20%, which corresponds to the 2 sigma warning level.

(C) Control limits of the RPE of plus and minus 30%, which correspond to the 3 sigma control level.

(iv) Each RPE value shall be plotted on the means control chart within 1 week of receiving the result from the laboratory. If the RPE value is outside the 3 sigma control level, all measurements shall cease until the problem is evaluated and corrected. All evaluations shall be documented.

(v) In addition to the means control chart, all spikes shall be documented on a form that contains all of the following:

(A) The radon chamber name.

(B) The device serial numbers.

(C) The RV from radon chamber.

(D) The measured spike value or values.

(E) The individual RPE results.

(F) The certification year beginning date and end date.

(G) The exposure dates.

(3) *Duplicate measurements.*

(i) Duplicates shall be made in at least 10% of the total number of test devices deployed each month, or 50 each month, whichever is smaller.

(ii) The RPD shall be calculated for all duplicate results with an average of greater than or equal to 2.0 pCi/L. Two control charts shall be constructed to monitor duplicate precision:

(A) One for duplicates when the average is greater than or equal to 4.0 pCi/L.

(B) One for duplicates when the average is greater than or equal to 2.0 pCi/L and less than 4.0 pCi/L.

(iii) Each RPD value shall be plotted on the control chart within 1 week of performing the duplicate measurement.

(iv) The RPD shall be tracked using control charts from "Protocols for Radon and Radon Decay Product Measurements in Homes," EPA 402-R-92-003, May 1993, Appendix B, Exhibits B-2 and B-3.

(v) For duplicates when the average is greater than or equal to 4.0 pCi/L, all of the following apply:

(A) The control level shall be set at an RPD of 14%.

(B) The warning level shall be set at an RPD of 28%.

(C) The control limit shall be set at an RPD of 36%.

(vi) For duplicates when the average is greater than or equal to 2.0 pCi/L and less than 4.0 pCi/L, all of the following apply:

(A) The control level shall be set at an RPD of 25%.

(B) The warning level shall be set at an RPD of 50%.

(C) The control limit shall be set at an RPD of 67%.

(vii) If the plotted RPD result falls outside of the control limit, the measurements shall cease until the problem is identified and corrected.

(viii) If the plotted RPD result falls outside of the warning level, "Protocols for Radon and Radon Decay Product Measurements in Homes," EPA 402-R-92-003, May 1993, Appendix B, shall be used to determine the action to be taken.

(ix) Documentation of duplicates must include all of the following:

(A) The device serial numbers.

(B) The exposure dates.

(C) Each duplicate measurement result.

(D) The RPD results.

(4) *Field blanks.*

(i) Field blank results shall be monitored and recorded. Field blanks shall be performed at a rate of 5% of the devices that are deployed each month, or 25 each month, whichever is smaller, or a minimum of 1 per certification year, unless tests are not performed. These devices shall be set aside, kept in a low-radon environment and labeled as QA when submitted to the laboratory.

(ii) If a field blank has a concentration greater than the lowest level of detection (LLD) as established by the laboratory, all of the following shall occur:

(A) The occurrence shall be documented and reported to the laboratory.

(B) The cause shall be investigated in conjunction with the laboratory and documented.

(iii) Documentation of field blanks must include all of the following:

(A) The device serial numbers.

(B) The date submitted to laboratory.

(C) The measurement results.

(D) The laboratory's reported LLD.

§ 240.606. QA requirements for laboratories.

(a) *CRMs for laboratories.*

(1) *Calibration.* Each Department-listed CRM must have a current calibration. To have a current calibration, the CRM shall be calibrated in a Department-approved calibration facility within 1 year from the date of the previous calibration and when alterations or repairs are made to the CRM. A current calibration certificate shall be retained for each monitor. Analysis may not be performed on a monitor that was not calibrated during any portion of the testing period.

(2) *Data collection log.* CRM data shall be tracked on a form that contains all of the following:

(i) The CRM serial number.

(ii) The exposure dates and times.

(iii) The test result.

(iv) The address of the building tested.

(v) The test location in the building.

(vi) The name of the tester who placed the CRM.

(vii) The name of the tester who retrieved the CRM.

(viii) The calibration, repair and Department listing dates.

(b) *CWLM for laboratories.*

(1) *Calibration.* Each Department-listed CWLM must have a current calibration. To have a current calibration, the CWLM shall be calibrated in a Department-approved calibration facility within 1 year from the date of the previous calibration and when alterations or repairs are made to the CWLM. A current calibration certificate shall be retained for each monitor. Analysis may not be performed on a monitor that was not calibrated during any portion of the testing period.

(2) *Data collection log.* CWLM data shall be tracked on a form that contains all of the following:

(i) The CWLM serial number.

(ii) The exposure dates and times.

(iii) The test result.

(iv) The address of the building tested.

(v) The test location in the building.

(vi) The name of the tester who placed the CWLM.

(vii) The name of the tester who retrieved the CWLM.

(viii) The calibration, repair and Department listing dates.

(c) *Electret ion chamber for laboratory analysis.*

(1) *Calibration.* Each Department-listed electret reader shall have a current calibration. To have a current calibration, the electret reader shall be calibrated in a

Department-approved calibration facility within 1 year from the date of the previous calibration and when alterations or repairs are made to the electret reader. Each electret reader shall be calibrated simultaneously with its corresponding reference electret's recertification.

(2) *Voltmeter routine instrument checks.*

(i) Proper operation of the surface voltmeter shall be monitored following the manufacturer's procedures for zeroing the voltmeter and analyzing the reference electrets.

(ii) A voltage reading of a reference electret difference of more than 2 volts from its specified value shall be considered a wrong reading and corrective action shall be taken.

(iii) If the voltmeter displays more than (±) 3 volts, corrective action shall be taken.

(iv) Voltmeter checks shall be conducted at least once each week while the voltmeter is in use and shall be documented. Documentation of routine instrument checks must include all of the following:

(A) The reader serial number.

(B) The date of analysis.

(C) Zero value.

(D) The reference electret values.

(E) Corrective actions performed.

(3) *Known exposure measurements (spikes).*

(i) Spikes shall be conducted at a rate of 3 for each 100 test devices deployed, with a minimum of 3 spikes for each certification year when tests were conducted in the certification year, and with a maximum of 6 spikes each month.

(ii) Spikes shall be analyzed in the same manner as all other testing.

(iii) Spikes shall be monitored using a means control chart. The means control chart must be established as follows:

(A) Using an RPE value of plus and minus 10%, which corresponds to the 1 sigma level.

(B) A warning level of the RPE of plus and minus 20%, which corresponds to the 2 sigma warning level.

(C) Control limits of the RPE of plus and minus 30%, which correspond to the 3 sigma control level.

(iv) Each RPE value shall be plotted on the means control chart within 1 week of return of the device from the radon chamber. If the RPE value is outside the 3 sigma control level, all measurements shall cease until the problem is evaluated and corrected. All evaluations shall be documented.

(v) In addition to the means control chart, all spikes shall be documented on a form that contains all of the following:

(A) The radon chamber name.

(B) The electret serial numbers.

(C) The RV from the radon chamber.

(D) The measured spike value or values.

(E) The individual RPE results.

(F) The certification year beginning date and end date.

(G) The exposure dates.

(4) *Duplicate measurements.*

(i) Duplicates shall be made in at least 10% of the total number of test devices deployed each month, or 50 each month, whichever is smaller.

(ii) The RPD shall be calculated for all duplicate results with an average of greater than or equal to 2.0 pCi/L. Two control charts shall be constructed to monitor duplicate precision:

(A) One for duplicates when the average is greater than or equal to 4.0 pCi/L.

(B) One for duplicates when the average is greater than or equal to 2.0 pCi/L and less than 4.0 pCi/L.

(iii) Each RPD value shall be plotted on the control chart within 1 week of performing the duplicate measurement.

(iv) The RPD shall be tracked using control charts from "Protocols for Radon and Radon Decay Product Measurements in Homes," EPA 402-R-92-003, May 1993, Appendix B, Exhibits B-2 and B-3.

(v) For duplicates when the average is greater than or equal to 4.0 pCi/L, all of the following apply:

(A) The control level shall be set at an RPD of 14%.

(B) The warning level shall be set at an RPD of 28%.

(C) The control limit shall be set at an RPD of 36%.

(vi) For duplicates when the average is greater than or equal to 2.0 pCi/L and less than 4.0 pCi/L, all of the following apply:

(A) The control level shall be set at an RPD of 25%.

(B) The warning level shall be set at an RPD of 50%.

(C) The control limit shall be set at an RPD of 67%.

(vii) If the plotted RPD result falls outside of the control limit, the measurements shall cease until the problem is identified and corrected.

(viii) If the plotted RPD result falls outside of the warning level, "Protocols for Radon and Radon Decay Product Measurements in Homes," EPA 402-R-92-003, May 1993, Appendix B, Exhibit B-5, shall be used to determine the action to be taken.

(ix) Documentation of duplicates must include all of the following:

(A) The device serial numbers.

(B) The exposure dates.

(C) Each duplicate measurement result.

(D) The RPD results.

(d) *AC and LS.*

(1) *Calibration.* All AC or LS laboratory systems shall be calibrated at least once every 12 months, when alterations or repairs are made to the system, or when a new batch of charcoal is received. This requires a determination of calibration factors for AC and LS devices by the exposure of these devices to a known concentration of radon in a Department-approved radon chamber. Calibration factors shall be determined for a range of exposure times and humidity levels.

(2) *Laboratory control devices.* The laboratory background level for each batch of AC and LS devices shall be established by each laboratory. Laboratories shall measure the background of at least 5% of unexposed AC and LS devices that have been processed according to their standard operating procedures (laboratory blanks).

(3) *Routine counting system checks.* Daily counting of a reference source shall be performed and documented. The characteristics of the check source (geometry, type of radiation emitted, and the like) must be similar to the samples to be analyzed. The count rate of the check sources must be high enough to yield reliable counting statistics in a short period of time, such as 1,000 to 10,000 counts per minute, to provide a maximum random uncertainty of 5%.

(4) *Known exposure measurements (spikes).*

(i) Spikes shall be conducted at a rate of 3 for each 100 test devices deployed, with a minimum of 3 spikes for each certification year when tests were conducted in the certification year, and with a maximum of 6 spikes each month.

(ii) Spikes shall be analyzed in the same manner as all other testing.

(iii) Spikes shall be monitored using a means control chart. The means control chart must be established as follows:

(A) Using an RPE value of plus and minus 10%, which corresponds to the 1 sigma level.

(B) A warning level of the RPE of plus and minus 20%, which corresponds to the 2 sigma warning level.

(C) Control limits of the RPE of plus and minus 30%, which correspond to the 3 sigma control level.

(iv) Each RPE value shall be plotted on the means control chart within 1 week of receiving the result from the laboratory. If the RPE value is outside the 3 sigma control level, all measurements shall cease until the problem is evaluated and corrected. All evaluations shall be documented.

(v) In addition to the means control chart, all spikes shall be documented on a form that contains all of the following:

(A) The radon chamber name.

(B) The device serial numbers.

(C) The RV from the radon chamber.

(D) The measured spike value or values.

(E) The individual RPE results.

(F) The certification year beginning date and end date.

(G) The exposure dates.

(5) *Duplicate measurements.*

(i) Duplicates shall be made in at least 10% of the total number of test devices deployed each month, or 50 each month, whichever is smaller.

(ii) The RPD shall be calculated for all duplicate results with an average of greater than or equal to 2.0 pCi/L. Two control charts shall be constructed to monitor duplicate precision:

(A) One for duplicates when the average is greater than or equal to 4.0 pCi/L.

(B) One for duplicates when the average is greater than or equal to 2.0 pCi/L and less than 4.0 pCi/L.

(iii) Each RPD value shall be plotted on the control chart within 1 week of performing the duplicate measurement.

(iv) The RPD shall be tracked using control charts from "Protocols for Radon and Radon Decay Product Measurements in Homes," EPA 402-R-92-003, May 1993, Appendix B, Exhibits B-2 and B-3.

(v) For duplicates when the average is greater than or equal to 4.0 pCi/L, all of the following apply:

(A) The control level shall be set at an RPD of 14%.

(B) The warning level shall be set at an RPD of 28%.

(C) The control limit shall be set at an RPD of 36%.

(vi) For duplicates when the average is greater than or equal to 2.0 pCi/L and less than 4.0 pCi/L, all of the following apply:

(A) The control level shall be set at an RPD of 25%.

(B) The warning level shall be set at an RPD of 50%.

(C) The control limit shall be set at an RPD of 67%.

(vii) If the plotted RPD result falls outside of the control limit, the measurements shall cease until the problem is identified and corrected.

(viii) If the plotted RPD result falls outside of the warning level, "Protocols for Radon and Radon Decay Product Measurements in Homes," EPA 402-R-92-003, May 1993, Appendix B, shall be used to determine the action to be taken.

(ix) Documentation of duplicates must include all of the following:

(A) The device serial numbers.

(B) The exposure dates.

(C) Each duplicate measurement result.

(D) The RPD results.

(e) *ATs.*

(1) *Calibration.* All AT laboratory systems shall be calibrated at least once every 12 months, when alterations or repairs are made to the system, or when each new batch or sheet of detector material is received. This requires a determination of calibration factors for AT devices by the exposure of these devices to different concentrations of radon in a Department-approved radon chamber.

(2) *Laboratory control detectors.* Laboratory control detectors for each batch of ATs shall be established and documented. Each laboratory shall measure the background of a statistically significant number of unexposed ATs. The laboratory control background value shall be subtracted from the field readings to produce a final result.

(3) *Known exposure measurements (spikes).*

(i) Spikes shall be conducted at a rate of 3 for each 100 test devices deployed, with a minimum of 3 spikes for each certification year when tests were conducted in the certification year, and with a maximum of 6 spikes each month.

(ii) Spikes shall be analyzed in the same manner as all other testing. The RV of a spike may not be revealed to the laboratory prior to analysis.

(iii) Spikes shall be monitored using a means control chart. The means control chart must be established as follows:

(A) Using an RPE value of plus and minus 10%, which corresponds to the 1 sigma level.

(B) A warning level of the RPE of plus and minus 20%, which corresponds to the 2 sigma warning level.

(C) Control limits of the RPE of plus and minus 30%, which correspond to the 3 sigma control level.

(iv) Each RPE value shall be plotted on the means control chart within 1 week of receiving the result from the laboratory. If the RPE value is outside the 3 sigma control level, all measurements shall cease until the problem is evaluated and corrected. All evaluations shall be documented.

(v) In addition to the means control chart, all spikes shall be documented on a form that contains all of the following:

(A) The radon chamber name.

(B) The device serial numbers.

(C) The RV from radon chamber.

(D) The measured spike value or values.

(E) The individual RPE results.

(F) The certification year beginning date and end date.

(G) The exposure dates.

(4) *Duplicate measurements.*

(i) Duplicates shall be made in at least 10% of the total number of test devices deployed each month, or 50 each month, whichever is smaller.

(ii) The RPD shall be calculated for all duplicate results with an average of greater than or equal to 2.0 pCi/L. Two control charts shall be constructed to monitor duplicate precision:

(A) One for duplicates when the average is greater than or equal to 4.0 pCi/L.

(B) One for duplicates when the average is greater than or equal to 2.0 pCi/L and less than 4.0 pCi/L.

(iii) Each RPD value shall be plotted on the control chart within 1 week of performing the duplicate measurement.

(iv) The RPD shall be tracked using control charts from "Protocols for Radon and Radon Decay Product Measurements in Homes," EPA 402-R-92-003, May 1993, Appendix B, Exhibits B-2 and B-3.

(v) For duplicates when the average is greater than or equal to 4.0 pCi/L, all of the following apply:

(A) The control level shall be set at an RPD of 14%.

(B) The warning level shall be set at an RPD of 28%.

(C) The control limit shall be set at an RPD of 36%.

(vi) For duplicates when the average is greater than or equal to 2.0 pCi/L and less than 4.0 pCi/L, all of the following apply:

(A) The control level shall be set at an RPD of 25%.

(B) The warning level shall be set at an RPD of 50%.

(C) The control limit shall be set at an RPD of 67%.

(vii) If the plotted RPD result falls outside of the control limit, the measurements shall cease until the problem is identified and corrected.

(viii) If the plotted RPD result falls outside of the warning level, "Protocols for Radon and Radon Decay Product Measurements in Homes," EPA 402-R-92-003, May 1993, Appendix B, Exhibit B-5, shall be used to determine the action to be taken.

(ix) Documentation of duplicates shall include all of the following:

(A) The device serial numbers.

(B) The exposure dates.

(C) Each duplicate measurement result.

(D) The RPD results.

(*Editor's Note*: Appendices B and C were added in the proposed rulemaking and are retained in this final-form rulemaking. They are printed in regular type to enhance readability.)

Appendix B. Non-interference Agreement for Real Estate Radon Testing

Property name:
Property address:
Property city, state, zip:
Dates of test:

I hereby agree to abide by the following conditions to ensure a valid radon test result:

1) I will maintain closed-house conditions during the entire test period, and for 12 hours prior to any test of less than 96 hours, by doing the following:

• Continuing normal operation of permanently installed HVAC systems.

• Minimizing operation of dryers, range hoods, bathroom fans and other mechanical systems, understanding that drawing air out of the building may adversely affect the test results.

• In buildings having permanently installed radon mitigation systems, keeping the mitigation system functioning during the testing interval.

• Operating window air conditioning systems if set to recycle interior air.

• Keeping all windows closed.

• Keeping all external doors closed except for normal entry and exit.

• Not operating whole-house fans. Removing portable window fans from the window or covering and sealing the window fan.

• Not operating fireplaces, wood/coal stoves or combustion appliances, except water heaters and cooking appliances, unless they are the primary sources of heat for the building.

• Not operating ceiling fans, portable dehumidifiers, portable humidifiers, portable air filters and window air conditioners within 20 feet of the detector.

2) I will not interfere with or move the radon test device.

If the certified tester determines that these conditions were not maintained, this test will be deemed invalid.

Signature of Person in Control of Property	Printed Name of Person in Control of Property	Date

Appendix C. Radon Exposure Tracking Record

Name _____ Month(s) _____

Company Name _____

Employee ID Number _____ Year _____

Date	Job Site	Radon Level (pCi/L)		Working Level (WL)		Hrs. of Exposure		Working Level Month (WLM)	Cumulative Exposure[1] (WLM)	Method used to assess Exposure[2]
			÷200=		×		÷170=			
			÷200=		×		÷170=			
			÷200=		×		÷170=			
			÷200=		×		÷170=			
			÷200=		×		÷170=			
			÷200=		×		÷170=			
			÷200=		×		÷170=			
			÷200=		×		÷170=			
			÷200=		×		÷170=			
			÷200=		×		÷170=			
			÷200=		×		÷170=			
			÷200=		×		÷170=			
			÷200=		×		÷170=			
			÷200=		×		÷170=			

[1]. Based upon an annual recommended health and safety limit of 4 working level months (4 WLM)

[2]. Highest Premitigation Level (a) or On-site Measurement (b)

WL = (pCi/L)/200 (assuming 50% ER)

[Pa.B. Doc. No. 18-1666. Filed for public inspection October 26, 2018, 9:00 a.m.]

TITLE 67—TRANSPORTATION

DEPARTMENT OF TRANSPORTATION

[67 PA. CODE CH. 403]

Hazardous Material Transportation

The Department of Transportation (Department), under the authority in 75 Pa.C.S. §§ 6103 and 8302 (relating to promulgation of rules and regulations by department; and powers and duties of department), amends Chapter 403 (relating to hazardous material transportation) to read as set forth in Annex A.

Purpose

The Federal Motor Carrier Safety Assistance Program (MCSAP), administered by the Federal Motor Carrier Safety Administration (FMCSA), provides financial assistance to states to reduce the number and severity of crashes and hazardous materials incidents involving commercial motor vehicles. As a condition of participating in MCSAP, each state must ensure that its laws and regulations are identical to or have the same effect as the Federal Motor Carrier Safety Regulations (FMCSR) and the Hazardous Materials Regulations. The purpose of this final-form rulemaking is to update existing regulations to match the FMCSR and Hazardous Materials Regulations by prescribing: the methods of packing, loading and unloading of hazardous materials; the specifications, marking, inspection, condition and equipment of vehicles transporting hazardous materials; the qualifications of drivers and other matters relating to operation of the vehicles; the routing and parking of the vehicles; and other factors affecting the nature and degree of risk involved in the transportation of hazardous materials.

Purpose and Explanation of this Final-Form Rulemaking

The Hazardous Materials Regulations are mandated by 49 CFR Part 350 (relating to Motor Carrier Safety Assistance Program and High Priority Program), generally, and 49 CFR 350.201 (relating to what conditions must a State meet to qualify for MCSAP Funds), specifically. The purpose of this final-form rulemaking is to

remove inconsistencies which currently exist between the Commonwealth's hazardous materials regulations and the Federal program requirements in 49 CFR 350.201.

Summary of Comments and Changes in this Final-Form Rulemaking

The Department published a proposed rulemaking at 46 Pa.B. 3957 (July 23, 2016). The proposed rulemaking was also submitted to the Independent Regulatory Review Commission (IRRC) and the House and Senate Transportation Committees.

No comments or objections were received from the public, the House and Senate Committees or IRRC. Consequently, no changes have been made in this final-form rulemaking as compared to how it was published in the *Pennsylvania Bulletin* as a proposed regulation.

Persons and Entities Affected

This final-form rulemaking directly affects anyone who is involved with the packaging, loading, unloading or transporting of hazardous materials.

Fiscal Impact

Implementation of this final-form rulemaking will likely not have a cost because carriers and drivers who transport hazardous materials are already complying with the Hazardous Materials Regulations.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), on July 11, 2016, the Department submitted a copy of this final-form rulemaking, as proposed, to the Legislative Reference Bureau published at 46 Pa.B. 3957; to IRRC and the Chairpersons of the House and Senate Transportation Committees for review and comment. No comments were received from IRRC, the House and Senate Committees or the public.

Under section 5.1(j.2) of the Regulatory Review Act (71 P.S. § 745.5a(j.2)), on September 12, 2018, this 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 September 13, 2018, and this final-form rulemaking was deemed approved pursuant to Section 5(g) of the Regulatory Review Act.

Effective Date

This final-form regulation will be effective upon its publication in the *Pennsylvania Bulletin*.

Sunset Date

The Department is not establishing a sunset date for these regulations, as the regulations are needed to administer provisions under 75 Pa.C.S. (relating to Vehicle Code) and FMCSA regulations for participation in MCSAP. The Department will continue to closely monitor these regulations for their effectiveness and to ensure continued eligibility for participation in MCSAP.

Contact Person

The contact person for technical questions about this final-form rulemaking is Jonathan Fleming, Highway Safety and Traffic Operations Division, Bureau of Maintenance and Operations, Department of Transportation, Commonwealth Keystone Building, 400 North Street, 6th Floor, Harrisburg, PA 17120, jonfleming@pa.gov.

Findings

The Department finds that:

(1) Public notice of the 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, 1 Pa. Code §§ 7.1 and 7.2.

(2) A public comment period was provided as required by law, and no comments were received.

(3) These regulations do not enlarge the purpose of the proposed rulemaking published at 46 Pa.B. 3957.

Order

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

(a) This final-form rulemaking of the Department, 67 Pa. Code Ch. 403, are amended to read as set forth in Annex A.

(b) The Department shall submit this final-form rulemaking to the Office of General Counsel and Office of Attorney General, as required by law, for approval as to form and legality.

(c) The Department shall submit this final-form regulation to the IRRC and the Senate and House Transportation Committees as required by law.

(d) The Department shall certify this final-form rulemaking and deposit it with the Legislative Reference Bureau, as required by law.

(e) This final-form rulemaking shall take effect upon publication in the *Pennsylvania Bulletin*.

LESLIE S. RICHARDS,
Secretary

Fiscal Note: Fiscal Note 18-469 remains valid for the final adoption of the subject regulations.

Annex A

TITLE 67. TRANSPORTATION

PART I. DEPARTMENT OF TRANSPORTATION

Subpart B. NONVEHICLE CODE PROVISIONS

ARTICLE I. VEHICLE-RELATED

CHAPTER 403. HAZARDOUS MATERIAL TRANSPORTATION

§ 403.1. General information and requirements.

(a) *Purpose.* The purpose of this chapter is to prescribe the methods of packing, loading and unloading of hazardous materials; the specifications, marking, inspection, condition and equipment of vehicles transporting hazardous materials; the qualifications of drivers and other matters relating to operation of the vehicles; the routing and parking of the vehicles; and other factors affecting the nature and degree of risk involved in the transportation of hazardous materials.

(b) *Application.* Application shall include the following:

(1) Every shipper and motor carrier and its officers, drivers, agents, employees and representatives involved or related to the transportation of interstate or intrastate commerce, or both, shall comply with this chapter.

(2) Officers, agents, representatives, drivers and employees of shippers and carriers involved or concerned

with the management, maintenance, operation or driving of vehicles shall be conversant and knowledgeable with this chapter.

(c) *General rule.*

(1) Hazardous materials that do not comply with the requirements of this chapter may not be offered for transportation or transported.

(2) Hazardous materials which are manufactured, packaged, stored, loaded, unloaded or transported shall be open to inspection upon request by a Pennsylvania State Police Officer or qualified Commonwealth employee.

(3) No person may represent, by marking or otherwise, that a container or package for the transportation of hazardous materials is safe, certified or in compliance with the requirements of the Department unless the container or package meets the requirements of this chapter.

§ 403.2. (Reserved).

§ 403.4. Adoption of portions of 49 CFR by reference.

(a) The Department incorporates by reference the following portions of 49 CFR (relating to transportation):

* * * * *

(8) Part 397 (relating to transportation of hazardous materials; driving and parking rules).

(9) Part 107, Subparts F and G (relating to registration of cargo tank and cargo tank motor vehicle manufacturers, assemblers, repairers, inspectors, testers, and design certifying engineers; and registration of persons who offer or transport hazardous materials).

(b) Appropriate parts of 49 CFR may be obtained from the following:

* * * * *

(3) United States Superintendent of Documents, United States Government Printing Office, Washington, D.C. 20402, (202) 655-4000.

§ 403.5. Interpretations of Federal Motor Carrier Safety Regulations, Federal Motor Carrier Safety Administration, United States Department of Transportation and Hazardous Materials Regulations, Pipeline and Hazardous Materials Safety Administration, United States Department of Transportation.

The Department will be guided by interpretations of the Federal Motor Carrier Safety Regulations issued by the Federal Motor Carrier Safety Administration, United States Department of Transportation, available at http://www.fmcsa.dot.gov/rules-regulations/administration/fmcsr/fmcsrguide.aspx?section_type=G., and Hazardous Materials Regulations issued by the Pipeline and Hazardous Materials Safety Administration, United States Department of Transportation, available at http://www.phmsa.dot.gov/hazmat/regs/interps.

§ 403.6. Effect of incorporation of the *Code of Federal Regulations*.

To reconcile differences between this chapter and the incorporated sections of Federal regulations and to effectuate their joint enforcement, unless the context indicates otherwise, the following words and phrases shall be substituted for the language of the Federal regulations. A reference to an authorized representative or special agent of the United States Department of Transportation, the Federal Motor Carrier Safety Administration or the Pipeline and Hazardous Materials Safety Administration means a Pennsylvania State Police Officer or qualified Commonwealth employee as the term is defined in 75 Pa.C.S. § 4102 (relating to definitions).

§ 403.7. Supplemental rules and regulations.

(a) *Towing of vehicles.* A motor vehicle transporting hazardous materials in a quantity requiring the motor vehicle to display markings or placarding may not be towed on a highway except to remove the motor vehicle and cargo to the nearest place of safety, in the judgment of the carrier or its representative after consultation where possible with police, fire or other emergency personnel. The motor vehicle may not be moved until the hazardous materials are stable unless failure to do so would constitute a threat to persons or property. For requirements regarding accidents involving specific types of hazardous materials, see 49 CFR 177.854 (relating to disabled vehicles and broken or leaking packages; repairs).

(b) *The Vehicle Code.* Title 75 of the *Pennsylvania Consolidated Statutes* (relating to Vehicle Code), and provisions of this title not inconsistent with this chapter, apply to the transportation of hazardous materials.

(c) *Presentation of documents.* A driver of a vehicle transporting a hazardous material on a highway shall present upon request to a member of the State Police or qualified Commonwealth employee, as the term is defined in 75 Pa.C.S. § 4102 (relating to definitions), all documents required under this chapter to be in the driver's possession.

§ 403.8a. Out-of-service criteria.

(a) *Application.* In determining whether a vehicle or driver of a vehicle, or both, will be placed out-of-service under 75 Pa.C.S. § 4704(c) (relating to inspection by police or Commonwealth personnel), State Police and qualified Commonwealth employees will use the criteria in this chapter.

(b) *Adoption of standards.*

(1) *General.* The out-of-service criteria in the "North American Standard Out-of-Service Criteria" are incorporated by reference.

(2) *Obtaining criteria.* The "North American Standard Out-of-Service Criteria" may be obtained by contacting the Commercial Vehicle Safety Alliance, 1101 17th Street NW, Suite 803, Washington, D.C. 20036, (301) 830-6143.

§ 403.10. (Reserved).

[Pa.B. Doc. No. 18-1667. Filed for public inspection October 26, 2018, 9:00 a.m.]

Title 70—WEIGHTS, MEASURES AND STANDARDS

DEPARTMENT OF AGRICULTURE

[70 PA. CODE CH. 9]

Weighmasters

The Department of Agriculture (Department) amends §§ 9.10 and 9.24 (relating to weighmaster's certificate; and limitations of certificate for anthracite) to read as set forth in Annex A.

Effective Date

This final-form rulemaking will be effective upon publication in the *Pennsylvania Bulletin*.

Authority

This final-form rulemaking is authorized under 3 Pa.C.S. §§ 4101—4194 (relating to Consolidated Weights and Measures Act) (act). Sections 4150 and 4190 of the act (relating to enforcement and regulations; and rules and regulations) authorize the Department to promulgate regulations as necessary to carry out the act and, more specifically, authorize the Department to promulgate regulations as necessary to carry out Subchapter C of the act (relating to public weighmasters).

Purpose

This final-form rulemaking deletes outdated and unnecessary regulatory requirements.

The Department issues licenses to public weighmasters under the act. A licensed public weighmaster is authorized to issue a weighmaster's certificate with respect to various commercial weighings he performs. The weight appearing on a weighmaster's certificate is used to determine a weight-based price in commerce. Licensed public weighmasters typically conduct commercial weighings using vehicle scales at quarries, landfills and the like.

As part of the process by which the Department renews or issues a license to a public weighmaster, the Department reviews the public weighmaster certificate forms the applicant plans to issue to ensure these forms meet basic content requirements. This final-form rulemaking is needed to delete outdated, burdensome provisions requiring that weighmaster's certificates and certificates of quality for anthracite coal be prepared in triplicate and bear additional language distinguishing the original certificate from the copies. These provisions are not required by statute, date from a time when multipage carbon copy forms were in extensive use and no longer serve a practical purpose.

The deletion of the previously described requirements will relieve licensed public weighmasters of an unnecessary regulatory burden and will help the Department make better use of its weights and measures enforcement staff. In a typical year the Department processes roughly 6,600 applications for renewals of weighmaster licenses. It requires that an applicant submit a sample of its weighmaster's certificate form as part of the application process. The Department finds problems or deficiencies in about 2,200 of these 6,600 applications. Approximately 1,650 (75%) of these 2,200 rejected applications are rejected for lack of compliance with one or more of the regulatory previously described requirements. The deletion of these outdated regulatory requirements will spare the Department the time, effort and expense of enforcement.

Section 9.24(a) imposes the same type of unnecessary regulatory burden as previously described, but pertains to the "certificate of quality" that must exist for certain weighings of anthracite coal. As previously described, the requirement of triplicate forms and notations distinguishing originals from copies no longer serves a practical purpose.

In summary, the Department is satisfied there is a need for this final-form rulemaking, and that it is otherwise consistent with Executive Order 1996-1, "Regulatory Review and Promulgation."

Comments and Responses

A notice of proposed rulemaking was published at 47 Pa.B. 5952 (September 23, 2017), affording the public, the Legislature and the Independent Regulatory Review Commission (IRRC) the opportunity to offer comments.

A single comment was received from the public. The commentator offered his comments on behalf of a company that utilizes licensed public weighmasters in its business. The commentator offered general support for the proposed regulation and estimated the regulatory change would save the commentator's business approximately $1,200 each year. The comment did not necessitate any change to the text of this final-form rulemaking.

IRRC offered two comments with respect to the proposed rulemaking.

IRRC's first comment recommended the Department either delete language at § 9.24(a) requiring that a certificate of quality for anthracite coal be "sufficiently mucilaged at the left end to permit it to be securely attached to the corresponding copies of the certificate of the weighmaster" or explain how this language is consistent with the purpose of the regulation. The Department agrees that the referenced language is outdated and serves no practical purpose, and has deleted it in this final-form rulemaking.

IRRC's second comment requested revisions to the timeline for this final-form rulemaking that was presented in Item No. 29 of the Regulatory Analysis Form that accompanied the regulatory package for the proposed regulation. The Department has made those revisions in the Regulatory Analysis Form for this final-form rulemaking.

Persons Likely to be Affected

This final-form rulemaking will have a positive impact on licensed public weighmasters and the Department.

Fiscal Impact

Commonwealth

This final-form rulemaking will have some positive fiscal impact upon the Commonwealth. The Department will save time and manpower costs associated with requiring compliance with the current outdated regulatory requirements. The Department estimates these annual savings at $14,850.

Political Subdivisions

This final-form rulemaking will have not have an appreciable fiscal impact on political subdivisions.

Private Sector

This final-form rulemaking will have some small positive fiscal impact upon the private sector in that licensed public weighmasters will no longer be required to obtain, produce or use triplicate forms for weighmaster's certificates and have forms that distinguish originals from copies. These savings cannot be readily quantified. In addition, the Department estimates that of the public weighmaster license applications that it receives each year and that are deficient and must be returned to applicants for corrections or additional information, approximately 1,650 of these are returned because the applicant has not complied with one or more of the provisions that are being deleted. The Department estimates this final-form rulemaking will save these applicants a total of $18,150 each year in postage and personnel costs.

General Public

This final-form rulemaking will have no appreciable fiscal impact on the general public.

Paperwork Requirements

This final-form rulemaking will simplify paperwork requirements for licensed public weighmasters in that it will do away with outdated regulatory requirements requiring triplicate forms. It will slightly lessen the Department's paperwork load in that applicants for public weighmaster licenses will no longer be required to submit copies of triplicate paper forms and the Department will not be required to review and retain them as part of the application review process.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), on September 11, 2017, the Department submitted a copy of the notice of proposed rulemaking, published at 47 Pa.B. 5952, to the Independent Regulatory Review Commission (IRRC) and the Chairpersons of the House and Senate Committees on Agriculture and Rural Affairs for review and comment.

Under section 5(c) of the Regulatory Review Act, the Department is required to submit to IRRC and the referenced Legislative Standing Committees copies of comments received during the public comment period, as well as other documents when requested. In preparing this final-form rulemaking, the Department has considered all comments from IRRC, the House and Senate Agriculture and Rural Affairs Committees and the public.

Under section 5.1(j.2) of the Regulatory Review Act (71 P.S. § 745.5a(j.2)), on September 13, 2018, this final-form rulemaking was deemed approved by the House and Senate Committees on Agriculture and Rural Affairs. Under section 5.1(e) of the Regulatory Review Act, IRRC met on September 13, 2018, and approved this final-form rulemaking.

Additional Information

Additional information may be obtained from Walter Remmert, Director, Bureau of Ride and Measurement Standards, Pennsylvania Department of Agriculture, 2301 North Cameron Street, Harrisburg, PA 17110-9408, (717) 787-9089.

Findings

The Department 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) and regulations promulgated thereunder, 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) The amendments made to this final-form rulemaking do not enlarge the purpose of the proposed rulemaking published at 47 Pa.B. 5952.

(4) The amendments to the regulations of the Department are necessary and appropriate for the administration of the authorizing statute.

Order

The Department, acting under its authorizing statute, orders that:

(1) The regulations of the Department, 70 Pa. Code Chapter 9, are amended by amending §§ 9.10 and 9.24 to read as set forth in Annex A.

(2) The Department shall submit this order and a copy of Annex A to the Office of the Attorney General and the Office of General Counsel for approval as required by law.

(3) The Department shall submit this order and a copy of Annex A to IRRC and the House and Senate Agriculture and Rural Affairs Committees, as required by law.

(4) The Department shall certify this order and Annex A and shall deposit them with the Legislative Reference Bureau as required by law.

(5) This final-form rulemaking shall take effect immediately upon publication in the *Pennsylvania Bulletin*.

RUSSELL C. REDDING,
Secretary

Fiscal Note: Fiscal Note 2-187 remains valid for the final adoption of the subject regulations.

Annex A

TITLE 70. WEIGHTS, MEASURES AND STANDARDS

PART I. WEIGHMASTERS

CHAPTER 9. WEIGHMASTERS

GENERAL

§ 9.10. Weighmaster's certificate.

* * * * *

(b) *Contents.* A weighmaster's certificate must contain the following information:

* * * * *

(9) Other relevant information the licensed public weighmaster deems necessary.

(c) *Variations in format and size.* The form and size of a weighmaster's certificate may be such as to suit any system or accounting device, as long as the certificate otherwise meets the requirements of this chapter.

SOLID FUEL

§ 9.24. Limitations of certificate for anthracite.

(a) *Certificate of quality required.* If solid fuel is transported to a licensed public weighmaster under authority of a certificate of transport as described in § 9.23 (relating to certificate affecting weighing requirements), and the solid fuel is anthracite (excluding barley and smaller sizes), the weighmaster may not weigh the anthracite unless the certificate of transport is accompanied by a certificate of quality. A certificate of quality shall be made out in ink or indelible pencil. The format of the certificate of quality must be as follows:

* * * * *

[Pa.B. Doc. No. 18-1668. Filed for public inspection October 26, 2018, 9:00 a.m.]