Regulatory Analysis Form

(Completed by Promulgating Agency)

(All Comments submitted on this regulation will appear on IRRC's website)

INDEPENDENT REGULATORY REVIEW COMMISSION

IRRC Number: 3169

(1) **Agency**

Department of Environmental Protection

(2) **Agency Number:**

Identification Number: 7-499

(3) **PA Code Cite:** 25 Pa. Code Article V. Radiological Health

(4) **Short Title:** Radiological Health Revisions

(5) **Agency Contacts (List Telephone Number and Email Address):**

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(6) **Type of Rulemaking (check applicable box):**

- ☐ Proposed Regulation
- ☒ Final Regulation
- ☐ Final Omitted Regulation
- ☐ Emergency Certification Regulation;
  - ☐ Certification by the Governor
  - ☐ Certification by the Attorney General

(7) **Briefly explain the regulation in clear and nontechnical language. (100 words or less)**

The Radiation Protection Act directs the Department of Environmental Protection (DEP) to develop and conduct comprehensive programs for the registration, licensing, control, management, regulation and inspection of radiation sources and radiation source users.

The Environmental Quality Board (Board) last updated its radiological health regulations in 2009. Significant technological advances in the use of radiation sources prompted the need to amend the regulations to establish and maintain adequate radiation protection standards and oversight.

This final-form rulemaking clarifies the radon certification application and reporting requirements for certified radon service providers. The amendments to the testing and mitigation protocol requirements and the quality assurance and quality control requirements will provide greater detail regarding the goals and designs these programs.

(8) **State the statutory authority for the regulation. Include specific statutory citation.**

The amendments to Chapters 215-221, 223-228, 230 and 232 are authorized under the following:

- Sections 301 and 302 of the Radiation Protection Act, 35 P.S. §§ 7110.301 and 7110.302.
- Section 1920-A of the Administrative Code, 71 P.S. § 510-20.

The amendments to Chapter 240 are authorized under the following:

- Sections 12 and 13 of the Radon Certification Act, 63 P.S. §§ 2012 and 2013.
- Section 302 of the Radiation Protection Act, 35 P.S. §§ 7110.302.
- Section 1920-A of the Administrative Code, 71 P.S. § 510-20.

(9) **Is the regulation mandated by any federal or state law or court order, or federal regulation? Are there any relevant state or federal court decisions? If yes, cite the specific law, case or regulation as well as, any deadlines for action.**

This regulation is not mandated by any federal or state law or court order, or federal regulation. These regulations are necessitated by technologic advances and practical needs to protect public health and safety. There are no relevant state or federal court decisions.

(10) **State why the regulation is needed. Explain the compelling public interest that justifies the regulation. Describe who will benefit from the regulation. Quantify the benefits as completely as possible and approximate the number of people who will benefit.**

See response to #7 above.

Radiological Health

This final-form rulemaking clarifies and strengthens requirements, most notably for computed tomography, fluoroscopy and emerging technology systems. Requirements for a new technology, electronic brachytherapy, were added to the regulations. Electronic brachytherapy requires licensure rather than registration due to the higher energies produced. Existing practices required by other sources and contained in long-standing guidance documents are now included.

In general, this rulemaking embodies the theory that regulatory clarity and codification of best practices can improve the quality of services to the public. 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 made known to the industry. Some requirements are already 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 existing technical guidance documents.

These standards include equipment checks, quality control, continuing education, and the requirement that businesses utilize a qualified medical physicist. As explained above, these requirements are already commonplace. Continuing education can be performed by the firm's own employees and is in many cases available for free. Businesses who would need a qualified medical physicist already employ at least one individual with the necessary qualifications due to existing requirements from the entities listed above.

As set forth in this final-form rulemaking, users of radiation sources will be required to comply with radiation protection standards that will protect and benefit employees and the public. This final-form rulemaking will ensure that trained professionals are operating radiation sources so that both the patient and the operator are adequately protected.

The regulated community and all citizens of the Commonwealth will benefit from this final-form rulemaking. For example, the approximately 5,500 dentists, 230 hospitals, 860 clinics, 750 chiropractors, 490 podiatrists, registered with the Department that perform, at a minimum, 10 scans per day resulting in millions of scans annually, will be required to establish and maintain appropriate radiation protection standards and oversight.

Radon

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

The U.S. Environmental Protection Agency (EPA) and other national and international health and radiation safety organizations have declared radon to be the second leading cause of lung cancer after smoking, and the leading cause of lung cancer in non-smokers. Pennsylvania residents are at particular risk because the radon levels in Pennsylvania are much more significant than in most other parts of the country.

All Pennsylvania residents, including those who have tested their homes for radon and subsequently taken action to reduce high levels with a certified radon mitigation contractor, will benefit from this final-form rulemaking that assures that radon testing is done properly and that radon mitigation systems are installed according to Department standards.

(11) **Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulations.**

There are no provisions that are more stringent than the federal standards.

(12) **How does this regulation compare with those of the other states? How will this affect Pennsylvania's ability to compete with other states?**

Radiological Health

Instead, this final-form rulemaking will allow better protection during medical procedures involving radiation exposure.

Radon

This final-form rulemaking will not put the Commonwealth at a competitive disadvantage. Regarding radon amendments, Pennsylvania has a wide geographic distribution of radon occurrence, and great potential for radon exposure given a population of 12.5 million. Recently a private home in Pennsylvania was measured with the highest radon value recorded in the world at 6,176 picocuries per liter (pCi/L). This value is over 900 times greater than the EPA guideline value of 4 pCi/L. Nine other states have similar licensing or certification programs for radon testing, mitigation, and laboratory analysis.

(13) **Will the regulation affect any other regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.**

The Department of Health (DOH) has regulations regarding radiation sources in 28 Pa. Code Chapters 51, 127, and 565 (relating to general information; radiology services; and laboratory and radiology services) that could be affected by this rulemaking. DOH is currently working on a regulatory update. DEP and DOH have held several meetings and have been working together to ensure DOH's regulations are consistent with DEP's regulations.

No other state regulations will be affected by Chapter 240.

(14) **Describe the communications with and solicitation of input from the public, any advisory council/group, small businesses and groups representing small businesses in the development and drafting of the regulation. List the specific persons and/or groups who were involved. ("Small business" is defined in Section 3 of the Regulatory Review Act, Act 76 of 2012.)**

This final-form rulemaking was reviewed by the Department's Radiation Protection Advisory Committee (RPAC). The committee represents various stakeholders, including radioactive materials licensees, radiation-producing machine registrants and radon service providers, as well as the general public. In addition, the RPAC formed a Radon Subcommittee, comprised of a mitigator, manufacturer and laboratory representative and led by the radon representative of RPAC, to review the Chapter 240 amendments. The Department presented the draft final regulations and a summary of the comments received on the proposed rulemaking to the RPAC on October 19, 2017. RPAC endorsed moving forward with this final-form rulemaking.

The proposed rulemaking was approved by the EQB on October 18, 2016, and published in the *Pennsylvania Bulletin* on May 13, 2017, with a 45-day public comment period. A webinar was presented for the proposed radiation-producing machines and radiation source regulations on May 31, 2017. Another webinar was presented for the radon certification regulation on May 31, 2017. 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.

(15) Identify the types and number of persons, businesses, small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012) and organizations which will be affected by the regulation. How are they affected?

See response to #10 above.

This final-form rulemaking affects approximately 11,000 X-ray machine registrants, 825 radioactive material licensees, 150 accelerator licensees, 325 X-ray service providers and 600 entities performing certified radon activities. While the Department does not collect information regarding the size of each business that is an X-ray registrant, licensee, or service provider, the Department considered the vast majority of these entities to be small businesses for the purpose of this rulemaking. All entities performing certified radon activities are considered small businesses for the purposes of this rulemaking.

Radiological Health

A small number of registrants will be affected by the requirement to use a qualified medical physicist, as newly defined in the regulatory amendments. Most registrants already employ the services of a qualified medical physicist. All registrants and licensees will be affected by the requirement to have a written directive (prescription) by a licensed physician before the administration of any radiation source.

As noted in #10 above, many of the requirements in the final-form rulemaking reflect current industry practice, as discovered through Department inspections and through conversation with industry members. Therefore, these amendments are not expected to impose additional burdens on the regulated community.

Requirements were added for a new technology: electronic brachytherapy. Electronic brachytherapy requires licensure rather than registration because the Department requires designation of a radiation safety officer, as well as a medical physicist and an authorized user, because of the high dose that is administered directly on or near a tumor site during this procedure. Small businesses will not be exempt from any of these requirements because of the health and safety implications associated with the new provisions.

Radon

The general public and businesses could be affected by the radon regulations if they use or provide radon services. The radon amendments in Chapter 240 of this final-form rulemaking generally codify long-standing guidance documents published by DEP, EPA and national organizations, and are considered standard practice.

Added requirements in § 240.310(a)(7) and 310(a)(8) of this final-form rulemaking of two new American National Standards Institute/American Association of Radon Scientists and Technologists (ANSI/AARST) standards to address testing and mitigation of multifamily dwellings may add a small cost of purchasing the standards. Following these standards, however, will ensure more accurate testing and mitigation results to protect health and safety. Documentation requirements added in §§ 240.102(b)(6)(iii) and 112(b)(6)(iii) of this final-form rulemaking regarding initial and ongoing training of employees by the certified individual replaced the more restrictive and costly requirement that was proposed for employees to take an approved course or exam. The documentation requirement

to show how a certified individual will maintain oversight and responsibility of employees replaces the more restrictive and costly previously proposed requirement of limiting the number of firm employees.

Other radon amendments in this final-form rulemaking will reduce the burden on businesses in both paperwork and operations, such as eliminating unnecessary equipment checks and eliminating the requirement to test before mitigation. Benefits to the public include greater consistency in the services provided and improved indoor air quality with subsequent health benefits.

(16) **List the persons, groups or entities, including small businesses, that will be required to comply with the regulation. Approximate the number that will be required to comply.**

Currently, there exist approximately 11,000 X-ray machine registrants, 825 radioactive material licensees, 150 accelerator licensees, 325 X-ray service providers and 600 entities providing certified radon services that will be required to comply with this final-form rulemaking. X-ray machine registrants include small medical and dental offices and large hospitals. Certified radon service providers include individuals and firms perform radon testing, mitigation, and laboratory analysis. All future registrants, licensees and certified radon service providers must also comply.

(17) **Identify the financial, economic and social impact of the regulation on individuals, small businesses, businesses and labor communities and other public and private organizations. Evaluate the benefits expected as a result of the regulation.**

Radiological Health

The benefit of the amendments to the radiological health regulations in this final-form rulemaking include the requirement for users of radiation sources to comply with radiation protection standards that will protect employees and 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 appropriately protected from the harmful effects of overexposure to radiation.

Other than new license fees in § 218.11(i) for electronic brachytherapy devices and § 218.11(j) for emerging technology devices, which the Department has assessed administratively since 2009 and now codifies in regulation, there are no changes to the fee schedules in Chapter 218 and Chapter 240, Appendix A, in this final-form rulemaking. The annual fee for electronic brachytherapy devices is $1,000 for the first unit (controller) at the facility plus $100 for each additional unit at the facility. Because this fee is existing practice, regulated entities will not experience any additional costs as a result of this final-form rulemaking. As noted in the answers to #10 and #15 above, the requirements for equipment checks, quality control, continuing education and the employment of a qualified medical physicist are already considered standard practice by the industry. Minor costs may be experienced if businesses are not following these standards, but the Department does not foresee this occurring. For example, many of the continuing education requirements can be satisfied through free courses.

Radon Certification

The benefits of the radon certification amendments in this final-form rulemaking include added clarity to the application and reporting requirements, making it easier for the regulated community to understand what is required during each process. For example, if a person is certified as both a tester and a

laboratory, § 240.306 of the final-form rulemaking clarifies that 16 hours of continuing education are required instead of 32 hours. Applicants will no longer be required to repay fees to reinstate a withdrawn certification application; depending on the type of certification, these final-form amendments will save a firm or individual from $450 to $1,125 for each certification. *See* 25 Pa. Code Chapter 240 Appendix A (relating to radon certification fee schedule).

The benefits of the amendments to the testing and mitigation protocols and quality assurance and quality control requirements in this final-form rulemaking include greater detail regarding how these programs should be designed which ensures that radon services provided to the public will more consistently protect the public. The quality assurance and quality control amendments also benefit the regulated community by eliminating certain equipment check requirements when the equipment is not used and by removing cross checks and duplicate tests for testers who use continuous monitors and continuous working level monitors.

The amendment in §§ 240.102(b)(6)(iii) and 112(b)(6)(iii) of this final-form rulemaking to eliminate the requirement to have one year of radon testing experience prior to certification benefits the regulated community by simplifying and shortening the process for an individual to become certified to test for radon.

The language in §§ 240.102(b)(4) and 112(b)(5) of the proposed rulemaking that would have required certified firms to employ one certified individual per five firm employees was deleted in this final-form rulemaking. Therefore, there will be no cost increase associated with this as detailed in the proposed rulemaking. Under §§ 240.102(b)(6)(iii) and 112(b)(6)(iii), the firm's certified individual or a third party may train other employees and provide continuing education, avoiding a potentially large burden on small businesses to pay for outside training.

In terms of other financial impact, the radon regulations codify portions of Department guidance documents. The Department expects that these are already standard practice. Some minor business costs may be experienced if firms are not currently following these guidelines. For example, when testing multi-family buildings, the ANSI/AARST MAMF guidance "Radon Mitigation Standards for Multifamily Buildings" (adopted at the suggestion of public comment) recommends testing every occupied unit in contact with the ground, which might require more test kits than a tester currently uses. Again, the Department expects that these standards are already being followed.

The social impacts of the radon amendments are expected to be positive. The U.S. EPA, as well as other national and international health and radiation safety organizations, have declared radon to be the second leading cause of lung cancer after smoking, and the leading cause of lung cancer in non-smokers. Residents of this Commonwealth are at particular risk because the radon levels in this Commonwealth are much more significant than in most other parts of the country. All Commonwealth residents who test their homes for radon and subsequently take action to reduce high levels through a certified radon mitigation contractor will benefit from this final-form rulemaking because this final-form rulemaking assures that testing is done properly and that mitigation systems are installed according to Department standards. The consumers of these services benefit by having improved indoor air quality with reduced exposure to this radioactive gas. Reducing the burdens on mitigators and improving regulatory clarity will ensure that these benefits are realized.

(18) **Explain how the benefits of the regulation outweigh any cost and adverse effects.**

There are only minor potential adverse effects associated with this final-form rulemaking. As noted in the answers to questions #10, #15, and #17 above, both the radiological health and radon amendments in this final-form rulemaking codify practices that are understood to be standard in the industry. The radiological health requirements are already imposed by insurance companies or are standards from national organizations. The radon requirements are contained in guidance documents have been implemented successfully by the regulated community. Costs will only be experienced by firms or individuals not currently following industry standards.

The benefits of this final-form rulemaking include protecting employees and the general public by requiring compliance with current radiation protection standards. This final-form rulemaking will ensure that trained professionals are operating radiation sources so that both the patient and the operator are adequately protected. The radiological health updates are partly motivated by recent reported events involving injuries to patients from inadequately trained personnel. The regulations address this risk by codifying standard practices and thereby making them enforceable.

The benefits of the radon certification amendments in this final-form are predicated on the theory that regulatory clarity and codification of best practices can improve the quality of services to the public. The amendments include adding clarity to the application and reporting requirements, making it easier for the regulated community to understand what is required during each process. The amendments also reduce unnecessary equipment checks and reduce the work experience needed before certification. The benefits of the amendments to the testing and mitigation protocols and quality assurance and quality control requirements include ensuring that radon services provided to the public will more consistently protect public health and welfare from the dangers of radon.

(19) **Provide a specific estimate of the costs and/or savings to the regulated community associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.**

In terms of costs, as noted in the responses to questions #10, #15, #17, and #18 above, the requirements of the final-form rulemaking are also typically imposed by other entities or are a codification of standards of national organizations and already considered standard practice. Therefore, no additional costs are associated with compliance for either radiological health or radon service providers.

In terms of savings, depending on the type of certification, the amendment in § 240.141 of the final-form rulemaking relating to reinstating a previously withdrawn radon certification application will save a firm or individual $450 to $1,125. (The certification fees are listed in Appendix A of Chapter 240, which has not been amended in this rulemaking). Other savings are less easily quantified, but nonetheless real: removing the requirement of one year's work experience before certification allows a firm to generate business more readily, and removing the requirements to check unused equipment and test for radon prior to mitigation allow a firm to maximize its work time and finish jobs more quickly. (Sections 240.102, 240.604(c)(2)(ii) and (c)(3)(v)(C) and 240.605(c)(1)(ii) and (c)(2)(v)(C) of the final-form rulemaking). See the answers to questions 15 through 18 above.

No legal, accounting or consulting procedures are required by the final-form rulemaking.

(20) **Provide a specific estimate of the costs and/or savings to the local governments associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.**

There will be no costs or savings to local governments associated with compliance.

(21) **Provide a specific estimate of the costs and/or savings to the state government associated with the implementation of the regulation, including any legal, accounting, or consulting procedures which may be required. Explain how the dollar estimates were derived.**

There will be no costs or savings to state government associated with compliance.

(22) **For each of the groups and entities identified in items (19)-(21) above, submit a statement of legal, accounting or consulting procedures and additional reporting, recordkeeping or other paperwork, including copies of forms or reports, which will be required for implementation of the regulation and an explanation of measures which have been taken to minimize these requirements.**

Several sections of this final-form rulemaking will change various records retention requirements to five years as indicated in the proposed rulemaking. This change was suggested by the Radiation Protection Advisory Committee 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 in §§ 240.102(b)(6)(iii) and 240.112(b)(6)(iii) 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 documentation requirement was added to this final-form rulemaking in exchange for the proposed requirement to limit certified firms to 5 employees, which was aimed at addressing span of control issues and will allow the Department to ensure that certified individuals responsible for firm activities are adequately training firm employees. These records need not be in paper format and may be stored electronically.

Other than these requirements, no legal, accounting or consulting procedures, or additional reporting, recordkeeping or other paperwork are anticipated for implementation of this final-form rulemaking.

(22a) **Are forms required for implementation of the regulation?**

Yes.

(22b) **If forms are required for implementation of the regulation, attach copies of the forms here. If your agency uses electronic forms, provide links to each form or a detailed description of the information required to be reported. Failure to attach forms, provide links, or provide a detailed description of the information to be reported will constitute a faulty delivery of the regulation.**

See attached.

(23) **In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years.**

	Current FY 2016/17	FY +1 2017/18	FY +2 2018/19	FY +3 2019/20	FY +4 2020/21	FY +5 2021/22
SAVINGS:	$	$	$	$	$	$
Regulated Community	0	0	0	0	0	0
Local Government	0	0	0	0	0	0
State Government	0	0	0	0	0	0
Total Savings	0	0	0	0	0	0
COSTS:						
Regulated Community	0	0	0	0	0	0
Local Government	0	0	0	0	0	0
State Government	0	0	0	0	0	0
Total Costs	0	0	0	0	0	0
REVENUE LOSSES:						
Regulated Community	0	0	0	0	0	0
Local Government	0	0	0	0	0	0
State Government	0	0	0	0	0	0
Total Revenue Losses	0	0	0	0	0	0

(23a) **Provide the past three-year expenditure history for programs affected by the regulation.**

This amendment will have no effect on program expenditures. The Commonwealth's Radiation Protection Fund covers all areas of Radioactive Material, Environmental Surveillance, X-Ray / Accelerators, Nuclear Safety and Radon. Decommissioning is also covered to the extent cleanup costs cannot be recovered from responsible parties and are not eligible for funding through other special funds administered by the Department.

Program	FY -3 2014/15	FY -2 2015/16	FY -1 2016/17	Current FY 2017-18
Radiation Protection Fund	$11,018,000	$11,628,000	$12,934,000	$14,746,000

(24) **For any regulation that may have an adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), provide an economic impact statement that includes the following:**

(a) An identification and estimate of the number of small businesses subject to the regulation.
(b) The projected reporting, recordkeeping and other administrative costs required for compliance with the proposed regulation, including the type of professional skills necessary

for preparation of the report or record.

(c) A statement of probable effect on impacted small businesses.

(d) A description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation.

(a) Small businesses covered by the radiological health provisions in this final-form rulemaking include, for example, dentist offices and private medical practices. The exact number of small businesses is not known to the Department, but the Department considered the vast majority of these entities to be small businesses for the purpose of this rulemaking. Radon businesses are generally small businesses, and there are around 600 certified entities in Pennsylvania.

(b) Any additional reporting or recordkeeping required by this final-form rulemaking is already required by other sources such as insurance companies. These amendments merely match regulations to those practices. The radon certification amendments in this final-form rulemaking have reduced administrative costs in several ways, as described in the answer to #17, above.

(c) The radiological health provisions in this final-form rulemaking mainly codify standard industry practice and should have negligible effect on small businesses. Requirements were added for a new technology: electronic brachytherapy. Electronic brachytherapy requires licensure rather than registration because the Department requires designation of a radiation safety officer, as well as a medical physicist and an authorized user because of the high dose that is administered directly on or near a tumor site during this procedure. Because of the health and safety reasons for these requirements, small businesses will not be exempt from any of these requirements. The radon provisions either codify current practice (as embodied in long-standing guidance documents) or reduce operational burdens, such as by removing the requirement to test for radon before installing mitigation equipment and removing the requirement to check unused equipment. Radon businesses should therefore see the same or lower operational costs. See the responses#19 for further examples.

(d) The Department did not analyze alternatives because the objective was to protect public health from unsafe practices regarding radiation by codifying current practice.

(25) **List any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, the elderly, small businesses, and farmers.**

No special provisions need to be developed. For the radiological health provisions, the requirements are either standard practice or added for emerging technologies. Radon businesses are generally small businesses, so the radon provisions were crafted with small businesses in mind.

(26) **Include a description of any alternative regulatory provisions which have been considered and rejected and a statement that the least burdensome acceptable alternative has been selected.**

No alternative regulatory provisions have been considered or rejected for the radiological health amendments in this final-form rulemaking because the majority of the amendments are current radiation protection industry practices.

Likewise, for the final radon certification amendments, no alternative regulatory provisions have been considered or rejected because the amendments in this final-form rulemaking are current industry practices and clarifications of current regulations and standard protocols.

(27) **In conducting a regulatory flexibility analysis, explain whether regulatory methods were considered that will minimize any adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), including:**

a) **The establishment of less stringent compliance or reporting requirements for small businesses;**
b) **The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses;**
c) **The consolidation or simplification of compliance or reporting requirements for small businesses;**
d) **The establishment of performance standards for small businesses to replace design or operational standards required in the regulation; and**
e) **The exemption of small businesses from all or any part of the requirements contained in the regulation.**

As explained in the response to #24 above, the requirements in this final-form rulemaking as applied to small businesses are either standard practices or added for emerging technologies to appropriately protect public health and safety.

(a) This final-form rulemaking generally reduces reporting requirements when compared to the current regulations.
(b) This final-form rulemaking does not impose new deadlines for compliance or reporting.
(c) The quality assurance and quality control provisions in this final-form rulemaking include greater detail in how these programs should be designed, which simplifies compliance. For radon businesses, which are generally small businesses, this final-form rulemaking removes the requirement that an employee must have one year of work experience before applying for certification. The number of hours of continuing education is clarified in this final-form rulemaking, which will save some firms 50% of their cost due to misinterpretation of the current regulation. The fee to reinstate a withdrawn radon certification application has been removed from this final-form rulemaking.
(d) No new design or operational standards are imposed by this final-form rulemaking, so the substitution of performance standards was not made for small businesses.

It was not necessary or appropriate to exempt small businesses from the requirements contained in the final-form rulemaking for the reasons given above.

(28) **If data is the basis for this regulation, please provide a description of the data, explain <u>in detail</u> how the data was obtained, and how it meets the acceptability standard for empirical, replicable and testable data that is supported by documentation, statistics, reports, studies or research. Please submit data or supporting materials with the regulatory package. If the material exceeds 50 pages, please provide it in a searchable electronic format or provide a list of citations and internet links that, where possible, can be accessed in a searchable format in lieu of the actual material. If other data was considered but not used, please explain why that data was determined not to be acceptable.**

Radon testing and mitigation data generated by the certified radon industry is reported to DEP and stored in a DEP Oracle database that is only accessible to authorized persons. Radon test records are confidential per the Radon Certification Act (Act 43), Section 9 (Confidentiality of Data). 63 P.S. § 2009.

To date, there are approximately 1.57 million radon test results and about 200,000 radon mitigations reported. The testing data highlights the severity of the impact of radon in this Commonwealth. Mitigation data shows that remedial measures are effective at reducing high radon levels.

In this Commonwealth, the average basement radon concentration is 7 pCi/L and the average first floor concentration is 3.5 pCi/L. The EPA has classified 49 of Pennsylvania's 67 counties as Zone 1 counties, which is the highest designation for radon occurrence in a county (predicted average level for a Zone 1 is greater than 4 pCi/L). The EPA has designated 17 Pennsylvania counties as Zone 2, which is the intermediate designation (predicted average level for a Zone 2 county is 2 to 4 pCi/L), and only one county (Philadelphia) as a Zone 3 county, which is the lowest designation (predicted average level is less than 2 pCi/L). This information can be found on the EPA's website, www.epa.gov.

Approximately 6,000 test results have been reported to the Department that are greater than 100 pCi/L, which is 25 times greater than the EPA guideline of 4 pCi/L.

This radon test data supports the continued need for regulations to assure that radon testing and mitigation are being performed accurately and appropriately.

(29) **Include a schedule for review of the regulation including:**

A. The length of the public comment period: 45 days

B. The date or dates on which any public meetings or hearings will be held: Webinar – May 31, 2017

C. The expected date of delivery of this final-form regulation: Quarter 3, 2018

D. The expected effective date of this final-form regulation: Quarter 1, 2019

E. The expected date by which compliance with this final-form regulation will be required: Quarter 1, 2019

F. The expected date by which required permits, licenses or other approvals must be obtained: N/A

(30) **Describe the plan developed for evaluating the continuing effectiveness of the regulations after its implementation.**

The Department will continue to work with RPAC and other stakeholders to evaluate the effectiveness of this final-form rulemaking after its implementation.

pennsylvania
DEPARTMENT OF ENVIRONMENTAL PROTECTION

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF ENVIRONMENTAL PROTECTION
BUREAU OF RADIATION PROTECTION

2.4.1 ACKNOWLEDGEMENT FORM FOR CERTIFIED INDIVIDUAL IN RESPONSIBLE CHARGE OF RADON TESTING ACTIVITIES

Individual's Name _____ Date _____

Firm's Name (if certified) _____

I am the certified individual in responsible charge of testing activities. I acknowledge that, as long as I am employed as the certified individual, I am responsible for compliance with Pennsylvania's radon certification regulations, 25 Pa. Code Chapter 240. My responsibilities include the following:

1. Supervising radon testing activities.
2. Exercising due diligence to ensure that radon testing will be conducted as described in the approved application and in compliance with Pennsylvania law and regulations.
3. Exercising due diligence to ensure that all individuals in the firm who perform radon testing, and are not DEP-certified as testing individuals, (a) have adequate training and knowledge of radon testing procedures, and (b) are listed with DEP as employees of a certified radon testing firm.
4. Exercising due diligence to ensure that all radon testing is performed in accordance with the quality assurance procedures set forth in the application. 25 Pa. Code §240.304.
5. Exercising due diligence to ensure that DEP provided written evidence of successful participation in the DEP-approved radon proficiency program for each radon measurement utilized. 25 Pa. Code §240.307.
6. Exercising due diligence to ensure that no testing is performed unless the potential client has first been provided the written information required by 25 Pa. Code § 240.302(a), including a price list of services offered, a notice that only certified persons may provide such services, and evidence of certification.
7. Approving all data obtained from radon testing, including but not limited to, grab working level (GW), continuous working level (CW), grab radon (GR), continuous radon (CR), and electret testing devices (EL&ES).
8. Exercising due diligence to ensure that the results of radon testing are reported to DEP (only for the devices you read/analyze) and to the owner or occupier of the building within 45 days of completion of the services in accordance with the provisions of 25 Pa. Code §240.303(a), (b).
9. Meeting at least monthly with employees of the firm who perform radon-related activities to review quality assurance/quality control programs, reporting, and health and safety records, and where necessary, to initiate corrective action (if applicable).
10. Being readily available to firm employees to discuss all matters related to radon testing including radon certification, regulatory requirements, and radon testing protocols (if applicable).
11. Exercising due diligence to ensure that the health and safety program is adequate to maintain exposure to radon as low as reasonably achievable (ALARA). 25 Pa. Code §240.305.

2.4.1 ACKNOWLEDGEMENT FORM FOR CERTIFIED INDIVIDUAL IN RESPONSIBLE CHARGE OF RADON TESTING ACTIVITIES (continued)

Individual's Name _____ Date _____

Firm's Name (if certified) _____

12. Exercising due diligence to ensure a radon-related service or product is not advertised with false or misleading statements regarding the offered service or product, or the risks to health or property value. 25 Pa. Code §240.301.

13. Ensuring that I will participate in a continuing education program consisting of at least 8 hours of DEP-approved courses or seminars on radon each certification year. 25 Pa. Code §240.306.

14. Ensuring that I will be in responsible charge of DEP-listed firm employees.

15. Ensuring that I will notify the DEP promptly if a condition of the firm's certification or a condition of my certification changes.

16. Ensuring that I will notify the DEP promptly if my employment or radon testing activities terminates.

17. Ensure that testing records are maintained as specified in 25 Pa. Code §240.305.and §240.306 (as applicable).and

18. Ensure that all primary device testing activities are reported to the DEP within 45 days after the latest *test end date* or if no reportable testing activities are performed within a 45-day period that this is reported to DEP.

19. Ensure that all 45-day reportable testing activities performed by any of that firm's employees and yourself, is submitted under your individual testing certification number.

Violation of my responsibilities as certified individual could result in the suspension of my certification or my decertification, as well as civil and criminal penalties.

_____
Name of Firm
(if certified)

_____
Print Name of Certified Individual

_____ _____
Signature of Certified Individual Date

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2.2 INITIAL CERTIFICATION CHECKLISTS

2.2.1 CHECKLIST A

INITIAL TESTING APPLICATION CHECKLIST FOR:
Testing Individual Certification Only OR Testing Individual with Firm Certification Added

Submit the items below in the order listed:

- A person may not provide radon-related services without current DEP-certification.
- If applicable, any testing individual certification application postmarked greater than one year after the expiration of the previous testing individual certification shall be submitted as an initial testing individual application and is not subject to the $150 late application fee.

☐ **General Section**
Complete and submit form in Section 2.4 (Pages 30 & 31). Include a check/money order for fees. (See Section 1.1.14, Page 4).

☐ **Compliance Information**
Submit all radon-related compliance information, including descriptions of notices of violation, administrative orders, civil penalties assessments and actions for violations of the act, this chapter or a term or condition of certification.

☐ **DEP-approved Course Certificate**
DEP accepts all NRPP or NRSB – approved Initial Radon Measurement Courses.

☐ **DEP approved Exam Results**
Submit proof of having passed a DEP approved radon measurement exam for the certified individual applicant. The certified individual applicant must have passed the exam within the past two years. This exam is an initial requirement only. For Department-approved exams see Section 4.1 (Page 75).

☐ **I.D. Card Photographs for the Certified Testing Individual**
Submit an updated photo taken within the last 3 months as a TIF or JPEG file via email to RA-EPRadon@pa.gov. See Section 7 (Page 98) for photograph guidelines.

☐ **Certified Individual Acknowledgment Form**
Complete and submit the completed form in Section 2.4.1 (Pages 32 & 33).

Quality Assurance Plan
Refer to Section 5 (Pages 77-83) for information on compiling this document. All primary testers see Section 1.7 (Page 12) QA Requirements for Primary Testers.

☐ **Client Information**

Submit a copy of the document containing the 'Notice of Clients' you will provide to the client prior to providing a radon related service. (The text of the 'Notice to Clients' is found in Section 6, Page 82, §240.302 of this guide.) Also, submit a copy of the radon test result reporting form you will provide the client, containing the 'Notice to Clients'. The Department's recommended radon test result reporting form to clients is found in Section 3.5.1 (Page 74) of this guide. Also, submit copies of price lists, brochures, and advertisements.

PRIMARY DEVICES

If applying as a primary tester for Continuous Monitor CM(s), complete and submit:

1. The CM Application form (See Section 2.4.4, Page 38).
2. Proof of calibration certificates for all serial numbers for the last 2 years.
3. The QA Form For CM Primary Testing and/or Laboratory (See Section 2.4.6, Pages 40-42).
4. $150 primary device fee.
5. Proof of Device Proficiency.

If applying as a primary tester for Electrets, complete and submit:

1. The Electret Reader Application form (See Section 2.4.5, Page 39).
2. Proof of calibration certificates for all electret readers for the last 2 years.
3. The QA Form for Electret Ion Chamber Primary Testing and/or Laboratory (See Section 2.4.7, Pages 43-46).
4. $150 primary device fee.
5. Proof of Device Proficiency.

Device Proficiency (must have been completed within the past 2 years) (Only required if reading/analyzing your own CMs or Electret ion chambers).

Separate proficiency is required for each model of continuous radon monitor (i.e. Sun Nuclear 1027, 1028, 1029, Pylon, Femto-TECH 510, etc.) short-term electrets, long-term electrets, and each model of continuous working level monitor. The following chambers are Department-approved:

Bowser-Morner Radon Chamber
4518 Taylorsville Road
Dayton, OH 45424
Phone (937) 236-8805
(Fax) (937) 233-2024
radon@Boser-Morner.com

TCS Industries Inc.
4326 Crestview Road
Harrisburg, PA 17112
Phone (717) 657-7032
(Fax) (717) 657-7032
radondetek.com

There is a $150 DEP fee each for electrets and continuous monitors. (See Section 1.1.14, Page 4).

For a current list of NRSB-approved primary and secondary chambers please visit their website at NRSB.org

For a current list of NRPP-approved primary and secondary chambers please visit their website at RADONGAS.org.

If ONLY applying for a Testing Individual Certification STOP HERE.
(For mailing instructions and review time frames please refer to the end of this checklist.)
If applying for a Testing individual Certification with a Testing FIRM Certification added also submit the following:

☐ **Employee Information**

- List each firm employee(s) who will be performing radon testing activities on the General Application.
- Submit each employee's educational background and related experience.

☐ **I.D. Card Photographs for Each Testing Firm Employee**
Submit an updated photo taken within the last 3 months for each testing firm employee as a TIF or JPEG file via email to RA-EPRadon@pa.gov. See Section 7 for photograph guidelines. ID badges should be worn while conducting radon activities.

☐ **The Radon Testing Employee Form**
Each testing firm employee must complete and submit this form. (See Section 2.9, Page 52).

☐ **Testing Firm Ownership Form**
See Section 2.12 (Page 55).

☐ **Testing Employee Fee**

Submit $150 for each firm testing employee (Except the first testing employee) Section 1.1.14 (Page 4).

Mail your completed renewal application to

Pennsylvania Department of Environmental Protection
Bureau of Radiation Protection
Radon Certification Section
400 Market Street
P.O. Box 8469
Harrisburg, PA 17105-8469

Time frame for reviewing applications

After review of the application - approximately two weeks - DEP will either certify, deny, or send a 20-day correction letter.

If a reply is not received to the correction letter within 20 days of the date of that letter, a 10-day intent to deny letter is sent. If the intent to deny letter is not answered within 10 days, the application is denied and a denial letter is sent.

DEP may require additional information to an applicant's qualifications or technical or administrative information related to radon testing, mitigation or laboratory analysis of radon samples. If so, a written request will be sent.

Notification of any changes

It is the certified individual's responsibility to notify DEP within 10 days of the occurrence of any changes which may affect your certification. All notifications of changes must be made in writing and bear the signature of the certified individual. Changes may be sent by postal mail, fax (717-783-8965), or by emailing a PDF of your scanned document.

For any questions about this application or radon certification, please call the Radon Certification Section of the Department of Environmental Protection at (717) 783-3594.

ALL FEES ARE NONREFUNDABLE!

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2.2.2 CHECKLIST B

INITIAL MITIGATION CERTIFICATION APPLICATION CHECKLIST FOR: Mitigation Individual Certification Only OR Mitigation Individual Certification with Mitigation Firm Certification Added

Submit the items below in the order listed:

- A person may not provide radon-related services without current DEP-certification.
  - If applicable, any mitigation individual certification application postmarked greater than one year after the expiration of the previous mitigation individual certification shall be submitted as an initial mitigation individual application and is not subject to the $150 late application fee.

☐ **General Section**
Complete and submit form in Section 2.4 (Pages 30 & 31). (Include check/money order for fees) See Section 1.1.14 (Page 4).

☐ **Compliance Information**
Submit all radon-related compliance information, including descriptions of notices of violation, administrative orders, civil penalties assessments and actions for violations of the act, this chapter or a term or condition of certification.

☐ **DEP-approved Course Certificate**
DEP accepts all NRPP or NRSB – approved Initial Radon Mitigation Courses.

☐ **Department-approved Exam Results**
Enclose proof of having passed a Department-approved radon mitigation exam within the past two years for the certified individual applicant. This exam is an **initial** requirement only. For Department-approved exams, see Section 4.1 (Page 75).

☐ **Experience**
Submit a description of:
- at least one year of professional radon mitigation experience as a DEP–listed mitigation firm employee, certified individual or from another state or country

OR

- three year's experience in architecture, engineering, electrical contracting, plumbing, carpentry, masonry, or related trades.

If you have any questions about your experience, please submit a detailed written explanation of that experience for approval prior to submittal of this application. All fees once submitted are nonrefundable.

☐ **I.D. Card Photographs for the Certified Mitigation Individual**
Submit an updated photo taken within the last 3 months as a TIF or JPEG file via email to RA-EPRadon@pa.gov. See Section 7 (Page 98) for photograph guidelines.

☐ **Certified Mitigation Individual Acknowledgment Form**
Complete and submit the completed form in Section 2.4.2 (Pages 34 & 35).

☐ **Election of Post Mitigation Testing Option Form**
Complete and submit the completed form in Section 2.8 (Page 51).

☐ **Client Information**
Submit a copy of the document containing the 'Notice to Clients' you will provide to the client prior to providing a radon related service. The 'Notice to Clients' is normally placed on the estimate form for the job. (The text of the 'Notice to Clients' is found in Section 6 (Page 93) §240.302 of this guide.) Also, submit copies of brochures, estimate forms, warranties, and advertisements.

If ONLY applying for Mitigation Individual Certification STOP HERE.
(For mailing instructions and review time frames please refer to the end of this checklist)

If applying for individual mitigation certification with mitigation FIRM certification also submit the following:

☐ **Employee Information**
- List each firm employee(s) who will be performing radon mitigation activities on the General Application
- Submit

☐ **I.D. Card Photographs for Each Mitigation Firm Employee**
Submit an updated photo taken within the last 3 months for each mitigation firm employee as a TIF or JPEG file via email to RA-EPRadon@pa.gov. See Section 7 (Page 98) for photograph guidelines. ID badges should be worn while conducting radon activities.

☐ **Mitigation Firm Ownership Form**
See Section 2.13 (Page 56)

☐ **The Radon Mitigation Employee Form**
Each mitigation firm employee must complete this form. See Section 2.10 (Page 53)

Mail your completed renewal application to

Pennsylvania Department of Environmental Protection
Bureau of Radiation Protection
Radon Certification Section
400 Market Street
P.O. Box 8469
Harrisburg, PA 17105-8469

Time frame for reviewing applications

After review of the application - approximately two weeks - DEP will either certify, deny, or send a 20-day correction letter.

If a reply is not received to the correction letter within 20 days of the date of that letter, a 10-day intent to deny letter is sent. If the intent to deny letter is not answered within 10 days, the application is denied and a denial letter is sent.

DEP may require additional information to an applicant's qualifications or technical or administrative information related to radon testing, mitigation or laboratory analysis of radon samples. If so, a written request will be sent.

Notification of any changes

It is the certified individual's responsibility to notify DEP within 10 days of the occurrence of any changes which may affect your certification. All notifications of changes must be made in writing and bear the signature of the certified individual. Changes may be sent by postal mail, fax (717-783-8965), or by emailing a PDF of your scanned document.

For any questions about this application or radon certification, please call the Radon Certification Section of the Department of Environmental Protection at (717) 783-3594.

ALL FEES ARE NONREFUNDABLE!

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2.13 MITIGATION FIRM CERTIFICATION OWNERSHIP FORM

Mitigation Firm Owner's Name (If Individual):		
Last:	**First:**	**Middle:**

-OR-

Mitigation Firm Owner Name (If Business Entity):			
Owner's Mailing Address: (address where DEP will send correspondence relating to this mitigaiton firm)			
City:	**State:**	**Zip:**	**County:**
Primary Phone:	**Secondary Phone:**	**Email:**	
Name of DEP-Certified Mitigation Firm:			
Name of DEP- Certified Mitigation Individual:			

I hereby agree as the owner of this firm certification to be responsible for submitting signed notification to DEP when any of the following change:

- the certified Mitigation individual for this firm, (including notifying DEP of the loss of that certified mitigation individual within 5 days)
- firm name,
- any of the contact information as submitted above, or
- the owner of this firm

NOTE: The certified Mitigation individual for this firm is in responsible charge of any DEP-listed firm mitigation employees for this firm and all their mitigation activities performed in Pennsylvania.

The certified mitigation individual is the only person who may submit a signed request to DEP to add or remove any mitigation firm employees to this firm's certification.

_____

Printed full Name of this Mitigation Firm Certification's Owner
(If the owner is a business entity, the name of the individual with the authority to sign on behalf of this business entity)

_____ _____

Signature of the Owner of This Mitigation Firm Certification **Date**
(If the owner is a business entity, the signature of an individual with the authority to sign on behalf of this business entity)

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2.4.6 QA FORM FOR CONTINUOUS RADON MONITOR PRIMARY TESTING AND/OR LABORATORY (PAGE 1 OF 3)

Individual's Name _____ **Date** _____

Testing Firm's Name (if certified) _____

1. **I as the certified testing or laboratory individual will ensure that each of the following is performed for each specific serial-numbered CRM that I am DEP-listed to test and/or analyze with in Pennsylvania.**

   Calibrations - Each continuous radon monitor must be calibrated in a Department-approved calibration facility (DEP currently approves NRPP/NRSB listed chambers) within one year from the date of the previous calibration (unless it is the initial calibration for a newly listed monitor) and whenever any alterations or repairs are made to the monitor. A current calibration sticker must be attached to each monitor. Current calibration must be verified prior to each test being performed. No testing will be performed with a CM that is not currently calibrated.

   Background measurements - shall be performed and documented after every 1,000 hours of operation of scintillation cell-type continuous radon monitors and whenever any type of continuous radon monitor is calibrated. The background shall be checked by purging the monitor with clean, aged air or nitrogen in accordance with the manufacturer's instructions. In addition, the background shall be monitored in accordance with the manufacturer's instruction.

   Check Source Counting - is required prior to each measurement and must be documented.

   Intercomparisons (Required for all CR monitors without a check source) - Continuous monitors without check source capability shall have an informal intercomparison measurement made with another NRSB/NRPP listed passive monitor that is analyzed by a Department-certified laboratory or another CR monitor with a hard copy printout at least every 10th measurement. Original printouts and/or Department-certified lab results must be kept for each intercomparison.

   - The informal intercomparison measurement shall be made in an environment that has been chosen for its stability and radon concentration that is above the lower limit of detection.
   - Informal intercomparisons shall be side-by-side measurements.
   - A measurement of at least 48 hours duration shall be conducted.

2. **I understand that once a monitor is DEP-listed I am required to perform all QA for that monitor even if I perform no testing with that monitor. The only exception to this requirement is after I have received written approval from the Department that removal of that specific serial-numbered monitor has been approved, then and only then am I no longer responsible for the QA requirements for that monitor and I also am also no longer allowed to perform testing with that monitor in Pennsylvania.**

2.4.6 QA FORM FOR CONTINUOUS RADON MONITOR PRIMARY TESTING AND/OR LABORATORY (PAGE 2 OF 3)

Individual's Name _____ **Date** _____

Firm's Name (if certified) _____

3. **I will follow the procedures as described below to add or remove a specific serial-numbered CRM(s) of the same type of CM or to add a new TYPE of CM (Examples of different types of CM include: femto TECH, Sun Nuclear, Pylon, Honeywell, Radon Away Rad Star).**

   I will submit the following **to remove** any CM:

   - A written request signed by the certified testing individual and sent by postal mail, faxed to 717-783-8965, or by emailing a PDF of the signed scanned request.
   - Including the type, model and serial number of each CM to be removed.

   After a written response from DEP is received, stating that the specific serial-numbered primary CM(s) has been removed from my certification, I understand that I am no longer required to perform any QA for that specific serial-numbered CM(s) and that I may no longer perform any radon testing in Pennsylvania with that CM(s).

   I will submit the following **to add a specific serial-numbered CM** (NOTE: These criteria apply only if you are already certified to use that specific TYPE of CM):

   - A written request signed by the certified testing individual and sent by postal mail, faxed to 717-783-8965, or by emailing a PDF of the signed scanned request.
   - Proof of current calibration for each serial-numbered CM to be added.
   - The manufacturer's name, model and serial number of each CM to be added.
   - Primary monitor proficiency for each new model of CM to be added (The Sun Nuclear 1027, Sun Nuclear 1028 and Sun Nuclear 1029 are each examples of different models of primary CMs).

   I will ensure I have received written approval from DEP to add a specific serial-numbered primary CM and will not perform any testing in Pennsylvania prior to the approval date specified by DEP in that written approval.

   I will submit the following **to add a new TYPE of CM** (Examples of different types of CM include: femto TECH, Sun Nuclear, Pylon, Honeywell, Radon Away Rad Star):

   - A written request signed by the certified testing individual and sent by postal mail, faxed to 717-783-8965, or by emailing a PDF of the signed scanned request.
   - Proof of current calibration for each serial-numbered CM to be added.
   - The manufacturer's name, model and serial number of each CM to be added.
   - Primary monitor proficiency for this type of CM.

   I will ensure I have received written approval from DEP to add a specific type of primary CM and will perform No testing prior to the approval date specified by DEP in that written approval.

2.4.6 QA FORM FOR CONTINUOUS RADON MONITOR PRIMARY TESTING AND/OR LABORATORY (PAGE 3 OF 3)

Individual's Name _____ **Date** _____

Firm's Name (if certified) _____

4. **I will use the following DEP-approved calibration facility for all CM calibrations (DEP currently approves NRPP/NRSB listed chambers) If I should wish to change the chamber I am using I will submit a written request signed by the certified testing individual and sent by postal mail, faxed to 717-783-8965, or by emailing a PDF of the signed scanned request and I will not use this newly requested calibration facility until after I have received written approval from the Department.**

_____
Printed Full Name of DEP-Approved Calibration Facility

5. **I am aware that I as the certified testing individual am required to comply with the responsibilities as outlined above and failure to comply with these responsibilities could result in the suspension of my certification or my decertification, as well as civil and criminal penalties.**

_____
Printed Full Name of Testing/LAB Firm (if certified)

_____
Printed Full Name of Testing/LAB Individual

_____ _____
Signature of Testing/LAB Individual Date

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2.4.7 QA FORM FOR ELECTRET ION CHAMBER PRIMARY TESTING AND/OR LABORATORY (PAGE 1 OF 4)

Individual's Name _____ **Date** _____

Firm's Name (if applicable) _____

1. **I as the certified testing or laboratory individual will ensure that all of the following QA requirements are performed.**

   Calibrations: Each DEP-approved electret reader shall be calibrated simultaneously with its corresponding reference electret's recertification. These requirements shall be performed by the manufacturer or manufacturer-approved calibration facility within one year from the date of the previous calibration or whenever any alterations or repairs are made to the reader. All calibration documents must be retained for a period of five years. Calibration factors for the electret ion chamber system shall be obtained from the manufacturer and documented. No electret reader will be used to analyze any testing performed in Pennsylvania unless currently calibrated and I have written approval from DEP to perform analysis with that reader.

   Known Exposure Measurements (Spikes): Spikes consist of electrets that have been exposed to known concentrations in a Department-approved radon chamber. Spikes shall be conducted at a rate of 3 per 100 test devices deployed, with a minimum of 3 per certification year when tests were performed in that certification year (DEP defines the certification year as each 12-month period beginning with the certification date of the certified individual required to perform the spikes) and a maximum required of 6 per month. These spiked detectors shall be labeled and analyzed in the same manner as ordinary tests. Spikes shall be monitored using a means control chart. The control chart is established using a warning level of plus and minus 20% and control limits of plus and minus 30%.

   In addition to the control charts, all spikes shall be documented on a form which contains at a minimum the following:

   - Radon chamber used
   - Device serial numbers
   - Reference value (chamber)
   - Measured value(s)
   - Individual RPE results
   - Certification year, from/to
   - Exposure dates
   - All corrective actions performed

   Duplicate Measurements (duplicates): Duplicates are measurements performed by placing two devices side-by-side. Duplicates shall be made in at least 10 percent of the total number of test devices deployed each month, or 50 each month, whichever is smaller. The duplicates shall be distributed systematically throughout the entire population of test locations.

2.4.7 QA FORM FOR ELECTRET ION CHAMBER PRIMARY TESTING AND/OR LABORATORY (PAGE 2 OF 4)

Individual's Name _____ **Date** _____

Firm's Name (if applicable) _____

The relative percent difference (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, one for duplicates where the average is greater than or equal to 4.0 pCi/L, and one for duplicates where the average is greater than or equal to 2.0 pCi/L and less than 4.0 pCi/L.

In addition to the control charts, all duplicates shall be documented on a form which contains at a minimum the following:

- Device serial numbers
- Dates
- Individual measurement results
- RPD result
- All corrective actions performed

Reader Routine Instrument Checks: Proper operation of the reader shall be monitored following the manufacturers procedures for analyzing the reference electrets and zeroing the reader. A voltage reading of a reference electret difference of more than (+/-) 3 volts from its specified value shall be considered a wrong reading. Corrective action(s) shall be taken. When zeroing the reader it should not display more than (+/-) 3 volts, if it does corrective action(s) shall be taken. These checks shall be conducted at least once a week while the reader is in use and shall be documented.

All routine instrument checks shall be documented on a form which contains at a minimum the following:

- Reader serial number
- Date of analysis
- Zero value
- Reference electret values
- All corrective actions taken

2.4.7 QA FORM FOR ELECTRET ION CHAMBER PRIMARY TESTING AND/OR LABORATORY (PAGE 3 OF 4)

Individual's Name _____ **Date** _____

Firm's Name (if applicable) _____

2. **I will retain all radon-related QA records and radon test result documentation for a minimum of five (5) years.**

3. **I will follow the procedures as described below to add or remove a specific serial-numbered electret reader.**

   I will submit the following **to remove** a specific serial-numbered electret reader from my individual certification:

   - A written request signed by myself as the certified testing individual and sent by postal mail, faxed to 717-783-8965, or by emailing a PDF of the signed scanned request.
   - Include the type, model and serial number of each electret reader to be removed or the specific name of the testing device.

   After a written response from DEP is received, stating that the specific serial-numbered reader has been removed from my certification as of the date specified by DEP, I understand that I am then no longer required to perform any QA for that specific serial-numbered reader and that I may also no longer perform radon analysis with that reader(s) of any electret testing performed in Pennsylvania. I also understand that the **only** exception to the requirement to perform the required QA for any DEP-certified specific serial-numbered electret reader is to receive written approval from the Department that removal of that specific serial-numbered electret reader has been approved and after the renewal date specified by DEP in that removal letter you are no longer required to perform QA for the reader nor can you perform any analysis or testing in Pennsylvania with that reader.

   I will submit the following **to add** a specific serial-numbered electret reader to my individual certification:

   - A written request signed by myself as the certified testing individual and sent by postal mail, faxed to 717-783-8965, or by emailing a PDF of the signed scanned request.
   - Proof of current calibration for each serial-numbered electret reader to be added.
   - The manufacturer's name, model and serial number of each CM to be added.

   I will ensure I have received written approval from DEP to add a specific serial-numbered electret reader and will perform no analysis of testing performed in Pennsylvania with that reader prior to the approval date specified by DEP in that approval letter.

4. **I will use the following DEP-approved calibration chamber(s) for all electret reader reference electret calibrations and electret spikes (DEP currently approves NRPP/NRSB listed chambers for electret spikes and the manufacturer or a manufacturer approved facility for performing calibrations of electret readers). If I should wish to change the chamber listed below I will submit a written request signed by the certified testing individual and sent by postal mail, faxed to 717-783-8965, or by emailing a PDF of the signed scanned request and I will not use this newly requested chamber or reader calibration facility until after I have received written approval from the Department.**

2.4.7 QA FORM FOR ELECTRET ION CHAMBER PRIMARY TESTING AND/OR LABORATORY (PAGE 4 OF 4)

Individual's Name _____ **Date** _____

Firm's Name (if applicable) _____

_____
Printed Full Name of DEP-Approved Reader Calibration Facility

_____
Printed Full Name of DEP-Approved Chamber For My Reference Electrets

_____
Printed Full Name of DEP-Approved Chamber Performing My Spikes

5. **I am aware that I as the certified testing individual am required to comply with the responsibilities as outlined above and failure to comply with these responsibilities could result in the suspension of my certification or my decertification, as well as civil and criminal penalties.**

_____
Printed Full Name of Testing/LAB Firm (If Certified)

_____
Printed Full Name of Testing/LAB Individual

_____ _____
Signature of Testing/LAB Individual Date

SECTION 2
RADON CERTIFICATION APPLICATION

2.1 RADON CERTIFICATION APPLICATION INSTRUCTIONS

Applicants must submit a correct and complete application including all required fees. (See Section 1.1.14, Page 4).

Step 1 Determine the type of certification you need.

The three types of certification are:

1) **Testing** – the certification required for any of the following:
   - the placing and retrieving of any radon testing device
   - the analysis of the tester's own continuous monitors or electret ion chambers.

2) **Mitigation** – the certification required for any repair or altering of a building or building design for the purpose, in whole or in part, of reducing the concentration of radon in the indoor atmosphere.

3) **Laboratory** – the certification required for any person who analyzes radon devices received from the public or from certified testers.

Step 2 Determine the category of certification.

The three types of certification (testing, mitigation and laboratory) are further divided into two categories:

1) **Individual Only Certification**
   - Under this category of certification, only the certified individual may perform the radon-related activity.
   - Radon certification as an "individual" results in only the given name of that individual being listed on the certificate and in DEP's Radon Services Directory.

2) **Firm Certification (Added to an Individual Certification)**
   - A certified individual may add a firm to that individual certification at any time. However, if for whatever reason, that certified individual is no longer in responsible charge of that radon-related activity for that firm that firm certification lapses and is void until DEP-approves another individual to be in responsible charge of that firm.
   - Certification as a "firm" results in the firm name, in addition to the certified individual's name, being listed on the certificate and in DEP's Radon Services Directory,.
   - In addition to the certified individual, the employees of the firm may also perform the radon-related activities for which the firm is certified, if the following conditions are met:
     - ☐ Each testing, mitigation, & laboratory employee must fill out the appropriate Employee Form(s).
     - ☐ Each employee performs the radon-related activities under the responsible charge of that firm's certified individual.
     - ☐ Each employee is listed with DEP, either through listing on the initial firm application or by written request to DEP by the firm.
     - ☐ For testing and/or mitigation firm employees, these additional items must be submitted:
       - * Submit an updated photo taken within the last 3 months of each employee as a TIF or JPEG file via e-mail to RA-EPRadon@pa.gov. (Photography guidelines are in Section 7 (Page 98) of this book.); ID badges shall be worn while conducting radon activities.

☐ • All mitigation and laboratory employees are free. Each additional testing employee is $150

☐ • Written approval for each firm employees and the required DEP I.D. card must be received from our Department prior to any employee commencing any radon-related activities in Pennsylvania.

Step 3 **If this is an initial application,** complete and compile the applicable checklist enclosed in this guide as Section 2.2.

CHECKLIST A	Initial Testing Certification Application Checklist (See Section 2.2.1, Pages 16-18)
CHECKLIST B	Initial Mitigation Certification Application Checklist (See Section 2.2.2, Pages 19 & 20)
CHECKLIST C	Initial Laboratory Certification Application Checklist (See Section 2.2.3, Pages 21 & 22)

If this is a renewal application, follow the Renewal Radon Certification Application Instructions enclosed in this guide as Section 2.3.

CHECKLIST D	Renewal Testing Certification Application (See Section 2.3, Pages 23-25)
CHECKLIST E	Renewal Mitigation Certification Application Checklist (See Section 2.3.1, Pages 26 & 27)
CHECKLIST F	Renewal Laboratory Certification Application Checklist (See Sections 2.3.2, Pages 28 & 29)

Step 4 Mail your completed application to:

(Note: Radon-related activities applied for in this application may not begin until you have received a DEP certification certificate for that radon-related activity.)

Pennsylvania Department of Environmental Protection
Bureau of Radiation Protection
Radon Certification Section
400 Market Street
P.O. Box 8469
Harrisburg, PA 17105-8469

Step 5 After review of the application, DEP will either_ certify, deny, or send a 20-day correction letter to the applicant.

If a reply is not received to the correction letter within 20 days of the date of that letter, a 10-day intent to deny letter is sent. If the intent to deny letter is not answered within 10 days, the application is denied and a denial letter is sent.

For any questions about this application or radon certification, please call the Radon Certification Section of the Department of Environmental Protection at (717) 783-3594.

Step 6 DEP may require additional information related to an applicant's qualifications or technical or administrative information related to radon testing, mitigation or laboratory analysis of radon samples. If so, a written request will be sent.

Step 7 Notification of Change

It is the certified individual's responsibility to notify DEP of the occurrence of any changes which may affect your certification within 10 days. All notification of changes must be made in writing and bear the signature of the certified Individual. Changes may be sent by postal mail, fax (717) 783-8965, or by e-mailing a PDF of your scanned document.

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2.3 CHECKLIST D

RENEWAL APPLICATION CHECKLIST FOR RADON TESTING CERTIFICATION

If you are renewing your:

- testing individual certification only, submit items in Section A
- testing individual and testing firm certifications, submit items in Sections A and B
- testing firm certification only, submit items in Section C (This option is only available if you have a currently DEP-certified testing individual who will be in responsible charge of this firm certification)

Section A: If applying for renewal of a Testing Individual certification submit the following:

☐ **General Section**
Complete and submit form in Section 2.4 (Pages 30 & 31). Include a check/money order for fees, see Section 1.1.14 (Page 4). (If adding or removing any new model/type of device that's different from your previous certification, see Section 1.2 (Page 5), for guidance on what must be submitted.)

☐ **Compliance Information**
Submit all radon-related compliance information, including descriptions of notices of violation, administrative orders, civil penalties assessments and actions for violations of the act, this chapter or a term or condition of certification.

☐ **Continuing Education**
Submit proof of having passed the appropriate DEP approved exam within the last two years,
- **OR** - of having completed 16 hours of NRPP or NRSB-approved continuing education.

☐ **I.D. Card Photographs for the Certified Testing Individual**
Please submit an updated photo taken within the last 3 month as a TIF or JPEG file via email to RA-EPRadon@pa.gov. See Section 7 (Page 98) for photograph guidelines.

☐ **Certified Testing Individual Acknowledgment Form**
Complete and submit the form in Section 2.4.1 (Pages 32 & 33)

☐ **If renewing as a primary tester for the same model/type of Continuous Monitor (CM), complete and submit:**
(If adding or removing any new model/type of device that's different from your previous certification, see Section 1.2 (Page 5), for guidance on what must be submitted.)

- ☐ The *CM Form* in Section 2.4.4 (Page 38)
- ☐ Proof of calibration for each serial-numbered CM for the previous 2 years
- ☐ The *QA For Primary CM Monitor Testing Form* in Section 2.4.6 (Pages 40-42)
- ☐ $150 primary device fee
- ☐ The Radon Result Report Form given to clients (which must include the CM calibration expiration date.) See page 73 and 74.

☐ **If renewing as a primary tester for Electrets, complete and submit:**
(If adding or removing any new model/type of device that's different from your previous certification, see Section 1.2 (Page 5), for guidance on what must be submitted.)

- ☐ The *Electret Reader Form* in Section 2.4.5 (Page 39)
- ☐ Proof of calibration for each electret readers for the previous 2 years
- ☐ The *QA Form for Primary Electret Ion Chamber Testing* in Section 2.4.7 (Pages 43-46)
- ☐ $150 primary device fee
- ☐ The Radon Result Report Form given to clients (which must include the CM calibration expiration date.) See page 73 and 74.

If ONLY applying for renewal of a Testing Individual Certification STOP HERE.
(For mailing instructions and review time frames please refer to Section D below.)

Section B: If applying for BOTH a testing individual and testing FIRM certification also submit the following:

☐ *I.D. Card Photographs for Each Testing Firm Employee*

Submit updated photos taken within the last 3 months for each testing firm employee as a TIF or JPEG file via email to RA-EPRadon@pa.gov. See Section 7 (Page 98) for photograph guidelines. ID badges should be worn while conducting radon activities.

☐ **The Radon Testing Employee Form**
Each testing firm employee must complete this form. See Section 2.9 (Page 52)

☐ **Testing Employee Fee**
Submit $150 for each firm testing employee (Except the first testing employee) Section 1.1.14 (Page 4).

☐ **Testing Firm Owner Form**
See Section 2.12 (Page 55)

Section C: If applying ONLY for testing FIRM certification, submit all four listed above in Section B and also the following: (This option is only available if you have a currently DEP-certified testing individual who will be in responsible charge of this firm certification)

☐ **General Section**
Complete and submit form in Section 2.4 (Pages 30 & 31) Include a check/money order for fees. See Section 1.1.14 (Page 4).

☐ **Certified Testing Individual Acknowledgment Form**
Complete and submit the form in Section 2.4.1 (Pages 32 & 33)

Section D: General Application Information

- **Mail your completed renewal application to:**
  Pennsylvania Department of Environmental Protection
  Bureau of Radiation Protection
  Radon Certification Section
  400 Market Street
  P.O. Box 8469
  Harrisburg, PA 17105-8469

- **Late Application Fee**

  Testing **Individual** Certification Applications postmarked:

  - prior to 1 year after the expiration of that certification shall be a renewal application and include the $150 late application fee. **These applicants and any applicants applying for testing firm certification should complete the applicable sections of this checklist.**

  - more than 1 year after expiration of that certification shall be an initial application and are not subject to the $150 late application fee but must submit as an initial applicant and submit all items in the ***Initial Testing Individual Checklist*** **on Page 16.**

- **In order to avoid a lapse in certification and the late application fee, applicants for certification renewal should file their application a minimum of 30 days prior to the expiration of their current certification.**
- **Submitting a renewal application does not extend the previous certification.**
- **A person may not provide radon-related services without current certification.**

- **DEP's Time Frame for Reviewing Applications**

  After review of the application - approximately two weeks - DEP will either certify, deny, or send a 20-day correction letter.

  If a reply is not received to the correction letter within 20 days of the date of that letter, a 10-day intent to deny letter is sent. If the intent to deny letter is not answered within 10 days, the application is denied and a denial letter is sent.

  DEP may require additional information to an applicant's qualifications or technical or administrative information related to radon testing, mitigation or laboratory analysis of radon samples. If so, a written request will be sent.

- **Notification of Changes to a Certification**

  It is the certified individual's responsibility to notify DEP within 10 days of the occurrence of any changes which may affect your certification. All notifications of changes must be made in writing and bear the signature of the certified individual. Changes may be sent by postal mail, fax (717-783-8965), or by emailing a PDF of your scanned document.

For any questions about this application or radon certification, please call the Radon Certification Section of the Department of Environmental Protection at (717) 783-3594.

ALL FEES ARE NONREFUNDABLE!

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2.3.1 CHECKLIST E

RENEWAL OF MITIGATION CERTIFICATION APPLICATION CHECKLIST

If you are renewing your:

- mitigation individual certification only, submit items in Section A
- mitigation individual certification WITH mitigation firm certification ADDED, submit items in Sections A and B
- mitigation firm certification only, submit items in Section C (This option is only available if you have a DEP-certified mitigation individual who will be in responsible charge of this firm certification.)

Section A: If applying for renewal of a Mitigation Individual certification submit the following:

☐ **General Section**
Complete and submit form in Section 2.4 (Pages 30 & 31) Include a check/money order for fees. See Section 1.1.14 (Page 4).

☐ **Compliance Information**
Submit all radon-related compliance information, including descriptions of notices of violation, administrative orders, civil penalties assessments and actions for violations of the act, this chapter or a term or condition of certification.

☐ **Continuing Education**
Submit proof of having passed the appropriate DEP approved exam within the last two years, - **OR** - of having completed 16 hours of NRPP or NRSB-approved continuing education.

☐ **I.D. Card Photographs for the Certified Testing Individual**
Please submit an updated photo taken within the last 3 months as a TIF or JPEG file via email to RA-EPRadon@pa.gov. See Section 7 (Page 98) for photograph guidelines.

☐ **Certified Mitigation Individual Acknowledgment Form**
Complete and submit the completed form in Section 2.4.2 (Pages 34 & 35)

☐ **Workers, Health and Safety Program**
Complete and submit the completed form in Section 2.5 (Pages 47 & 48)

☐ **Election of Post-Mitigation Testing Options Form**
Complete and submit the completed form in Section 2.8 (Page 51)

If ONLY applying for renewal of a Mitigation Individual Certification your checklist STOP HERE.

(For mailing instructions and review time frames please refer to Section D below)

Section B: If applying for renewal of BOTH a mitigation individual and FIRM certification also submit the following:

☐ ***I.D. Card Photographs for Each Mitigation Firm Employee***
Submit updated photos taken within the last 3 months for each testing firm employee as a TIF or JPEG file via email to RA-EPRadon@pa.gov. See Section 7 (Page 98) for photograph guidelines. ID badges should be worn while conducting radon activities.

☐ **The Radon Mitigation Employee Form**
Each mitigation firm employee must complete this form. See Section 2.10 (Page 53)

☐ **Mitigation Firm Owner Form**
See Section 2.13 (Page 56)

Section C: If applying ONLY for Mitigation FIRM certification, submit the three items listed above in Section B and also the following: (This option is only available if you have a currently DEP-certified mitigation individual who will be in responsible charge of this firm certification.)

☐ **General Section**
Complete and submit form in Section 2.4 (Pages 30 & 31) Include a check/money order for fees. See Section 1.1.14 (Page 4)

☐ **Certified Mitigation Individual Acknowledgment Form**
Complete and submit the form in Section 2.4.2 (Pages 34 & 35)

Section D: General Application Information

- **Mail your completed renewal application to:**
  Pennsylvania Department of Environmental Protection
  Bureau of Radiation Protection
  Radon Certification Section
  400 Market Street
  P.O. Box 8469
  Harrisburg, PA 17105-8469

- **Late Application Fee**
  Mitigation **Individual** Certification Applications postmarked:

- prior to 1 year after the expiration of that certification shall be a renewal application and include the $150 late application fee and all additional items as outlined on this checklist.

- more than 1 year after expiration of that certification shall be an initial application and are not subject to the $150 late application fee but must submit as an initial mitigation applicant and submit all items outlined on. **the *Initial Mitigation Individual Checklist* on Page 20.**

- **In order to avoid a lapse in certification and the late application fee, applicants for certification renewal should file their application a minimum of 30 days prior to the expiration of their current certification.**

- **Submitting a renewal application does not extend the previous certification.**

- **A person may not provide radon-related services without current certification.**

- **DEP's Time Frame for Review of Applications**

  After review of the application - approximately two weeks - DEP will either certify, deny or send a 20-day correction letter.

  If a reply is not received to the correction letter within 20 days of the date of that letter, a 10-day intent to deny letter is sent. If the intent to deny letter is not answered within 10 days, the application is denied and a denial letter is sent.

  DEP may require additional information to an applicant's qualifications or technical or administrative information related to radon testing, mitigation or laboratory analysis of radon samples. If so, a written request will be sent.

- **Notification of Changes to a Certification**
  It is the certified individual's responsibility to notify DEP within 10 days of the occurrence of any changes which may affect your certification. All notifications of changes must be made in writing and bear the signature of the certified individual. Changes may be sent by postal mail, fax (717-783-8965), or by emailing a PDF of your scanned document.

For any questions about this application or radon certification, please call the Radon Certification Section of the Department of Environmental Protection at (717) 783-3594.

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2.12 TESTING FIRM CERTIFICATION OWNERSHIP FORM

Testing Firm Owner's Name (If Individual):		
Last:	**First:**	**Middle:**

-OR-

Testing Firm Owner Name (If Business Entity):			
Owner's Mailing Address: (address where DEP will send correspondence relating to this testing firm)			
City:	**State:**	**Zip:**	**County:**
Primary Phone:	**Secondary Phone:**	**Email:**	
Name of DEP-Certified Testing Firm:			
Name of DEP- Certified Testing Individual:			

I hereby agree as the owner of this firm certification to be responsible for submitting signed notification to DEP when any of the following change:

- the certified testing individual for this firm, (including notifying DEP of the loss of that certified testing individual within 5 days)
- firm name,
- any of the contact information as submitted above, or
- the owner of this firm

NOTE: The certified testing individual for this firm is in responsible charge of any DEP-listed firm testing employees for this firm and all their testing activities performed in Pennsylvania.

The certified testing individual is the only person who may submit a signed request to DEP to add or remove any testing firm employees to this firm's certification.

Printed full Name of this Testing Firm Certification's Owner
(If the owner is a business entity, the name of the individual with the authority to sign on behalf of this business entity)

Signature of the Owner of This Testing Firm Certification **Date**
(If the owner is a business entity, the signature of an individual with the authority to sign on behalf of this business entity)

CDL-1

FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

RECEIVED
JUL 16 2018
Independent Regulatory Review Commission

DO NOT WRITE IN THIS SPACE

Copy below is hereby approved as to form and legality. Attorney General

By:
(Deputy Attorney General)

DATE OF APPROVAL

☐ Check if applicable
Copy not approved. Objections attached.

Copy below is hereby certified to be true and correct copy of a document issued, prescribed or promulgated by:

DEPARTMENT OF ENVIRONMENTAL PROTECTION
ENVIRONMENTAL QUALITY BOARD

(AGENCY)

DOCUMENT/FISCAL NOTE NO. 7-499

DATE OF ADOPTION JUNE 19, 2018

BY

TITLE PATRICK MCDONNELL
CHAIRMAN

EXECUTIVE OFFICER CHAIRMAN OR SECRETARY

Copy below is hereby approved as to form and legality Executive or Independent Agencies

BY

JUL 13 2018
DATE OF APPROVAL

(Deputy General Counsel)
~~(Chief Counsel - Independent Agency)~~
(Strike inapplicable title)

☐ Check if applicable. No Attorney General Approval or objection within 30 days after submission.

NOTICE OF FINAL RULEMAKING

DEPARTMENT OF ENVIRONMENTAL PROTECTION
ENVIRONMENTAL QUALITY BOARD

Radiological Health

25 Pa. Code Chapters 215-221, 223- 228, 230, 232, and 240

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

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

This order was adopted by the Board at its meeting on June 19, 2018.

A. *Effective Date*

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

B. *Contact Persons*

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

C. *Statutory Authority*

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

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

D. *Background and Purpose*

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

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

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

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

E. *Summary of Changes to the Proposed Rulemaking*

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

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

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

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

Chapter 215. General provisions

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

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

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

Chapter 217. Licensing of Radioactive Material

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

Chapter 218. Fees

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

Chapter 219. Standards for protection against radiation

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

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

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

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

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

Chapter 221. X-rays in the healing arts

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

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

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

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

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

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

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

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

Chapter 223. Veterinary Medicine

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

Chapter 240. Radon certification

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

General IRRC Comments

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

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

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

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

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

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

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

IRRC Comments and Public Comments

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

Chapters 215-230

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

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

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

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

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

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

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

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

Chapter 240

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

G. *Benefits, Costs and Compliance*

Benefits

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

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

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

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

Compliance Costs

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

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

Compliance Assistance Plan

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

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

Paperwork Requirements

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

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

H. *Pollution Prevention*

Pollution prevention is not applicable to this rulemaking.

I. *Sunset Review*

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

J. *Regulatory Review*

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

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

Under section 5.1(j.2) of the Regulatory Review Act, on ___(blank)___, the final-form rulemaking was deemed approved by the House and Senate Committees. Under section 5.1(e) of the Regulatory Review Act, IRRC met on ___(blank)___ and approved the final-form rulemaking.

K. *Findings of the Board*

The Board finds that:

(1) Public notice of proposed rulemaking was given under sections 201 and 202 of the act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. §§ 1201 and 1202) and regulations promulgated thereunder at 1 Pa. Code §§ 7.1 and 7.2.

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

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

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

L. Order of the Board

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

(a) The regulations of the Department, 25 Pa. Code Chapters 215-221, 223-228, 230, 232 and 240, are amended to read as set forth in Annex A.

(b) The Chairperson of the Board shall submit this order and Annex A to the Office of General Counsel and the Office of Attorney General for review and approval as to legality and form, as required by law.

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

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

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

PATRICK McDONNELL,
Chairperson

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.

* * * * *

(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.

* * * * *

§ 215.14. Availability of records [for public inspection].

The following Department records **[are not available for public inspection,] 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**[, not pertaining to safety and health in industrial plants,]** 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 **[files] records**, the disclosure of which would **[operate to the prejudice or impairment of a person's reputation or personal safety] 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 **[fitting]** devices or machines which use **[fluoroscopic,]** X-ray or **[radiation principles for the purpose of selling footwear through commercial outlets] 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) Auxiliary personnel employed by a health care facility regulated by the Department of Health, the Department of Public Welfare or the Federal government may only use radiation sources in the healing arts in accordance with written job descriptions and employee qualifications.

(d) Subsections (b) and (c)] (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 **[subsections (b) and (c)] subsection (b)** to use radiation sources in the healing arts.

EXEMPTIONS

§ 215.31. Granting exemptions.

(a) The Department may**[, upon application therefor or upon its own initiative,]** grant exemptions from this article **on its own initiative or upon application from a licensee** when the Department determines that **[they] 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. ~~Address~~ 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) **[and license].**

(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 **[of address, owner or radiation safety officer or number of machines] 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.

[After July 17, 2004, a] 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(h)] § 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(h)] § 218.11(k)** has been paid.

(4) **[A person who, on July 17, 2004, is currently in the business of providing radiation-producing machine services shall apply for registration by September 15, 2004.] 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 **[under preventative maintenance]** 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 .5 mrem (.005 mSv) per hour at 5 ~~centimeter~~ **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 are exempt from registration.]** Accelerators **[shall be], 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 **[until the Commonwealth becomes an agreement state on the date published in the *Federal Register*]**.

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(a)(6)] 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 **[and, for NRC licenses, to the NRC until agreement state status is in effect]**.

§ 217.133. [Persons possessing a license for source, byproduct or special nuclear material in quantities not sufficient to form a critical mass on the date the Commonwealth becomes an agreement state as published in the *Federal Register*] (Reserved).

[On the date the Commonwealth becomes an agreement state as published in the *Federal Register*, a person who possesses a general or specific license issued by the NRC for source, byproduct or special nuclear material in quantities not sufficient to form a critical mass, is deemed to possess a like license issued under this chapter and the act. The license shall expire either 90 days after receipt from the Department of a notice of expiration of the license, or on the date of expiration specified in the NRC license, whichever is earlier.]

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 **[and, for NRC licenses, to the NRC until agreement state status is in effect]**.

§ 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 ~~37 MBq~~ 1 mCi (~~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 ~~3.7 MBq~~ 0.1 mCi (~~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 **[and, for NRC licenses, to the NRC until agreement state status is in effect]**.

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 **[and, for NRC licenses, to the NRC until agreement state status is in effect]**.

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 **[and, for NRC licenses, to the NRC until agreement state status is in effect]**.

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 **[and, for NRC licenses, to the NRC until agreement state status is in effect]**.

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 agreement 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 **[and, for NRC licenses, to the NRC until agreement state status is in effect]**.

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**[, other than accelerators,]** 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 **[are] 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 ~~check payable~~**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 **[are payable] 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.

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

[(i)] (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. [Special provisions for calculating fees during agreement state transition period] (Reserved).

[(a) The fees for the NRC licenses that are transferred to the Commonwealth on the date the Commonwealth becomes an agreement state will be invoiced on the license's next anniversary date.

(b) During the first year after the date the Department attains agreement state status, the annual fee for each NRC license transferred to the Commonwealth will include a proportional amount, based on the schedule of fees in Appendix A, for the period from the date agreement state status is attained until the license's next anniversary date, in addition to the amount assessed for the year following the license's anniversary date.

(c) In the event that the Commonwealth attains agreement state status prior to January 1, 2009, the provisions of this section and § 218.11 and Appendix A (relating to registration, renewal of registration and fees; and fees for radioactive material licenses) will be applied retroactively to NRC licenses transferred to the Commonwealth.]

CHAPTER 219. STANDARDS FOR PROTECTION AGAINST RADIATION

Subchapter A. GENERAL PROVISIONS

§ 219.3. Definitions.

The following **[term] terms**, when used in this subchapter, **[has the following meaning] 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 ~~3 Gy~~ 1500 RAD (~~300 rad~~ 15 Gy).

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

(iii) A dose to the wrong patient, or wrong site for the entire procedure, and exceeding ~~0.5 Gy~~ 50 RAD (~~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 **[when the result is an increase in the total expected doses inside or outside of the intended treatment volume for organs, tissue or skin that exceeds 20% of the total prescribed dose for the intended target volume.] 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.

[(iii) A total dose delivered to the treatment site identified in a written directive for therapy that is outside the prescribed dose range or differs from the total prescribed dose by more than 20%, or for a fractionated dose, when the weekly administered dose differs from the weekly prescribed dose by more than 30%.]

§ 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 **[and, for NRC licenses, to the NRC until agreement state status is in effect], except as required under 10 CFR 20.2206 (relating to reports of individual monitoring).**

* * * * *

Subchapter M. REPORTS

§ 219.229. ~~Other medical~~ 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 **[therapeutic or diagnostic]** 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; **[inspections] 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 **[and, for NRC licenses, to the NRC until agreement state status is in effect]**.

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, .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 **[in order]** 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.

[*Certified components*—Components of X-ray systems which are subject to regulations promulgated under the Radiation Control for Health and Safety Act of 1968 (42 U.S.C.A. §§ 263b—263n).]

***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:**

DLP (mGy − cm) = $CTDI_{vol}$ (mGy) × 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 ~~therapy~~.

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 **[(HVL)]**—

(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 ~~utilizes~~ uses energies of less than 1 million electron volts that could exceed skin doses of 200 ~~rads~~ 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—**[A device] 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 = $100\ (V_n - V_l)/V_l$

where

V_n = No-load line potential and

V_l = 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]** **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 his 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 _____, (*Editor's Note*: The blank refers to the effective date of adoption of this ~~proposed~~ FINAL rulemaking.) 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 _____, (*Editor's Note*: The

blank refers to the effective date of adoption of this ~~proposed~~ FINAL rulemaking.) 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.

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

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, ~~including~~ 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) **[A chart] 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. **[This chart] 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 ~~film~~ **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 **[3] 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 **[hand-held] 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 other 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 ~~proposed~~ 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	.5 millimeters
50—70	1.5 millimeters
Above 70	2.5 millimeters

TABLE II

[*Design operating range (Kilovolts peak)*	*Measured potential (Kilovolts peak)*	*Minimum half-value layer (millimeters of aluminum)*	
		Specified dental systems*	**All other X-ray systems**
Below 51	30	1.5	0.3
	40	1.5	0.4
	50	1.5	0.5
51 to 70	51	1.5	1.2
	60	1.5	1.3
	70	1.5	1.5
Above 70	71	2.1	2.1
	80	2.3	2.3
	90	2.5	2.5
	100	2.7	2.7
	110	3.0	3.0
	120	3.2	3.2
	130	3.5	3.5
	140	3.8	3.8
	150	4.1	4.1]

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.

[* Dental systems manufactured after December 1, 1980, designed for use with intraoral image receptors.]

(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~~, including those that are expected to drive the system to maximum output~~ in all modes clinically used, including fluoroscopy, high-level control, acquisition, ~~digital subtraction~~ and CINE, when available. Measurements shall be performed with a ~~calibrated~~ dosimetry system CALIBRATED WITHIN 2 YEARS PRECEDING THE MEASUREMENTS. ~~per manufacturer recommendations not to exceed 2 years and records~~ 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 ~~of~~ 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~~ and collimation in the fluoroscopy and spot film modes~~.

(6) AN EVALUATION OF THE COLLIMATION IN THE FLUOROSCOPY AND SPOT-FILM OR DIGITAL ACQUISITION MODES.

(~~6~~7) An evaluation of the availability and accuracy of technique indicators and integrated radiation dose displays.

(~~7~~8) An evaluation of ANY changes that may impact patient and personnel ~~protection devices~~ 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 ~~all of the following~~ OTHER information necessary to estimate the radiation dose to the skin in accordance with established protocol or ONE OR MORE OF the following~~, as neeessary~~:

(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.

§ ~~221.57~~ 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] 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(f)(1)] 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 ~~12~~ 14 months, and 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.

(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 ~~capable of operating at no greater than 100 kV or 20 mA are exempt from an annual QMP performance evaluation~~ 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 §§ ~~Section~~ 221.202(a) AND 221.204(a)(4)(xi) -(relating to equipment requirements; AND PERFORMANCE EVALUATIONS, ROUTINE QC AND SURVEYS) ~~is exempted~~.

(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) §Section 221.204(a)(4)(xi) is exempted.~~

~~(4)~~(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 number*—The number used to represent the X-ray attenuation associated with each elemental area of the CT image.]

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.

[*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.]

$CTDI_{100}$—**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 .0929 foot-candles.

[*MSAD—Multiple scan average dose*—The calculated average dose to the tissue within each slice in a series utilizing an ion chamber. The MSAD is calculated using the following equation:

$MSAD = (F \times K \times L \times E)/(T \times N)$

Where

F = Factor to convert exposure in air to absorbed dose in lucite in RADS/mR

K = Calibration factor to account for the ion chamber's response and volume.

L = Effective length of ion chamber in millimeters (mm)

E = Exposure reading in milliroentgen (mR)

T = Nominal slice thickness in millimeters (mm) and

N = Number of slices per scan]

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

Multiple tomogram system—A **[computed tomography] 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 **[contrast scale] 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.**

[(a)] (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.

[(b)] (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.

[(c)] (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.

[(d)] (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.

[(e)] (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.

[(f)] (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 ± **[10.0] 7.0** CT number units. The facility's performance phantom shall be utilized, with the technique factors specified by the **[qualified expert] QMP**, to confirm compliance. In instances when a CTN of 0 for water is inappropriate, as in 3D treatment planning, the **[qualified expert] 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. [Radiation measurements and performance evaluations] Performance evaluations, routine QC and surveys.

[(a) *Radiation measurements.*

(1) The CTDI or MSAD along the two axes specified in paragraph (2)(ii) shall be measured. The CT dosimetry phantom shall be oriented so that the measurement point 1.0 centimeter from the outer surface and within the phantom is in the same angular position within the gantry at the point of maximum surface exposure identified. The CT conditions of operation shall be reproducible and correspond to typical values used by the registrant. If the point of maximum surface exposure constantly changes due to system design, then measurements shall be taken at four different locations—top left, top right, bottom left, bottom right—1 centimeter from the outer surface of the phantom.

(2) CT dosimetry phantoms shall be used in determining the radiation output of a CT X-ray system. The phantoms shall meet the definition for a CT dosimetry phantom under 21 CFR 1020.33(b)(6) (relating to computed tomography (CT) equipment).

(i) The phantoms shall be specifically designed for CT dosimetry and deemed appropriate by the facility's qualified expert and the Department.

(ii) CT dosimetry phantoms shall provide a means for the placement of dosimeters along the axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom. The means for the placement of dosimeters or alignment devices at other locations may be provided.

(iii) Any effects on the doses measured due to the removal of phantom material to accommodate dosimeters shall be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom.

(iv) Dose measurements shall be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuation materials present.

(3) In addition to the items in subsection (b), the following items shall be evaluated annually or after any component repair or change which in the opinion of the qualified expert may ~~effect~~ AFFECT the performance of the CT unit:

(i) HVL (half value layer) determination at the most commonly used kVp or 120 kVp.

(ii) CTDI or MSAD as specified in § 221.201 (relating to definitions) for commonly used techniques.

(iii) Tomographic plane indication (light/laser alignment).

(iv) Slice thickness as specified in § 221.202(g)(7) (relating to equipment requirements).

(v) Distance readout calibration.

(4) The measurement of the radiation output of a CT X-ray system shall be performed with a dosimetry system that has calibration traceable to National Institute of Standards and Technology. The calibration of the system shall be in accordance with an established calibration protocol. The calibration protocol published by the AAPM is accepted as an established protocol. Other protocols which are equivalent will be accepted, but the user shall submit that protocol to the Department for concurrence that the protocol is equivalent.

(5) An mR/mAs value shall be determined at least annually for the head and body.

(6) Procedures and results shall be maintained for 5 years and be available for review by the Department.]

(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) [*Performance evaluations*] ***Routine QC.***

(1) Written **[performance evaluation] routine QC** procedures shall be developed by a **[qualified expert] QMP**. These procedures shall be available for review by the Department.

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

(i) Noise.

[(ii) Contrast scale.

(iii) Spatial resolution (low and high contrast).

(iv)] **(ii)** Mean CT number for water.

[(v) Acceptable tolerances.]

(iii) Artifact evaluation.

(3) **[The performance evaluation shall be performed at intervals not to exceed 3 months by the qualified expert or an individual designated by the qualified expert.] The routine QC shall be performed at intervals not to exceed 1 week.**

(4) **[The qualified expert need not be present during the performance evaluation, but shall be informed within 48 hours of any problems or unacceptable deviations.] The QMP need not be present during the routine QC.**

(5) **[Performance evaluations] 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).

[(6) Records of the performance evaluations shall be maintained for inspection by the Department for at least 4 years.]

(c) ***Radiation protection surveys.***

(1) ~~**All**~~ **CT X-ray systems** ~~**installed after _____, (*Editor's Note:* The blank refers to the effective date of adoption of this proposed FINAL rulemaking.) and those systems not previously surveyed**~~ **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) Information shall be available at the control panel regarding the operation and performance evaluations of the system. The information shall include the following:

(1) The dates of the latest radiation measurements and performance evaluation and the location within the facility where the results of those tests may be obtained.

(2) Instructions on the use of the CT phantoms including a schedule of performance evaluations 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.

(3) A current technique chart available at the control panel which specifies for each routine examination the CT conditions of operation and the number of scans per examination.]

(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.

[(b)] (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 **[qualified expert] QMP**, the use of the CT X-ray system on patients shall be limited to those uses permitted by established written instructions of the **[qualified expert] 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 Part 35, Subparts F, G, H and K but is exempt from 10 CFR 35.632—35.645 and 35.2632—35.2645] 10 CFR Part 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 ~~in the room~~ 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~~and, for NRC licenses, to the NRC until agreement state status is in effect~~**.

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 **[and, for NRC licenses, to the NRC until agreement state status is in effect]**.

§ 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 **[commencing] 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 **[34.52] 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 **[3] 5** years.

CHAPTER 226. LICENSES AND RADIATION SAFETY REQUIREMENTS FOR WELL LOGGING

PARTICLE ACCELERATORS

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, 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 shall be directed to the Department ~~and, for NRC licenses, to the NRC until agreement state status is in effect~~.

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 **[procedures]** 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 **[30] 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) Except as provided in subsection (d), a person may not operate a particle accelerator after October 3, 1998, without having obtained a license from the Department.

(d) A registrant possessing an accelerator before October 3, 1998, may continue to operate the accelerator provided an application for a license is filed in duplicate with the Department by October 4, 1999.

(e)] **(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.

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

[(g)] **(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, **[including] 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 **[4] 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:

* * * * *

[(5)] (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 **[shall include, but not be limited to,] 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 **[at least annually] 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) **[New equipment shall meet] 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) **[Existing equipment shall meet] 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 **[both X-ray therapy and electron therapy shall meet] 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 **[both stationary beam therapy and moving beam therapy shall meet] 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**.

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CHAPTER 230. PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

Subchapter A. SCOPE AND DEFINITIONS

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§ 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 shall be directed to the Department ~~**and, for NRC licenses, to the NRC until agreement state status is in effect**~~.

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

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§ 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 shall be directed to the Department ~~**and, for NRC licenses, to the NRC until agreement state status is in effect**~~.

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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) Subchapter F (relating to interim certification) specifies the requirements for persons certified under the Department's Interim Certification Program.

(g)] **(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 ~~all~~ **A** persons except **WHEN THE a** person **IS:**

(1) Testing for or mitigating against radon contamination in a building that the person owns or **[occupies] 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 ~~Department-approved~~ 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 **[certified] valid.**

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

(5) Purveying**[, but not placing, or retrieving passive radon testing devices, such as charcoal canisters or track etch monitors] secondary devices** supplied by a certified laboratory, if radon concentrations determined by the laboratory are **only** reported directly to the owner or **[occupier] 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 ~~who performs~~ 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.**

~~***ALARA—As low as reasonably achievable*—Making every reasonable effort to maintain exposures as far below the dose limits as is practical, taking into account economic considerations and other societal concerns.***~~

***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.**

~~***Blind study*—A study in which the certified person's device is exposed to a specific radon concentration that is unknown to the certified person.***~~

***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 person, other than an individual.] 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 ~~AC~~ 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 determining radon concentrations in air, water, soil or passive radon testing devices.] 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 **[listed]** in this definition.

[*Picocurie per liter*—2.2 disintegrations per minute of radioactive material per liter of air.]

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

Primary tester—A tester who reads or analyzes, or both, **[the continuous monitors or electrets, 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 ~~QC~~ 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 examining a building, soil, air or water for the presence of radon, including taking air, soil or water samples, or the act of diagnosing the cause of radon contamination in a building.] 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_] _Working level_—[One working level is that amount of potential alpha-particle energy dissipated in air by the short-lived daughters in equilibrium with 100 pCi/1 of Radon-222. One WL is equal to 130,000 Mev of alpha-particle energy deposited per liter of air.] 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. [Requirement] 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 **[or building lot]** in this Commonwealth**[,]** unless the person has first applied for and obtained certification **[to test] 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 ~~person~~ INDIVIUDAL certified to test] ~~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. [Not everyone within the firm is required to be certified to test. An individual performing testing and not working for a certified radon testing firm shall obtain radon testing certification prior to performing testing.]**

(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 **[passive radon monitors, such as charcoal canisters] secondary radon testing devices, such as AC**, from a certified radon laboratory does not also have to **[become] 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 **[done the following]**:

(1) **[Taken] Completed** a Department-approved course on radon.

(2) **[Taken and passed] 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 **[an official] a** copy of exam results to the Department.

[(3) Had 1 year of professional experience in performing radon measurements or equivalent as determined by the Department.

(4)] **(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. **[If the firm loses its certified individual, the certification automatically lapses and is void until the firm has notified the Department of employment of another certified individual. Within 5 days' the firm shall notify the Department in writing when it loses its certified individual. Each testing firm employee, after the first initial testing firm employee, will be charged a fee as set forth in Appendix A (relating to radon certification fee schedule).]**

(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) The firm's certified individual may not also be a testing firm employee.**~~

~~**(3)**~~ **(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 ~~5~~ 10 BUSINESS days of this change.

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

~~**(4) A testing firm may list a maximum of five testing firm employees at one time.**~~

~~**(5)**~~ **(3) Each testing firm employee shall conduct activities in accordance with the signed testing firm employee application.**

~~**(6)**~~ **(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) ~~Proof of passing a Department-approved radon measurement exam.~~ FOR FIRM EMPLOYEES HIRED AFTER _____ (*EDITOR'S NOTE:* THE BLANK REFERS TO THE EFFECTIVE DATE OF THIS FINAL RULEMAKING.), 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.

~~(iv)~~ (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).

~~(7)~~ (5) The firm's certified individual shall receive written approval from the Department ~~before~~ OF a testing firm employee ~~may conduct radon testing activities~~.

(6) FOR FIRM EMPLOYEES HIRED AFTER _____ (*EDITOR'S NOTE:* THE BLANK REFERS TO THE EFFECTIVE DATE OF THIS FINAL RULEMAKING.), 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)-(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 **[quality assurance program, a health and safety]** QA program and a continuing education program as **[required in §§ 240.304—240.307] 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 **[the EPA] a Department-approved** radon measurement proficiency program **[or equivalent, as required in §§ 240.304—240.307] 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 **[both] an** individual **[and] 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)**[, including the services offered and experience in each. If the applicant is a firm, the]. The** application must **[also]** 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~~ and, if the applicant is an individual, the applicant's date of birth~~. 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).

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

[(7)] (8) A verification by **[a responsible official of]** the applicant that the information contained in the application is correct to the best of the **[official's] 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 **[and any].**

(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. [Requirement] 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 **[or building lot]** 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** ~~**person]**~~ ~~**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. [Not everyone within the firm is required to be certified to mitigate. An individual performing mitigation and not working for a certified radon mitigation firm shall obtain radon mitigation certification 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 **[he has done the following] the individual has**:

(1) **[Taken] Completed** a Department-approved course on radon mitigation.

(2) **[Taken and passed] 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 **[an official] a** copy of exam results to the Department.

(3) Had 1 year professional experience **[or supervised 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. **[If the firm loses its certified individual, the certification automatically lapses and is void until the firm has notified the Department of employment of another certified individual. Within 5 days the firm shall notify the Department in writing when it loses its certified individual.]**

(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) The firm's certified individual may not also be a mitigation firm employee.**~~

~~**(3)**~~ **(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 ~~5~~ 10 BUSINESS days of this change.

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

~~**(4)**~~ **(3) The mitigation firm employee shall conduct activities in accordance with the signed mitigation firm employee application.**

~~**(5) A mitigation firm may list a maximum of five mitigation firm employees at one time.**~~

~~**(6)**~~ **(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) ~~Proof of passing a Department-approved course on radon mitigation or passing a Department-approved mitigation exam.~~ FOR FIRM EMPLOYEES HIRED AFTER _____ (*EDITOR'S NOTE:* THE BLANK REFERS TO THE EFFECTIVE DATE OF THIS FINAL RULEMAKING.), 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.

~~(7)~~ (5) The firm's certified individual shall receive written approval from the Department ~~before~~ OF a mitigation firm employee ~~may conduct radon mitigation activities.~~

(6) FOR FIRM EMPLOYEES HIRED AFTER _____ (*EDITOR'S NOTE:* THE BLANK REFERS TO THE EFFECTIVE DATE OF THIS FINAL RULEMAKING.), 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 **[both individual and] 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)**[, including the services offered and experience in each]. [If the applicant is a firm, the applicant shall also] 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**~~, and, if the applicant is an individual, the applicant's date of birth~~**. 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).

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

[(6)] (8) A verification by **[a responsible official of]** the applicant that the information contained in the application is correct to the best of the **[official's] 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) (RELATING TO PREREQUISITES FOR RADON MITIGATION 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 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. [Requirement] 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 **[he] 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 **[done the following]**:

(1) **[Taken] 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. **[If the firm loses its certified individual, the certification automatically lapses and is void until the firm has notified the Department of employment of another certified individual. Within 5 days the firm shall notify the Department in writing when it loses its certified individual.]**

(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) The firm's certified individual may not also be a laboratory firm employee.**~~

~~(3)~~ (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 ~~5~~ 10 BUSINESS days of this change.

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

~~(4)~~ (3) Activities of the laboratory firm employee shall be conducted in accordance with the signed laboratory firm employee application.

~~(5)~~ (4) Each laboratory firm employee applicant shall ~~submit a completed and signed laboratory firm employee application as provided by the Department.~~ ALL OF THE FOLLOWING:

(i) A COMPLETED AND SIGNED LABORATORY FIRM EMPLOYEE APPLICATION AS PROVIDED BY THE DEPARTMENT.

(ii) FOR FIRM EMPLOYEES HIRED AFTER _____ (*EDITOR'S NOTE:* THE BLANK REFERS TO THE EFFECTIVE DATE OF THIS FINAL RULEMAKING.), A DOCUMENT SIGNED BY THE CERTIFIED INDIVIDUAL THAT THE FIRM EMPLOYEE RECEIVED INITIAL TRAINING PURSUANT TO SUBSECTION (b)(6).

~~(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 _____ (*EDITOR'S NOTE:* THE BLANK REFERS TO THE EFFECTIVE DATE OF THIS FINAL RULEMAKING.), 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 **[quality assurance] QA** program and a continuing education program as **[required in §§ 240.304—240.307] 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 the EPA radon measurement proficiency program or equivalent, as required in §§ 240.304—240.307.] 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)**[, including the services offered and experience in each]. [If the applicant is a firm, the applicant shall also] 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~~ and, if the applicant is an individual, the applicant's date of birth~~. 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 **[a responsible official of]** the applicant that the information contained in the application is correct to the best of the **[official's] 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 **[and any].**

(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) **[The person has obtained] Obtains** certification to do so from a state with which the Department has entered into a reciprocal agreement.

(2) **[The person conducts] Conducts** that activity in this Commonwealth **[less] 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 **[at least]** 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 **[certificatin from] certification from the** foreign state.

(2) A nonrefundable fee **[of $200] as set forth in Appendix A (relating to radon certification fee schedule)**.

(3) The applicant's name, address**, [and]**~~,~~ telephone number~~ and, if the applicant is an individual, date of birth~~. 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 **[a responsible official of]** the applicant that the information contained in the application is correct to the best of the **[official's] 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~~who wishes to reapply for certification shall submit a new application along with the appropriate fee set forth in Appendix A (relating to radon certification fee schedule)~~.

(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 ~~wear prominently the Department-issued identification card while performing radon-related activities and~~ 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 **[certification]** 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 **[to] 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 **[other radon-related activity] 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 **[his] all** activities as described in the approved application.

(2) The certified person shall allow the Department, its agents and **[employes] 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 **[employes] 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 **[person shall continue to direct] individual shall remain in responsible charge of** the radon-related activities. The certified **[person] 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 ~~RPE~~ RELATIVE PERCENT ERROR of less than or equal to ±25% of the ~~RV~~ 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 **[shall] 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 **[certification]** 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 **[offered service or product, or the risks to health] 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 **[has previously obtained] 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. [Notice to clients] 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 **[a person who mitigates against radon] mitigators**, a written estimate for services shall constitute a price list. The notice **[shall] must** read substantially as follows:

NOTICE TO CLIENTS:

[The Radon Certification Act requires that anyone who provides any radon-related service or product to the general public must be certified by the Pennsylvania Department of Environmental Protection. You are entitled to evidence of certification from any person who provides such services or products. You are also entitled to a price list for services or products offered. All radon measurement data will be sent to the Department as required in the Act and will be kept confidential. If you have any questions, comments or complaints concerning persons who provide radon-related services, please contact the Department at the Bureau of Radiation Protection, Department of Environmental Protection, P.O. Box 8469, Harrisburg, Pa. 17105-8469, (717) 783-3594.]

Pennsylvania law requires that anyone who performs radon testing, mitigation or laboratory analysis activities ~~for the general public~~ 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.

[(a) Within 45 days after testing, mitigation or other radon-related service is provided, the person providing the service shall submit to the Department in a format approved by the Department the results of testing, including screening measurements, follow-up measurements, premitigation measurements, postmitigation measurements and the method used to mitigate against radon contamination. If no testing, mitigation or radon-related service has been provided during this 45-day period, that person shall inform the Department of same in writing. Anyone required to provide this 45-day reporting who does not report within 90 days of the completion of the activity will be subject to the Late 45-Day Reporting Fee as set forth in Appendix A (relating to radon certification fee schedule). At a minimum, these results will be retained for 2 years. The information must include:

(1) The name of the person providing the service.

(2) The name and address of the owner or occupant of the building involved.

(3) The address and location of the building involved, including street and number, post office, full zip code and county.

(4) The date each measurement was taken, or the mitigation performed.

(5) The type of house or building, the types of measurements, location within the building of specific measurements, and the results in picocuries per liter or in working levels.

(6) The type and price of mitigation system installed.

(b) Within 45 days after testing, mitigation or other radon-related service is provided, the person providing radon-related services shall report in writing to the owner or occupier of the building the results in picocuries per liter and when appropriate in working levels of radon measurements taken in the building. If a person provides the service through a certified intermediary, it is the responsibility of the intermediary to report the results.

(c) For a person performing mitigation, each building shall be tested for radon levels before and after the mitigation is performed. Each test must be at least 48 hours in duration and follow EPA- or DEP-approved protocols. The postmitigation test shall be conducted no sooner than 24 hours after completion of the mitigation. The results of radon testing shall be reported in accordance with this section.]

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 ~~of~~ 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 ~~secondary~~ CERTIFIED tester provides the service through a certified laboratory, it is the responsibility of the certified ~~individual~~ 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 ~~before and~~ after the mitigation is performed. Each test must be at least 48 hours in duration and follow Department-approved protocols IN~~,~~ § ~~240.308(c) (relating to radon mitigation standards) after system installation and~~ § 240.309 (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. [Quality assurance program] (Reserved).

[A person conducting radon testing or radon laboratory analysis activities shall have a quality assurance program to assure that measurements are accurate and errors are controlled. The program shall insure that testing devices are routinely and properly calibrated. The program shall provide the information related to 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) Quality assurance reports to management.]

§ 240.305. Health and safety program.

[A person conducting radon-related activities] A certified individual shall have a radon health and safety program to protect himself and **[employes] firm employees** from exposure to radon **[during the course of their employment] THAT, AT A MINIMUM, INCLUDES MINIMIZING ONE'S TIME IN THE BUILDING AND PROVIDING FRESH AIR INTAKE FROM OUTSIDE AIR, WHEN APPROPRIATE.** The program **[shall] must** include records of each **[individual's] mitigator's** exposure to radon **during the course of employment. [Persons conducting radon-related activities shall maintain exposure to radon as low as reasonably achievable.] 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 ~~shall maintain exposure to radon ALARA. A tester or mitigator~~ may not exceed 4 WLM/yr in radon exposure.**

§ 240.306. Continuing education program.

[A person conducting radon-related activities shall have a radon education program to assure that the applicant and all employees have a minimum of 4 hours initial training, and the certified person shall participate in a continuing education program consisting of a minimum of 8 hours of Department-approved courses or seminars on radon testing or mitigation each year. Course providers are required to submit course information as requested by the Department and the Course Provider Fee as set forth in Appendix A (relating to radon certification fee schedule) prior to Department approval of any course.] 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. ~~Continuing education credit hours may only be used for one certification period for each certification activity.~~

§ 240.307. [EPA Radon Measurement Proficiency Program] Radon measurement proficiency program.

[A person conducting radon testing or radon laboratory activities shall provide written evidence of successful participation in the most recent EPA Radon/Radon Progeny Measurement Proficiency Program or an alternative program approved by the Department for each radon measurement utilized.] 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. [Testing and mitigation protocols] 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.

~~(a)~~ (b) *Terminal discharge.* To prevent re-entrainment of radon, ~~fan~~ 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.

~~(1)~~ (2) The termination point must be vertical, upward, outside the structure and discharging to the atmosphere. A 45-DEGREE ELBOW IS PERMITTED. Rain caps ~~or terminal bends~~ may not be used.

~~**(2) For vent pipes attached to the side of a building, the termination point must be above the immediate edge of the roof.**~~

~~**(3) For vent pipes that penetrate the roof, the termination point must be at least 12 inches above the surface of the roof.**~~

~~(4)~~ (3) The termination point must be 10 feet or more above the ground level nearest to the point of discharge.

~~(5)~~ (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.

~~(6)~~ (5) The termination point must be AT LEAST ~~10~~ 5 feet ~~or more~~ horizontally from a vertical wall that extends above the roof OR HIGHER THAN THE VERTICAL WALL.

~~(7)~~ (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.

~~(b)~~ (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 ~~heated or cooled~~ 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.

~~(c)~~ (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) ~~Openings or cracks in the foundation or at expansion~~ EXPANSION or control ~~joint~~ 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, ~~or that openings or cracks are inaccessible,~~ then the mitigator may leave those areas unsealed and shall provide the following written statements to the homeowner:

(i) This technique may contribute to ~~an~~ increased heating and cooling ~~penalty~~ COSTS.

(ii) This technique may ~~decrease the effieiency~~ REDUCE THE EFFECTIVENESS of the radon mitigation system.

(iii) This technique may increase the potential for backdrafting natural draft combustion appliances.

~~(d)~~ (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 ~~mitigator~~ 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."

~~(e)~~ (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 completed copy of the Radon Mitigation Project Record FORM from PROVIDED BY THE DEPARTMENT "Pennsylvania Radon Mitigation Standards," 294-2309-002, October 1, 1997, Appendix A, OR EQUIVALENT.~~

~~(2)~~ (1) A copy of contracts and warranties for the mitigation system.

~~(3)~~ (2) A description of the installed mitigation system and its basic operating principles.

~~(4)~~ (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.

~~(5)~~ (4) A list of appropriate actions for the client to take if the system failure warning device indicates system degradation or failure.

~~(6)~~ (5) **A recommendation to retest at least every 2 years.**

~~(7)~~ (6) **A recommendation to have an electrical inspection performed on the applicable components of the installed system.**

~~(f)~~ (g) *Compliance.* A person conducting radon **[testing or mitigation for radon contamination] mitigation activities** shall conduct the **[testing and]** mitigation in accordance with **[EPA- or DEP-approved protocols] 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 ~~sources~~**SOURCE**:

~~Environmental Protection Agency~~
~~Office of Radiation Programs~~
~~Washington, D.C. 20460~~

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

§ ~~240.309~~ 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 ~~sustained~~ 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~~ and shall be documented~~.

(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) ~~Testing devices shall be secured against movement by employing anti-tampering methods~~ 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 ~~at every building entry~~ 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 ~~MSMF-2010~~ 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.

~~(8)~~ (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.

~~(9)~~ (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.

~~(10)~~ (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 ~~working~~ 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 ~~severe weather conditions~~ 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 Citizen's Guide to Radon."

(2) A laboratory shall use a Department-approved Result Report Form. Laboratories shall provide the client with a completed Result Report Form within 10 ~~working~~ 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 Citizen's Guide to Radon."

Subchapter E. ENFORCEMENT AND DECERTIFICATION

§ 240.401. Inspection.

(a) The Department and its agents and **[employes] employees** will:

* * * * *

(b) The Department, its agents and **[employes] 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 **[employe] 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. [INTERIM CERTIFICATION] (Reserved)

§ 240.501. [Scope] (Reserved).

[This subchapter applies to persons certified in accordance with the Department's interim certification program as required under section 11 of the act (63 P.S. § 2011).]

§ 240.502. [Reapplication when this chapter is adopted as final] (Reserved).

[A person granted interim certification by the Department shall reapply for certification under this chapter. If a person fails to apply for certification within 60 days of Departmental notification, the interim certification automatically lapses and is void.]

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 activity is 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 radioactive 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 ~~radioactive~~ 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 radioactive 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 ~~radioactive~~ check source.

(i) A CWLM without radioactive 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 electret chamber serial number.**~~

~~**(iii)**~~ **(ii) The initial voltage reading.**

~~**(iv)**~~ **(iii) The final voltage reading.**

~~**(v)**~~ **(iv) The exposure dates and times.**

~~**(vi)**~~ **(v) The test result.**

~~**(vii)**~~ **(vi) The serial number of duplicate electret.**

~~**(viii)**~~ **(vii) The RPD value.**

~~**(ix)**~~ **(viii) The address of the building tested.**

~~**(x)**~~ **(ix) The test location in the building.**

~~**(xi)**~~ **(x) The name of the tester who placed the electret.**

~~**(xii)**~~ **(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) The control and warning levels identified in subparagraph (iii) shall be adjusted when the RPE of at least 20 spike results has been calculated. The standard deviation of the 20 or more RPE values shall also be calculated and the warning and control limits shall be re-established on new control charts.**~~

~~(v)~~ (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.

~~(vi)~~ (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 electret chamber serial numbers.**~~

~~(D)~~ (C) The RV from radon chamber.

~~(E)~~ (D) The measured spike value or values.

~~(F)~~ (E) The individual RPE results.

~~(G)~~ (F) The certification year beginning date and end date.

~~(H)~~ (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) *Electret voltage drift.* The tester shall maintain documentation that electret voltage drift testing has been performed as follows:**~~

~~(i) For each new shipment of 20 electrets or fewer, a minimum of 1 electret shall be set aside from each new shipment and evaluated for voltage drift.~~

~~(ii) For each new shipment of more than 20 electrets, a minimum of 5% of the electrets or 10 electrets, whichever number is smaller, shall be evaluated for voltage drift.~~

~~(iii) Electrets shall be covered with protective caps in a low-radon environment.~~

~~(iv) For short-term and long-term electrets, an initial and a final voltage reading shall be made.~~

~~(A) For short-term electrets the final voltage reading shall be made at 4 weeks.~~

~~(B) For long-term electrets the final voltage reading shall be made at 3 months.~~

~~(v) If the short-term voltage loss is greater than 6 volts per month or if the long-term voltage loss is greater than 12 volts over a 3-month period, testing with this shipment may not occur until the voltage loss is corrected.~~

~~(vi) Documentation of electret voltage drift must include all of the following:~~

~~(A) Whether it is a short-term or long-term electret.~~

~~(B) The date of receipt of the new shipment.~~

~~(C) The electret serial number.~~

~~(D) Initial voltages and dates.~~

~~(E) Final voltages and dates.~~

~~(F) The reader serial number.~~

~~(G) Corrective actions performed.~~

~~(6)~~ (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 radioactive 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 ~~radioactive~~ 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 radioactive 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 ~~radioactive~~ check source.

(i) A CWLM without radioactive 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 electret chamber serial number.**~~

~~**(iii)**~~ **(ii) The initial voltage reading.**

~~**(iv)**~~ **(iii) The final voltage reading.**

~~**(v)**~~ **(iv) The exposure dates and times.**

~~**(vi)**~~ **(v) The test results.**

~~**(vii)**~~ **(vi) The serial number of duplicate electret.**

~~**(viii)**~~ **(vii) The RPD value.**

~~**(ix)**~~ **(viii) The address of the building tested.**

~~**(x)**~~ **(ix) The test location in the building.**

~~**(xi)**~~ **(x) The name of the tester who placed the electret.**

~~**(xii)**~~ **(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) The control and warning levels identified in subparagraph (iii) shall be adjusted when the RPE of at least 20 spike results have been calculated. The standard deviation of the 20 or more RPE values shall also be calculated and the warning and control limits shall be re-established on new control charts.~~

~~(v)~~ (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.

~~(vi)~~ (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 electret chamber serial numbers.~~

~~(D)~~ (C) The RV from radon chamber.

~~(E)~~ (D) The measured spike value or values.

~~(F)~~ (E) The individual RPE results.

~~(G)~~ (F) The certification year beginning date and end date.

~~(H)~~ (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) The control and warning levels identified in subparagraph (iii) shall be adjusted when the RPE of at least 20 spike results has been calculated. The standard deviation of the 20 or more RPE values shall also be calculated and the warning and control limits shall be re-established on new control charts.**~~

~~**(v)**~~ **(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.**

~~**(vi)**~~ **(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) The control and warning levels identified in subparagraph (iii) shall be adjusted when the RPE of at least 20 spike results has been calculated. The standard deviation of the 20 or more RPE values shall also be calculated and the warning and control limits shall be re-established on new control charts.**~~

~~(v)~~ (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.

~~(vi)~~ (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.

~~**(5) *Electret voltage drift.***~~

~~**(i) For shipments of 20 electrets or fewer, a minimum of 1 electret shall be set aside from each new shipment and evaluated for voltage drift.**~~

~~**(ii) For shipments of more than 20 electrets, a minimum of 5% of the electrets or 10 electrets, whichever number is smaller, shall be evaluated for voltage drift.**~~

~~**(iii) Electrets shall be covered with protective caps in a low radon environment.**~~

~~**(iv) For short term and long term electrets, an initial and a final voltage reading shall be made.**~~

~~**(A) For short term electrets the final voltage reading shall be made at 4 weeks.**~~

~~(B) For long-term electrets the final voltage reading shall be made at 3 months.~~

~~(v) If the short-term voltage loss is greater than 6 volts per month or if the long-term voltage loss is greater than 12 volts over a 3-month period, testing with this shipment may not occur until the voltage loss is corrected.~~

~~(vi) Documentation of electret voltage drift must include all of the following:~~

~~(A) Whether it is a short-term or long-term electret.~~

~~(B) The date of receipt of the new shipment.~~

~~(C) The electret serial number.~~

~~(D) Initial voltages and dates.~~

~~(E) Final voltages and dates.~~

~~(F) The reader serial number.~~

~~(G) Corrective actions performed.~~

(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) The control and warning levels identified in subparagraph (iii) shall be adjusted when the RPE of at least 20 spike results has been calculated. The standard deviation of the 20 or more RPE values shall also be calculated and the warning and control limits shall be re-established on new control charts.**~~

~~**(v)**~~ **(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.**

~~**(vi)**~~ **(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) The control and warning levels identified in subparagraph (iii) shall be adjusted when the RPE of at least 20 spike results has been calculated. The standard deviation of the 20 or more RPE values shall also be calculated and the warning and control limits shall be re-established on new control charts.**~~

~~(v)~~ (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.

~~(vi)~~ (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%.

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(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 the 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)

pennsylvania
DEPARTMENT OF ENVIRONMENTAL PROTECTION

Bureau of Radiation Protection

COMMENT AND RESPONSE DOCUMENT

RADIOLOGICAL HEALTH

25 Pa. Code Chapters 215-221, 223, 225, 227, 228, 230 and 240
47 Pa.B. 2722 (October 18, 2016)
Environmental Quality Board Regulation #7-499
(Independent Regulatory Review Commission #3169)

On May 13, 2017, the Environmental Quality Board (Board, EQB) published a notice of public comment period for a proposed rulemaking concerning revisions to 25 Pa. Code Chapters 215-221, 223, 225, 227, 228, 230 and 240.

The amendments to Chapters 215-221, 223, 225, 227, 228, and 230 were proposed to establish and maintain adequate radiation protection standards and oversight due to significant technological advances in the use of radiation sources and were based on standards set by recognized accrediting bodies and national organizations, such as the National Council on Radiation Protection and Measurements (NCRP) and the Conference of Radiation Control Program Directors (CRCPD).

The amendments to Chapter 240 were proposed to revise the radon certification application requirements and the reporting requirements for certified radon service providers to add clarity to both processes. Additionally, the amendments to the testing and mitigation protocol requirements and the quality assurance and quality control requirements were proposed to provide greater detail regarding how these programs should be designed and what goals they should accomplish.

Public Comment Period and Public Hearings

Notice of the public comment period on the proposed radiological health amendments was published in the *Pennsylvania Bulletin* on May 13, 2017 (47 Pa.B. 2722). The EQB's public comment period opened on May 13, 2017, and closed on June 26, 2017.

This document summarizes the comments received during the Board's public comment period as well as the comments submitted by the Independent Regulatory Review Commission (IRRC). Each comment is listed with an identifying number for each commentator that made the comment. A list of the commentators, including name and affiliation (if any) can be found on pages 3–5 of this document. The House and Senate Environmental Resources and Energy Committees did not submit comments on the proposal.

Copies of all comments received by the Board are posted on the IRRC website at http://www.irrc.state.pa.us (search by Regulation # 7-499 or IRRC #3169); and on the e-Comment page of the Department of Environmental Protection's website at http://www.dep.pa.gov.

Table of Commentators for the Environmental Quality Board
Proposed Rulemaking for
Radiological Health
Environmental Quality Board # 7-499
(IRRC # 3169)

ID	Name/Address
1.	Paul Houle University Educational Svcs., Inc. 229 Rock Ridge Rd. Mt. Pocono, PA 18344
2.	A. LaMastra A.B.E. Radiation Measurements Laboratory P.O. Box 214 Lenhartsville, PA 19534
3.	Kendall Berry Fox Chase Cancer Center 333 Cottman Ave. Philadelphia, PA 19111
4.	John Keklak Thomas Jefferson University 919 Walnut St., Ste 820 Philadelphia, PA 19107
5.	Michael Sheetz University of Pittsburgh 3500 Fifth Ave., Suite 400 Pittsburgh, PA 15213
6.	Aaron L. Fisher President, SWAT Environmental of Pennsylvania 201 Penn Center Blvd., Suite 400 Pittsburgh, PA 15235
7.	Jay F. Bauder Bauder Basement System, Inc./ARRST National Board 110 South Line Rd. Ephrata, PA 17522
8.	Janice Wirth 4439 Frame Dr. Pittsburgh, PA 15239

9.	John Niemkiewicz 1240 S. Cedar Crest Blvd. Schnecksville, PA 18078
10.	Eric Gingold Thomas Jefferson University 132 S. 10th St. Philadelphia, PA 19107
11.	Bill Brodhead WPB Enterprises, Inc. 2844 Slifer Valley Rd. Riegelsville, PA 18077
12.	Nathaniel Lim Avid Radiopharmaceuticals 3711 Market St., Ste. 710 Philadelphia, PA 19104
13.	Bruce Thomas Certified Radon Tester #1478 17 Fosterville Rd. Greensburg, PA 15601
14.	Richard J. Martin, JD American Association of Physicists in Medicine 1631 Prince St. Alexandria, VA 22314
15.	Glen Naekel Lehigh Valley Health Network 1200 S. Cedar Crest Blvd. Allentown, PA 18103
16.	Nancy Bredhoff Radon Testing Corporation of America, Inc. 2 Hayes St. Elmsford, NY 10523
17.	Xiaoqian Wen Christiana Care Health System 4755 Ogletown-Stanton Rd. Newark, DE 19718
18.	Shawn Price Accustar Labs 929 Mount Zion Rd. Lebanon, PA 17046
19.	Celia Rajkovich #1 Radon Tester, LLC 122 West 5th Ave. Derry, PA 15627

20.	Nathaniel Burden PA AARST President 2221B Pileggi Rd. Warrington, PA 18976
21.	Susan Wertz Pennsylvania Society for RT's 325 Bristol Ln. Hollidaysburg, PA 16648
22.	Margaret Blackwood, MS, DABR Allegheny Health Network 320 East North Ave. AGH 18th Fl., South Tower Pittsburgh, PA 15212
23.	John Mallon Owner, Radon Detection and Control 4027 Jordan St. PO Box 419 South Heights, PA 15081
24.	David Sumner Independent Regulatory Review Commission (IRRC) 333 Market Street 14th Floor Harrisburg, PA 17101

Acronyms used in this Comment/Response Document

AAPM – American Association of Physicists in Medicine
AARST – American Association of Radon Scientists and Technologists
ABR MOC – American Board of Radiology Maintenance of Certification Program
AC – Activated charcoal
ACR – American College of Radiology
ALARA – As Low As Reasonably Achievable
ANSI – American National Standards Institute
ARRT – American Registry of Radiologic Technologists
ASRT – American Society of Radiologic Technologists
AT – Alpha track
BRP – Bureau of Radiation Protection
CBCT – Cone beam computed tomography
CFR – Code of Federal Regulations
CMS – Centers for Medicare & Medicaid Services
CNR – Contrast to noise ratio
CR – Computed radiography
CRCPD – Conference of Radiation Control Program Directors
CT – Computed Tomography
CTDI – Computed tomography dose index
DAP – Dose area product
DDR – Direct digital radiography
DEP – Department of Environmental Protection
DOH – Department of Health
DR – Digital radiography
DRL – Diagnostic reference level
EI – Exposure index
ENT – Ears, nose and throat
EPA – U.S. Environmental Protection Agency
EQB – Environmental Quality Board
FDA – Food and Drug Administration
FGI – Fluoroscopic-guided interventional
Gy – Gray
HIC – Home improvement contractor
IRP – Interventional Reference Point
IRRC – Independent Regulatory Review Commission
KAP – Kerma air product
kVp – Peak kilovoltage
LS – Liquid scintillation
mA – Multiples of Ampere
MSAD – Multiple scan average dose
NCRP – National Council on Radiation Protection and Measurements
NMTCB – Nuclear Medicine Technology Certification Board

NRC – U.S. Nuclear Regulatory Commission
NRPP – National Radon Proficiency Program
NRSB – National Radon Safety Board
OSHA – Occupational Safety and Health Administration
PA – Physician's Assistant
PET – Positron emission tomography
PSD – Peak Skin Dose
QA – Quality assurance
QC – Quality Control
QE – Qualified expert
QMP – Qualified Medical Physicist
Rad – Radiation Absorbed Dose
RAF – Regulatory Analysis Form
REX – Radiation exposure
RMS – Radon Mitigation Standards
RPA – Radiation Protection Act, Act 147 of 1984
RPAC – Radiation Protection Advisory Committee
RPD – Relative percent difference
RPE – Relative percent error
RRA – Regulatory Review Act
RRNC – Radon resistant new construction
RV – Reference level
SI – International System of Units
SIRG – State indoor radon grant
SNR – Signal to noise ratio
SPECT – Single photon emission computed tomography
TJC – The Joint Commission
WLM – Working level month

COMMENTS AND RESPONSES

General Comments

1. **Comment:** Regulations normally have an effective date of so many days following publication to allow the affected community time to make changes. Why is this effective upon publishing? Does that mean the DEP has no intention of changing its proposed regulations? That appears to be making a joke of the whole process of publishing proposed regulations for comment. (2)

   Response: The effective date refers to the final-form rulemaking and is independent from consideration of public comments and incorporation of revisions to the proposed rule. The review process can take up to two years before a regulation is finalized. However, the Department agrees that additional time after the final-form rulemaking is published is warranted for regulated entities and has therefore designated the effective date as 90 days following publication of the final-form rulemaking in the *Pennsylvania Bulletin*.

2. **Comment:** Gender neutral language should be used throughout these regulations. (22)

   Response: According to the Commonwealth's rules of statutory construction, words used in the masculine gender include the feminine and neuter. *See* 1 Pa.C.S. § 1902.

3. **Comment:** All deadlines should be delineated as working or business days. (7, 16, 20, 23)

   Response: The Department agrees and has changed all deadlines throughout the final-form rulemaking to read "business" days.

4. **Comment:** Chapter 215. How does this apply to a radon mitigator? (7)

   Response: Chapter 215 does not apply to a radon mitigator. Chapter 215 applies to radioactive materials.

Chapter 219

5. **Comment:** Re § 219.3. Definitions. "Medical reportable event for radiation-producing diagnostic or interventional X-ray procedures." Subsection (iii) currently reads "(iii) A dose to the wrong patient or wrong site for the entire procedure and exceeding 0.5 Gy (50 rad) to any organ." As worded, a 'wrong patient' dose would have to be delivered over an entire procedure AND exceed 0.5 Gy to an organ in order to meet the criteria. I do not believe the intent was to necessitate that a wrong patient dose would have to be delivered over the entire procedure. Also, the dose criteria would seem to make the phrase "over an entire procedure" unnecessary. I suggest the following wording (in its entirety): "A dose to the wrong patient or unintended site and exceeding 0.5 Gy (50 rad) to any organ." (At the very least, a comma should follow "patient" and a second comma should follow "procedure.") (4)

Response: The Department acknowledges the comment. Commas have been added in the final-form rulemaking after "patient" and "procedure" as suggested by the commentator.

6. **Comment:** § 219.3 Definitions – Medical reportable event for radiation-producing diagnostic or interventional X-ray procedures, (i), (ii), and (iii) – The intent of the regulation as currently written is not clear and there is no apparent advantage to this reporting requirement. I suggest following hospital accreditation standards and using wording similar to this: "(i) Prolonged fluoroscopy with cumulative (over the previous 6 months) dose greater than 15 Gy (1500 rads) to a single field." (3)

   The 3 Gy dose threshold is too low as it likely would not even be noticed by the patient, and will not result in any severe or permanent skin damage. (5, 15, 22)

   The definition for "unintended dose" does not appear in regulations until § 221.2 Definitions. I recommend that the definition should be contained within Chapter 219. (15)

   The term "unintended" is subjective and will result in varying interpretations and inconsistent reporting. There are no established "dose" protocols in high-risk FGI procedures to use as a reference as there are in radiation oncology. (5, 22)

   The commentators recommend using the Joint Commission Sentinel Event threshold of 15 Gy PSD. If 15 Gy peak skin dose (PSD) is reached there is a root cause investigation conducted without any regard to whether the dose was "unintended" or not. This will remove any opinion-based interpretation of the regulation and the state would learn about all events >15Gy. This is a dose where significant skin effects are expected; however, skin effects are not frequently observed with fluoroscopic cases even at these doses. (3, 5)

   Response: The Department's intent is to stress the importance of good quality assurance during diagnostic and interventional X-ray procedures. The proposed 3 Gy limit is recommended by NCRP as an appropriate substantial radiation dose limit. However, the Department has taken the concerns of the commentators under consideration and agrees that a 15 Gy limit is acceptable and still maintains the importance of a good quality assurance program. The 3 Gy limit has been changed to 15 Gy in the final-form rulemaking. Because the definition of "unintended dose" addresses diagnostic or interventional X-ray, it is more appropriately placed in Chapter 221 (relating to x-rays in the healing arts).

7. **Comment:** § 219.3. Definitions. – Medical reportable event for radiation-producing machine therapy – If the intent of the regulations in this chapter is to monitor and ensure the safety of the public who are having radiation therapy treatments, I believe the appropriate events to report are those that have clinical significance. The proposed changes create confusion because they are redundant and poorly written. The current (i) should stay as is. The wrong treatment site is covered in (ii), and using a treatment delivery intended for another individual is also covered in (ii). The new (ii)(B) omits the reference to fractionated treatment (to which it applies) making it less clear. The phrases "from the prescribed dose" and "from the

intended prescribed dose" are use twice in the same sentence and should not be. I propose the following:

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.
(ii) An administration of a **therapeutic dose identified in a written directive that differs from the intended prescribed dose for the treatment site, or for any other organ, by one of the following:**
(A) More than 20% of the prescribed total dose.
(B) More than 30% of the prescribed weekly dose of a multi-fraction plan.
(C) More than 50% of the prescribed single-fraction dose of a multi-fraction plan.

I believe this would adequately cover clinically significant events, and would be significantly easier to properly interpret compared to the proposed changes. (9)

I believe that the administration of a therapeutic radiation dose to the wrong individual and using a treatment delivery intended for another individual are essentially the same thing. No treatment can be delivered without a treatment plan. If the treatment is delivered to the wrong individual, the treatment must be intended for a different individual. (17)

Response: The Proposed definition was the result of many discussions with members of the Radiation Protection Advisory Committee (RPAC). It does not differ significantly from the suggested comment. No change to this definition has been made in the final-form rulemaking.

8. **Comment:** Re § 219.229. "Other medical reports". Subsection "(b)" reads: "Upon discovery of a medical event, the registrant or licensee shall...". I believe that the word "reportable" needs to be inserted between "medical" and "event", since "medical event" is not defined relevant to the type of event intended to be reported. (4)

Response: The Department agrees with the comment and has changed the term to "medical reportable event" in the final-form rulemaking. This change also creates consistency with the definitions in § 219.3.

9. **Comment:** § 219.229 (a) and (b) – Part (a) requires actions to be completed within 30 days while Part (b) requires some elements of these same actions to be completed in 1 or 15 business days. The two Parts are not consistent. (5)

§ 219.229 (b)(2) and (3) - Due to the difficulties of determining patient exposures, I would request the times for providing the written report to PA DEP and the clinical summary to the

prescribing physician and patient be extended from the 15 days currently in the proposed regulation to 30 days. (22)

Response: The 30-day requirement in 219.229(a) refers to the fact that it may take up to 30 days from the date of the procedure to determine if damage has occurred to a patient. However, when that determination is made the registrant is required to report to the Department within 1 day followed by a written report within 15 days. The 1-day and 15-day requirements are consistent with 10 C.F.R. 35.3045. Therefore, no change has been made in the final-form rulemaking.

Chapter 221

10. **Comment:** Chapter 221 – No requirements for ongoing Qualified Medical Physicist (QMP) evaluations of radiographic equipment, only for fluoroscopic and computed tomography (CT) systems. Was this an oversight or intentional? (15)

    Response: This was not an oversight. The Department only added additional requirements regarding fluoroscopic and computed tomography systems primarily due to harmful events that have occurred throughout the nation involving these devices.

11. **Comment:** § 221.2. Definitions. "High-risk procedure - Any radiologic procedure that utilizes energies of less than 1 million electron volts that could exceed skin doses of 200 rads." SI units should be used here for consistency – 2 Gy (200 rads). (3)

    Response: The Department agrees that SI units should be used for consistency. The Department has added the units in parenthesis following the common roentgen units in the final-form rulemaking.

    High-risk procedure – Any radiologic procedure that utilizes energies of less than 1 million electron volts that could exceed skin doses of 200 rads. The wording should be changed to read "that could likely exceed skin doses..." (5)

    Response: The Department's intent is to provide a specific quantity for this definition. To add the word "likely" would imply that it would probably happen. Therefore, no change has been made.

12. **Comment:** As currently proposed in § 221.2, the definition of QMP provides three alternative pathways to be considered a "Qualified Medical Physicist." The American Association of Physicists in Medicine (AAPM) believes that the pathways as proposed are insufficient to assure that individuals providing the designated medical physics services are qualified to do so. This is especially true given the complexity of modern X-ray equipment, including CT. The AAPM recommends that PA EQB consider adopting AAPM's definition as stated in AAPM's Professional Policy Statement[2] or the definition of QMP from the Conference of Radiation Control Program Directors (CRCPD) Suggested State Regulations for Control of Radiation (CRCPD SSRCR), Part F, Sec. F.2, p. 11[3].

The AAPM is particularly concerned by the alternate pathways to QMP status presented in paragraphs ii and iii of the § 221.2 Definition of QMP. The pathway in (ii) allows an individual to practice as a QMP without obtaining a board certification or working through an accredited residency program. We do not believe that working under the supervision of a QMP for three years provides the equivalent of education and training represented by board certification. Moreover, there are great variations in practice environments that may limit the structure, consistency and sufficiency of on-the-job training received under the supervision of a QMP for three years. The AAPM recommends designating individuals who meet the education and training requirements in (ii) as "Qualified Experts" (QE) rather than QMPs. This would allow the QE to provide clinical services as specified by the PA EQB.

The pathway in (iii) allows an individual to practice as a QMP without board certification. We believe this requirement should not be side-stepped, and we recommend that individuals meeting the requirements of (iii) also be designated as QEs. This would allow those individuals who are currently providing clinical services to continue to serve in their current roles, without any disruption caused by rule implementation.

The AAPM believes that for the benefit of patient, worker and general public safety it is essential that "QMP" be uniformly defined. The certification requirement and the training and experience necessary to obtain and maintain board certification serve to improve patient safety by ensuring only qualified individuals perform essential services within the scope of clinical medical physics practice. Accordingly, this distinction should be recognized by limiting the QMP designation to only those who are board certified. (14)

Response: AAPM's definition is a restricted definition. The Department believes the individuals providing the medical physics services are already qualified to do so. The Department solicited advice from the RPAC and other reputable organizations in determining appropriate qualifications. It would not be reasonable to say the individuals already performing these services are not qualified to do so. Therefore, the proposed definition has not been changed in the final-form rulemaking and will allow equivalent qualifications.

13. **Comment:** § 221.2. Definitions. – CR- computed radiography, DDR- direct digital radiography and DR-digital radiography. It seems these definitions are describing the digital receptor technologies as well as the final radiographic image using the same terminology. According to nationally accepted medical physics standards, DDR detectors are a subset of all digital detectors. The DDR definition in the regulations describes both indirect and direct digital detectors while both direct and indirect as well as photostimuable phosphors found in CR systems produce "digital images." Our recommendation is to eliminate the terms CR and DDR in the definition and in the following regulations, and use CR detector systems and DR detector systems with digital radiography images instead of digital radiography, as alternatives. (22)

Response: The general terms for CR and DR are widely used in the industry and are familiar terms in radiology. Substituting "CR detector systems" would still require a definition for CR, that is, "a digital X-ray imaging method" as defined in the proposed

rulemaking. Likewise, DR and DDR are believed to be appropriately defined. Therefore, no changes have been made in the final-form rulemaking.

14. **Comment:** § 221.2. Definitions. – FGI-Fluoroscopic-guided interventional procedures. This definition should be expanded to include the differentiation between low-risk and high-risk procedures within this definition. The primary rationale for this request is that later in the regulations there are requirements for FGI equipment without reference to patient risk categorization, and these proposed changes are not appropriate for low-risk FGI.

    Although "high-risk procedure" is defined later in the definitions as any radiological procedure that can exceed 200 rads of potential skin dose, this definition does not agree with nationally recognized standards and is unnecessarily broad. NCRP Report 168 defines "potentially-high radiation dose procedure" as a procedure in which more than 5% of procedures result in greater than 3 Gy (300 rad) air kerma skin dose. Although all fluoroscopic equipment, including that used for FGI procedures, can theoretically deliver patient PSD of 3 Gy or higher, it is the type of procedure and not the equipment which determines the low or high-risk procedure definition. The "high-risk" definition should be 3 Gy, not 2. (22)

    Response: The 2 Gy criteria is a referenced benchmark in the industry and is considered the threshold dose for early transient erythema. It is also referenced in existing § 219.8 (relating to requirement for a radiation safety committee). For these reasons, the suggested change regarding the 2 Gy criteria was not made. The Department agrees, however, that the definition of FGI should include a differentiation between low-risk and high-risk procedures. The Department discussed this issue with the RPAC and amended the definition of FGI in this final-form rulemaking to only include high-risk fluoroscopic-guided interventional procedures

15. **Comment:** § 221.2. Definitions. – Image Intensifier. This definition should be expanded to include flat-panel digital fluoro detectors, in response to current technology. (22)

    Response: The Department believes expanding the definition of "image intensifier" is unnecessary because it includes the term "an image receptor," which is also defined in § 221.2 and includes flat-panel digital fluoro detectors. Therefore, no changes have been made in the final-form rulemaking.

16. **Comment:** § 221.2. Definitions. – QE. Why is QE defined in § 215.2 and how does it differ from QMP? Clarify or combine them and have both in one chapter. (22)

    Response: The QE definition in § 215.2 is intended for both medical and non-medical operations, whereas the proposed QMP definition is in Chapter 221 (relating to x-rays in the healing arts). The QMP requires additional qualifications due to operations of medical devices that are "high-risk." These devices are included in Chapter 221. No changes have been made.

17. **Comment:** I am not confident that CT fits the definition of "high-risk" as defined by the Department: "High-risk procedure – Any radiologic procedure that utilizes energies of less than 1 million electron volts that could exceed skin doses of 200 rads." If CT does not qualify as high-risk, this would further exempt technologists from being required to achieve advanced CT certification. Does CT qualify as high-risk? (8)

    Response: CT can range in a vast number of modalities. Some modalities may not be classified as "high-risk," such as simulation procedures; however, others may be "high-risk," for example, brain perfusion. No changes have been made in the final-form rulemaking.

18. **Comment:** § 221.11. Registrant responsibilities. § 221.11(l) – Quality assurance program – eliminate "For CT, each study shall be checked. If an artifact is present, the registrant shall take corrective action as appropriate." This is redundant in that the Quality Assurance (QA) program includes "image quality and artifacts" and QA programs should provide a review process for all X-ray modalities, including CT. (22)

    Response: The Department has retained this statement in the final-form rulemaking to stress the importance of this quality assurance check.

19. **Comment:** § 221.11. Registrant responsibilities. § 221.11(n) – What is the purpose for inclusion since this requirement is addressed in § 219.229? (22)

    Response: The purpose of the registrant responsibilities section is to outline administrative controls necessary for appropriate operations. Numerous subsections of § 221.11 are referenced elsewhere in the regulations for ease in following the regulations.

20. **Comment:** § 221.11(c) – References protocol information in the vicinity of the control panel. Since most modern X-ray control panels allow for storage of techniques, the commentators suggest referencing an allowance for the electronic storage of pre-programmed techniques. (15, 22)

    Response: The Department agrees that the newer control panels allow protocols to be displayed electronically and confirms that electronic storage of protocols complies with the regulation. No changes have been made in the final-form rulemaking because there are numerous older models in use that still print protocols and post them near the control panel.

21. **Comment:** § 221.11(l) – It is not clear what type if any documentation is required for daily ongoing evaluation of CT systems for artifacts. (15)

    Response: A good QA program will provide appropriate guidelines regarding documentation. Artifacts can degrade the quality of a CT image. Modern scanners minimize some types of artifacts, and can partially be corrected by the scanner software. However, there are many instances in which careful patient positioning and

the optimum selection of scan parameters are the most important factors in avoiding image artifacts. These are a few examples of how the registrant can take corrective actions.

22. **Comment:** On the required training and competency as it relates to operators of CT Scanners in §§ 221.11, 221.16 and 221.205 – It is my understanding that the Department's intent is to require CT Technologists have advanced certification in CT. If that's accurate, I am not certain the regulations make a case for the need nor do they establish a timeline for compliance.

    As written, I do not see where these regulations support the argument which requires advanced certification ARRT(R)(CT). The sections discuss "...certification or registration in the applicable specialty by a professional organization recognized by the Department." In my opinion, the "applicable specialty" is radiography (as opposed to other healthcare specialties; nursing, respiratory, medical assistant, etc.). As written, ARRT (R), or equivalent, should satisfy that requirement and the Department could choose to recognize those credentials.

    The Joint Commission has rescinded its earlier proposal requiring CT certification for technologists by January 1, 2018 (see attached). Likewise, the American College of Radiology (ACR) does not require CT Certified Technologists in order to obtain CT accreditation.

    It is my experience that hospitals accept ARRT (R), or equivalent, couple with CT experience/training as minimum hiring qualifications for CT Technologists. Some hospitals may expand that by requiring achievement of ARRT (CT) within an established timeframe, while some hospitals may require it upon hire. Surely, availability of technologists contributes to each hospital's hiring criteria. Hospitals recruit technologists from resources within their market; smaller or rural hospitals may be placed at a distinct disadvantage placing access to CT services at risk. Is the intent of the regulations governing training and competency to require CT Technologists to hold advanced CT certification? (8)

    Response: During the initial development of the proposed rulemaking, the Department agreed with The Joint Commission's stance on CT certification. The Department now realizes the concerns presented to The Joint Commission and the reasoning for the Joint Commission's rescission. Thus, the Department will accept individuals having the applicable specialty in radiography, such as ARRT(R) or equivalent, to perform CT procedures, if the procedure is considered low-risk, as defined in § 221.2. CT procedures that are considered high-risk, for example, brain perfusion studies, will require a subspecialty in CT, such as ARRT(R)(CT) Section 221.11 has been revised as follows: "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."

23. **Comment:** In § 221.16 – Regarding the word "privileged" – "...registered or credentialed and privileged in the applicable specialty by a professional organization recognized by the

Department." Privileging is a process conducted and granted by the institution, not a professional organization. Privileging may be based on professional credentials, but can vary among institutions. (8)

Response: The proposed language "registered or credentialed and privileged" was used to prevent disqualification of appropriately qualified individuals who have been granted privileges by an institution and is retained in the final-form rulemaking.

24. **Comment:** § 221.16 – New section on Training and Continuing Education. Will this still support the "List of Resources Satisfying initial and continuing education requirement..." that supplements the old technical guidance document #291-4200-001 (the document our policy is based off?). The "List" includes American Board of Radiology (ABR) Maintenance of Certification (MOC) participation right now. Obviously, the old technical guidance document will be N/A, but I am wondering if this "List" will be reworked into the new § 221.16. (15)

    Response: The "List" will be a separate document from the technical guidance document that will be rescinded, so it will remain available.

25. **Comment:** § 221.16. Training, competency and continuing education. This section is duplicative of § 221.11(a)-(b). Additionally, it provides differing requirements. These two sections should be combined into one section. (22)

    Response: Section 221.16 provides specific training and competency requirements and expands on the requirement for continuing education, and the requirements do not differ from the requirements in Section 221.11. Section 221.11 outlines administrative controls necessary for appropriate operations and are referenced in other subsections throughout the regulations. For these reasons, these sections are not combined in the final-form rulemaking.

26. **Comment:** § 221.16(a)(2) – For operators of hybrid imaging devices (PET/CT and SPECT/CT) where the CT is used for attenuation correction and localization only, is ARRT (CT) required or would other certification such as Nuclear Medicine Technology Certification Board (NMTCB) be acceptable? (10, 15)

    Response: American Registry of Radiologic Technologists (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.

27. **Comment:** § 221.16(b)(1) – Continuing education required for high- and low-risk users every 2/4 years, respectively. Will more detailed guidance be provided as to number of hours or how inspectors will determine what is adequate? (15)

    Response: The Department has not codified the number of hours due to confusion that often occurs when applying educational units or contact hours to continuing education

requirements. Therefore, additional guidance is not anticipated. Department staff are available to field questions that may arise regarding continuing education. The radiation safety training must be documented to satisfy the regulation.

28. **Comment:** 221.35a. Fluoroscopic X-ray Systems. § 221.35a (a) General requirements – The language is unnecessarily narrow citing that all fluoroscopic systems shall use an image intensifier. Because not all fluoroscopic units utilize this technology, this should also include language for flat panel detectors and future fluoroscopic detector technologies. (10)

Response: See response to Comment #15.

§ 221.35a(c) QMP evaluations – Fluoroscopic equipment shall be evaluated...under general direction of a QMP. I disagree with "At a minimum, evaluations shall include all of the following:" It is reasonable to assume that "any maintenance of the [fluoroscopic] system that may affect the exposure rate" would not affect many of the listed required evaluation tasks for fluoroscopic X-ray systems such as contrast or collimation. Instead of requiring a full evaluation after any maintenance affecting the output, the QMP should be allowed to make a determination to evaluate those components affected, e.g., only the exposure output in cases when maintenance would not also affect system contrast, collimation, or other system elements. (10)

Response: 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 has been made in the final-form rulemaking.

§ 221.35a(c)(1) –No compulsory dosimetry system calibration schedule should be enforced (drop "not to exceed 2 years"). Manufacturer in-house testing of dosimeters will determine the best calibration schedule and future advances may require more or less frequent schedules. I currently see less than 2% changes between calibrations and diagnostic calibrations don't demand the under 2% accuracy of therapy systems. I disagree with § 221.35a(c)(1) because no limits are enforced on exposure rates in acquisition, digital subtraction, or cine modes by any regulating or accrediting body, evaluation of these maximum rates is not always recommended. Considering the potential damage to the fluoroscopic tubes and detectors from maximum output operation, and that manufacturers have installed fail-safes to disable X-ray production at maximum exposure rates in these modes, evaluation of these maximum exposure rates should not be mandated. (22)

Clean up language regarding calibrated dosimetry system. I think the intention is: "a dosimetry system that has been calibrated within the prior 2 years according to manufacturer's recommendations." (10)

Response: The Department has changed the language to "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." The Department has removed the proposed

language "including those that are expected to drive the system to maximum output," in the final-form rulemaking in response to the comment.

§ 221.35a (d) Additional requirements for facilities performing FGI. Change to "…performing high-risk FGI." These should not apply to low-risk FGI. For (iv), the review of established procedures should be established by the facility and not mandated by DEP. (2) – what is the rationale for requiring a justification for revisions of policies or procedures? This should be eliminated. The language in (d)(3)(iv) and (d)(4) is confusing. The regulation mandates recording of PSD, cumulative air kerma, or dose area product (DAP) if available on the fluoroscopic unit, if not available then four additional pieces of information must be recorded. NCRP Report 168 recommendation 13, cumulative fluoroscopy time alone can be used as a least preferred method of skin dose estimation without additional recorded information. This method can also be used if use of dose estimation from air kerma, DAP or PSD is not practical or possible but still available. This should be changed to align with nationally accepted practices of patient dose monitoring and recording. (22)

Response: 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.

29. **Comment:** Re § 221.35a. "Fluoroscopic X-ray systems." Subsection (b)(4) allows for operation of a fluoroscopic system by "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." I believe that this provision for individuals in clinical training needs to be made applicable to individuals in clinical training for any modality (CT, general radiography, etc.) and should therefore be moved to a location within the regulations that apply to all, or should be added individually to each appropriate section of the regulations. (4)

    Response: The current regulations address clinical training in human use of radiation sources in § 215.24(d), which has been renumbered as § 215.24(c) and expanded in the fluoroscopy section because it addresses other students as well as personal supervision requirements. These two sections adequately address training requirements for other modalities.

30. **Comment:** § 221.35a(b)(1) – Operation of fluoroscopic systems: I would like clarification on "licensed practitioner working within his scope of practice." It seems that Physician Assistants (except Radiology PAs?) can no longer be trained to utilize fluoroscopy, since their "Professional and Vocational Standards" do not cover operation of fluoroscopic equipment. Is this accurate? (15)

    Response: No, it is not accurate. Currently, Physician Assistants (PAs) are licensed by the Department of State. Title 49, Subchapter G (relating to medical doctor delegation of medical services) of this Commonwealth's regulations 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.

31. **Comment:** § 221.35a(c)(3) – Replace "spot-film modes" with "radiographic modes." Spot-film is an outdated term. (10, 15, 22)

    Response: The term "spot-film" may be considered outdated; however, it is still relevant and a familiar term and defined appropriately in § 221.2. Therefore, the Department has not amended it in the final-form rulemaking.

32. **Comment:** § 221.35a(c)(4) – I recommend eliminating the evaluation of the 5-minute timer. The 5-minute timer contributes to "alarm fatigue" without offering any advantage for radiation safety and protection. Its original intention may have been good but with modern radiation metrics, it has outlived its usefulness. (10)

    Response: Evaluation of the 5-minute timer remains relevant for older units that are still in operation and therefore has not been eliminated in the final-form rulemaking.

33. **Comment:** § 221.35a(c)(6) – An evaluation of the availability and accuracy of technique indicators...The only technique indicator we evaluate is kVp. I assume this is acceptable! (15)

    Response: The Department expects both tube potential "kVp" and tube current "mA" to be measured as technique indicators. Exposure time or "pulse width" for a pulsed fluoroscopy system should also be evaluated.

34. **Comment:** § 221.35a(d)(1)(ii) – This should reference monitoring dose as indicated by cumulative air kerma meter, i.e., dose to interventional reference point or other practical means. (15)

    § 221.35a(d)(1)(ii) – Monitoring actual patient dose during FGI is not practical. I recommend monitoring cumulative dose to a standard location in space (e.g., the Interventional Reference Point, or IRP). (10)

    Response: Cumulative dose and actual dose are both acceptable methods for monitoring patient radiation dose during FGI procedures.

35. **Comment:** § 221.35a(d)(4)(i) – In practice, the fluoroscopic mode may change during an FGI procedure. Some systems do not report the various modes that were used during a procedure. (10)

    Response: The Department has amended proposed subsection (d)(4)(i) in the final-form rulemaking for clarity.

36. **Comment:** § 221.57. Facilities using CR and DR. This section should be incorporated into

§ 221.11(l) referring to the QA/QC program. Section (c) provides vague tests including contrast/noise and workstation monitors; this section should be eliminated as section (b) addresses this adequately. (22)

Response: CR/DR should be and is referred to directly in the QA/QC section of § 221.11(l); however, due to the importance of systems using CR or DR, proposed § 221.57 was created specifically to address CR/DR. This entire section has been renumbered as § 221.50 in the final-form rulemaking.

37. **Comment:** § 221.57(a) – To implement a process to investigate consistent deviations from established exposure indicator ranges requires some method to electronically record and analyze the exposure indicator data. Some CR & DR manufacturers may not provide such capability as an integral part of their systems. This could be a great burden. I recommend that wording be added to allow an exemption from this requirement if the necessary tools are not an inherent capability of the CR or DR system. (10)

§ 221.57(a) – Establishing an acceptable range for exposure indicators can be a burdensome process. Some unit's report Exposure Index (EI), others report Radiation Exposure (REX), etc. Also, clinical factors greatly impact the exposure indicator such as collimation, patient centering, etc. While it is agreed that monitoring EI is important, we still need more support and guidance from the system manufacturers. Implementation and enforcement of this section will need more clarification from the Bureau. (15)

Response: An exemption is inherent in subsection (a), which begins with the language "When exposure indicators are available…". If exposure indicators are not available, the registrant should still develop a means to determine if exposure values for each image are necessary for adequate radiation protection. Section 221.57 was renumbered as § 221.50 in the final-form rulemaking for proper placement in the regulation. No other changes to the section were made in the final-form rulemaking.

38. **Comment:** § 221.57(c) – I believe that requiring quarterly testing of CR/DR systems is unnecessary. For large institutions that may have many (hundreds) of CR image plates, this is also impractical. Most DR systems include software that forces the user to perform a self-test or calibration on a regular basis (approximately monthly). Creating a regulatory requirement to force all CR and DR users to meet this standard is extremely burdensome. (10)

§ 221.57(c) – Requiring quarterly phantom evaluations of CR/DR systems seems to be excessive. Perhaps requiring manufacturer's recommended Quality Control (QC) (with phantoms if supplied by manufacturer), or simpler evaluation for artifacts would be more reasonable. Exposure indicator consistence tracking is also difficult. (15)

Response: The Department believes strongly that quarterly testing requirements are necessary and appropriate to assure adequate radiation protection. A number of organizations such as ACR and ASRT recommend monthly checks as Best Practice

requirements. This entire section has been renumbered as § 221.50 in the final-form rulemaking. No other changes to the section were made in the final-form rulemaking.

39. **Comment:** § 221.57(c) – Many DR systems now come with self-test procedures that analyze uniform ("flat-field") images for sensitivity, uniformity, artifacts, and noise. These self-tests are often performed with a uniform beam filter. Its purpose is to harden the beam like a patient. Would this filter be considered a "phantom?" In addition, these self-tests do not evaluate spatial resolution or detector contrast. For electronic DR systems consisting of a matrix of fixed detector elements, the detector contrast and the detector resolution does not change over time so, testing spatial resolution on a routine basis is unnecessary. I suggest removing (2) Spatial resolution. (10)

    Response: Advanced technology in newer DR systems use different techniques that perform the same function as a phantom. These advanced systems are acceptable for the evaluation requirements proposed in § 221.57, which has been renumbered as § 221.50 in the final-form rulemaking.

40. **Comment:** § 221.63. Therapy imaging guidance systems. – § 221.63(a) The AAPM publishes guidelines on many topics including QA of CT Simulators. These guidelines clearly state that they are for guidance only and it is the responsibility of the assigned medical physicist and/or a departmental quality assurance committee to establish QA procedures that apply to a particular site. I am concerned that the way the proposed rule is worded, it can be interpreted by a PA state inspector that a site is expected to follow all of the QA procedures described in a document published by a national organization and by the device manufacturer. I suggest: "The QMP shall develop QC procedures and tolerances for therapy imaging guidance systems using nationally-recognized standards or those recommended by the manufacturer for guidance." The same comment applies for §§ 221.64 (a)(2) and (a)(3). (9)

    Response: The proposed rulemaking stipulated that it is the QMP's responsibility to develop QC procedures. The Department will inspect against those procedures. This requirement is retained in the final-form rulemaking.

41. **Comment:** § 221.64(a)(2) – In other areas of the proposed regulations, test intervals not to exceed 14 months are allowed, but in this section, it is 12 months. Please be consistent at 14 months. (10, 15)

    Response: The Department agrees with this comment and has amended this section in the final-form rulemaking to 14 months for consistency.

42. **Comment:** § 221.64(a)(2) CBCT. This is a higher supervisory standard than potentially high-risk fluoroscopy or CT. This also does not conform to any nationally recognized QC standard and should be changed to general supervision.

    (6)(b)(1) – Not all CBCT systems have phantoms.

(c) – What is the basis for this exemption and the specific operating factors? (22)

Response: The Department agrees and has changed the supervisory standard in proposed subsection (a)(2) to "...under the direct supervision of a QMP or QE" in the final-form rulemaking. The FDA requires all CT systems to be evaluated with a phantom, and current regulation requires compliance with FDA regulations. Proposed § 221.64(c) has been changed in the final-form rulemaking to "CBCT systems are exempt from § 221.202(a) (relating to equipment requirements)."

43. **Comment:** § 221.64. CBCT. – Commentators are not sure of the need for § 221.64(a)(4). What is the rationale? Cone beam computed tomography (CBCT) is typically used for navigational purposes; these are not doing "typical CT scans" with typical protocols. There is no need to address deviations from existing protocols. For (b)(2), there is no need for an operator to know the full extent of the schedule for QC. They only need to know the ones they are expected to perform. (9, 22)

    For (b)(4), it is not clear what is being sought here. The operator needs to evaluate the results of their QC tests and take appropriate action. Otherwise, the QC results need to be reviewed by the QMP. (9)

    Response: The purpose of proposed § 221.64(a)(4) is to record deviations from established protocols. Not recording them would make it difficult to track any trends that may be occurring. As for proposed subsection (b)(2), operators should be fully aware of all routine QC, including the schedule to perform QC. As for proposed subsection (b)(4), operators need to be aware of the results of the last QC checks to determine if the QC passed or failed. These provisions are retained in the final-form rulemaking.

44. **Comment:** § 221.201. Definitions. Eliminate contrast scale, $CTDI_{100}$, dose profile, elemental area, MSAD (multiple scan average dose), multiple tomogram system, and noise, as they are not referred to in the regulations. (22)

    Response: All terms listed, except for MSAD, are defined and referenced in various sections of the regulations. The term "MSAD" was deleted in the proposed rulemaking. No change has been made from proposed in the final-form rulemaking.

45. **Comment:** § 221.202. Equipment Requirements. Why is DEP requiring accreditations? If DEP is going to mandate accreditations, then there is no need for detailed CT equipment testing as the site will need to meet the accreditation testing. (22)

    Response: CT accreditation is now a common requirement for medical imaging primarily due to payment under Part B of the Medicare Physician Fee Schedule. Regardless, accreditation will never replace having a good QA program. Routine QC assures the device is operating correctly and verifies safety to patients and staff.

46. **Comment:** § 221.202(a) – Diagnostic CT systems must be accredited by an organization "recognized by the Department." Some more clarification is needed as to which accrediting bodies will be acceptable. (15)

    Response: The current regulations address organizations recognized by the Department in § 221.11(l). The regulations also state that the Department's guidelines and a list of recognized organizations will be maintained and made available on the Department's website and upon request. Therefore, no change has been made.

47. **Comment:** § 221.202(a) – I recommend that CT scanners that are intended for non-diagnostic use (e.g., treatment planning/simulation, attenuation correction) be exempt from the accreditation requirement. I also recommend exempting CBCT for oral/maxillofacial/ENT, extremity imaging, etc. The ACR CT accreditation program does not support these types of CT devices. (10)

    Response: The proposed rulemaking already limits this requirement to "diagnostic CT X-ray systems." This limit is retained in the final-form rulemaking. Simulators, therapy imaging guidance, and attenuation correction systems are not considered diagnostic. CBCT has been exempted in § 221.64(c) in the final-form rulemaking.

48. **Comment:** § 221.204. Performance evaluations, routine QC and surveys. Subsection (d) reads "Records. Records of the performance evaluations and surveys shall be maintained for at least 1 year." Please strike the words "at least" before "5 years" and "1 year." Subjective regulations never go well for the regulated community when being inspected by the regulators. No other records retention requirements described in these proposed changes uses the term "at least" please provide consistency and strike these words in this section. (3)

    Response: The term "at least" has been used consistently in the existing regulations and need not be deleted. The Department is prescribing the minimum amount of time to retain these records; however, the facilities may retain records for longer periods of time if they wish.

49. **Comment:** § 221.204. Radiation Measurements. CT dosimetry is in flux due to the multi-detector CT scanners which have invalidated the current CT dose testing methods. My recommendation is for the regulations to mandate the dosimetry phantom and testing protocols to meet accreditation requirements or other nationally-recognized standards so as not to be locked into the outdated current state of CT dosimetry. In (3), eliminate (i) HVL, (ii) MSAD. In (5), eliminate mR/mAs value determination for head and body. (22)

    Response: The performance phantom is included in proposed § 221.202(h)(4) and therefore does not need to be duplicated elsewhere. All other provisions noted in this comment--§ 221.204(3)(i)-(ii) and §221.204(5)—were proposed for deletion.

50. **Comment:** § 221.204(a) – Performed under the general supervision of QMP. (22)

Response: The QMP is responsible for performance evaluation, and this requirement must stay under the direction of the QMP. Changing it to "general supervision" will not make a difference as the overall direction and control remain with the QMP. Therefore, no change has been made from the proposed rulemaking in the final-form rulemaking.

51. **Comment:** § 221.204(a)(3) – Requires initial performance evaluation of CT system prior to patient use. This should be consistent with requirements for X-ray, fluoroscopic, and other systems. (15)

    Response: This requirement is consistent with X-ray, fluoroscopic and other systems; however, because CT systems have the potential to be high-risk, the initial performance evaluation is required. Therefore, no change has been made from the proposed rulemaking in the final-form rulemaking.

52. **Comment:** § 221.204(a)(4)(x) – The requirement to review and assess the dose of the specified procedures should not be mandated. The ACR and other recognized accrediting bodies do not require submission of specific protocols beyond the adult head and abdomen scans. For example, many clinics do not perform pediatric studies or brain perfusion studies and do not have these clinical protocols set-up to be evaluated. The regulation should require only a review and dose assessment of the most generic (adult head and adult abdomen) protocols. Alternatively, the regulation could either match the required reviews with those submitted for accreditation or allow the QMP to select a variety of clinically relevant protocols for annual review and assessment. (22)

    Response: It remains the responsibility of the QMP to determine the protocols that are deemed appropriate. If brain perfusion, for example, is not performed, the protocol does not need to be reviewed. Therefore, no change has been made from the proposed rulemaking in the final-form rulemaking.

53. **Comment:** § 221.204(a)(4)(xi) – Additional clarification is required in the instruction to "review DRL." Diagnostic reference levels are defined by national guidelines such as NCRP Report 172 as the bottom of the 75th percentile of diagnostic doses allowing for differences in populations. Specific DRLs reported in such references typically consider a national population. If it is the intent that a review of the DRLs should consider only the national populations and no other more specific populations, the section ought to specify that requirement. It is also unclear how, if at all, these DRLs should be interpreted with respect to the notification and alert levels. Furthermore, although XR-29 mandates a reduction in CT study reimbursements for scanners without the capability to set notification levels and alert levels, neither CMS nor any nationally recognized accrediting body has forbidden the operation of such scanners without these capabilities. The regulations should clarify that DRL, notification level, and alert review are only required for scanners that are XR-29 compliant. (22)

    Response: The DRL is an investigational level the facility uses to review its methods. The purpose is to achieve acceptable image quality at the lowest possible dose. The

review of DRLs, notification values and alert values are important in the performance evaluation of the CT system and recommended by NCRP as well as other recognized bodies such as ACR and AAPM. Therefore, no change has been made from the proposed rulemaking in the final-form rulemaking.

54. **Comment:** § 221.204(b)(2) – (2)(c) The procedures mention tracking noise. CT image quality measurements do not track noise without context to the signal or tube output. Because CT numbers are calculated relative to water attenuation, noise can vary greatly from several factors such as slice thickness, tube output, and reconstruction algorithm. Metrics such as CNR and SNR are better performance indicators and should replace "noise" in the regulation. (22)

    Response: Noise is an important characteristic of the CT image that affects the ability to visualize anatomic structures. The current Article V (relating to radiological health) regulations require an evaluation of noise in determining performance. Therefore, no change has been made to § 221.204(b)(2) in the final-form rulemaking. CNR or SNR are acceptable indicators in evaluating noise.

55. **Comment:** § 221.204(b)(5) specifies that all routine QC be performed only under clinical modes. This is not recommended by any CT manufacturer. These manufacturers provide specific phantoms to be run under specific CT operating modes which are to be processed by specific QC reconstruction algorithms. Only then can the resulting values be compared to manufacturer specifications. Running phantoms, protocols, or reconstruction algorithms that are not specified for QC by the manufacturer will not yield the same QC results and will cause incorrect and falsely out-of-tolerance results. (22)

    Response: There has been no change to paragraph (5) in the final-form rulemaking other than changing "Performance evaluation" to "Routine QC." Subsection (b)(5) does not require that QC be performed only under clinical modes.

56. **Comment:** § 221.204(b)(4) – The Routine QC for CT looks like it is only required weekly? Several manufacturers recommend daily QC with their supplied phantom. We would most likely stick with this routine. (15)

    Response: It is acceptable to perform routine QC at a frequency greater than what is required.

57. **Comment:** § 221.205 (relating to operating procedures) – Add the requirement for operators to be appropriately trained in the specific techniques and modalities they will be utilizing and be certified by "certification organization." A national certification organization that specializes in the certification and registration of medical imaging or radiation therapy technical personnel and is accredited by the National Commission for Certifying Agencies, the American National Standards Institute, the International Organization for Standardization, or another accreditation organization recognized by the board. (21)

Response: The Department does not believe this is necessary because operator requirements are specified in various sections of the regulations, including §§ 215.24, 221.35a, 221.64, and 221.205.

58. **Comment:** § 221.205(3)(a) – This requirement states a CT system is to be operated only by an individual who has been specifically trained in its operation. During the webinar, it was stated this means that all CT techs must be specialty-certified in CT. This is not correct. There are other alternative trainings which can meet these criteria including those detailed in the newest Joint Commission diagnostic imaging standards. (22)

    Response: The Department will accept individuals having the applicable specialty in radiography, such as, ARRT(R), or equivalent, to perform CT procedures if the procedure is considered low-risk, as defined in proposed § 221.2. However, high-risk procedures, for example brain perfusion studies, will require the advanced certification in CT such as ARRT(R)(CT). The Department has changed the language proposed in § 221.11(b)(1) to reflect this in the final-form rulemaking.

59. **Comment:** § 221.205(3)(c) – It is important to note that the role of the QMP is mischaracterized in this section. Under no circumstances can the QMP forbid a physician from scanning or treating a patient if the physician feels the procedure will benefit the patient. Indeed, this is a nuanced qualification. The QMP's role is to act as an advocate for both the safest possible use of radiation and for the best possible diagnostic quality. If the QMP feels that a scan or treatment is not appropriate due to malfunctioning equipment, his/her obligation is to cite acceptable standards of radiation use for diagnostic studies to the staff and physicians and recommend that the procedure be done on a fully functioning unit. The obligation however, ends there and any expectation that QMP ought to have a regulated list described in § 221.205(c) is inviting conflict with licensed caregivers and exposing the state and hospitals to potential litigation. (22)

    Response: Section 221.205 has been implemented since 1998 under the authority of the Radiation Protection Act. The only revision to section 221.205(c), which was proposed as section 221.205(b), is changing "qualified expert" to "QMP" in the final-form rulemaking. The regulation does not forbid a physician from scanning or treating a patient. Rather, it stipulates that it is the responsibility of the QMP to determine if a device is functioning safely. If it is not, the use of the CT system on patients shall be limited by the QMP.

60. **Comment:** General comments on the remaining Chapter 221 sections addressing fluoroscopic X-ray systems, CR/DR equipment, CBCT and CT – All testing requirements should be done by or under the general supervision of a QMP. There is no testing which must always be done by the QMP directly.

    The rapid technological changes occurring in diagnostic images, including computerization and automation, require additional flexibility in these proposed regulations to allow appropriate responses to these ever-accelerating changes and improvements. I do not agree with the very prescriptive testing requirements detailed in these sections. The QMP expertise

should be fully utilized in developing appropriate written testing and QA/QC protocols, inconsistent with manufacturer, nationally-recognized recommendations and the long-accepted image quality metrics of low and high contrast resolution, SNR (signal to noise ratio) and CNR (contrast to noise ratio) and exposure metrics and indicators. There is no need for detailed DEP mandates which will quickly become outdated and irrelevant. (22)

Response: Final-form Chapter 221 does not include additional requirements that will become outdated or irrelevant. The chapter describes requirements that, left unaddressed, could result in misinterpretation of manufacturer and nationally recognized recommendations.

Chapter 223

61. Comment: § 223.1. Purpose and Scope. – The proposed change adds "research on animals" to the Veterinary Medicine section. I agree with this clarification to the rules and would like to comment on what I hope was an unintended consequence of this change. I currently use a Siemens Inveon Multimodal PET/CT unit in our facility that is under registration with the PA DEP. The PET/CT unit is manufactured as a cabinet X-ray system and is located and used in a room not dedicated entirely to the use of the PET/CT unit. Since this unit is used for research and would now be subject to the rule, per § 223.31(d), we would be required to have any personnel not directly associated with use of the X-ray to vacate the room during use of the X-ray. We have conducted exposure measurements around the cabinet X-ray unit and currently allow personnel not directly associated with the use of the PET/CT to be in the room during X-ray use without using any additional personnel shielding. Access to the room is already restricted based on the use of unsealed sources of radioactive materials in the room.

I propose that § 223.31(d) be revised as follows, to allow other personnel to be in the room if the X-ray is a cabinet X-ray or enclosed X-ray system and that § 223.31(d)(3) would not apply to use of such cabinet or enclosed X-ray systems:

> (d) Only the staff, ancillary facility personnel or other persons required for the medical procedure or training may be in the room during the radiographic exposure, unless the radiographic equipment is a cabinet or enclosed X-ray system. All of the following requirements apply to persons involved in the examination:
>
> > (3) Unless the radiographic equipment is a cabinet or enclosed X-ray system, each person shall be protected... (12)

Response: This regulation applies to all veterinary medicine practitioners using radiation sources, whether for research or for animal treatment. There is no need to limit the type of equipment to be other than "a cabinet or enclosed X-ray system." The Department agrees there may be individuals present in the room during the operation of the device and allows persons to be in the room. The final-form rulemaking adds that they cannot be within 2 meters of the device during operation.

Chapter 228

62. Comment: § 228.11a. Licensee responsibilities. – The proposed amendment adds qualification requirements for operators of accelerators used in the healing arts to address radiation safety. This includes operators who need additional instruction including certification in the applicable specialty. Does this restrict the operation of a linac by a student even if they are under the supervision of a trained and certified operator? If so, this is a bit restrictive. Also, there are times an accelerator needs to be operated by service personnel and others for testing. This does not seem to be accounted for in proposed additional language. (9)

Response: The regulations address clinical training in § 215.24(d), which has been renumbered as § 215.24(b) in the final-form rulemaking. Chapter 216 addresses the requirements for service providers.

63. Comment: § 228.36. – The proposed rule states "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." The daily testing of the Primalert is conducted as part of the morning QA when the beam is turned on. The Cs-137 check source is not utilized for the daily testing. Can you please confirm the current testing method (using beam, not check source) satisfies the daily testing requirement? (17)

Response: The regulation does not stipulate how the monitoring system should be tested, only that it must be tested. Both "beam on" or "check source" are acceptable means of testing.

64. Comment: § 228.73. Selection of stationary beam therapy or moving beam therapy. – The proposed change does not make sense in this section since the rules apply only to linacs capable of BOTH stationary AND moving beam therapy. (9)

Response: The proposed amendment was to account for linacs that may only do one type of therapy, such as an NRT Novak 7 accelerator. No change to the proposed language was made in the final-form rulemaking.

Chapter 240

65. Comment: We are often asked to bid on large jobs (schools, nursing homes, condos, etc.) where the client specifies the number of tests. We provide two bids: one for the number of tests specified in the specs, and two for what would meet EPA criteria, explaining that this is what is required. If the client specifically wants us to only test what was specified, are you saying we cannot test the number of locations specified on the purchase order? This is another form of interference in a legitimate business decision between a client and a provider of a service, where the client specifies what they want, knowing what the DEP requirements are. (2)

Response: There are certain required testing practices, such as those required for testing during real estate transactions, testing a school building, and testing in multi-family units, for which protocols require a certain number of tests to be placed in certain locations. The client cannot dictate how many or where the test kits will be placed.

66. **Comment:** A proposed amendment in Chapter 240 limits individuals per certified individual in a firm to five. This number is too small; this could mean only two to three job sites when the certified individual could supervise around five each day. The number of individuals should be raised to 10. (1)

§ 240.102 (b)(4) – There is absolutely no justification for this. This is strictly a business decision and no concern of the Radon Section as to how many employees a company hires. This section should be deleted. (2)

Paragraph 240.112(b)(5) – stipulates that any mitigation FIRM can have no more than 5 employees. This is overly restrictive and arguably beyond the scope of the statute's intent. Limiting the size of a given business enterprise would seem to exceed the authority of the department. *How are the citizens of the state better protected by limiting the size of a mitigation business enterprise given the ongoing obligation of the FIRM's certified individual to insure regulatory compliance?* (6)

§ 240.102 and 240.112 – I agree with most of the points, however I cannot agree to limiting the number of employees. As long as there is a single certified person in charge, there is accountability. Forcing a firm to hire a second certified individual could be the business equivalent to training a competitor who could become disgruntled and open up shop down the street and put you out of business. It could get as ugly as a divorce! I do not know that the employee limit would pass a constitutional challenge, and fear the Department may risk having the entire radon regulation thrown out depending on how the case was presented. (7)

§ 240.102 – This section does exactly the opposite of its intended purpose. By limiting the number of employees, if a company had enough work, the firm would have to be split and a second company would have to be established. This situation would create confusion between the two management teams. Employee testers (in the same company structure) would switch between companies and be uncertain who their real supervisor is. The clerical staff would be constantly confused which company they were working for and how to report to DEP and management. Confusion would be such that mistakes are inevitable. The number 5 is arbitrary and has no basis in real world company management. If the staff is properly trained and adequate levels of management exist, the number of employees is irrelevant. If the staff and supervisors are not properly trained, the company will make mistakes thereby providing poor customer service as well as accuracy and precision in all services provided. The properly supervised number of employees has nothing to do with the intent of this change. In addition, service prices will have to be raised because of doubling company costs. (13)

§ 240.102 – This limit of 5 employees is arbitrary. There are no supporting data, papers or labor performance studies in coming up with the limit of 5 persons either for testing or mitigation. It is the responsibility of the certified radon testing individual and/or owner to ensure that all persons, whether 1, 2, 5, 10, or 20 adhere to PA DEP radon regulations, company approved quality assurance and SOP program, including the EPA and AARST ANSI standards. If I have 20 radon testers working for me as the certified and responsible person, and I ensure proper personnel training, structural management, internal communication systems, and QA/QC procedures and internal audits, then I should be able to properly monitor my people with good business and QA/QC practices. Why the limit of 5? Why not 3? Why 15? This is viewed as a restriction on business and on business growth. PA DEP should show the studies and data supporting the limit of 5 persons-firm employees or eliminate this unduly restrictive and unsupported number limit of firm employees (both radon testing and radon mitigation). There are hospitals and facilities with more than 5 X-Ray machines, can you limit them to only 5 persons running 5 machines, because you are concerned about if they have the mental and organization and performance base capabilities? PA DEP has decided that they are going to restrict your business growth, because they do not trust you to have more than 5 firm employees. Where did that 5 firm persons limit come from? There are large air conditioning HVAC companies with hundreds of technicians performing HVAC business services with no lessening or failure of management and quality in the execution of their business. Surely, it is not because of the immense complexity of doing HVAC installations, both residential and commercial. What about all of the technicians and repair men and women working for a cable or phone company. The complexity of their business is no less more complex than the radon business. They have 100s of technicians performing services with no threat to the public or system installations. What if there was a medical office that performed knee replacements with 10 doctors and 20 supporting personnel, then should they also be restricted to 5 doctors and 5 supporting persons? What about a large builder with 100 employees building homes? You cannot tell me that building a house is less complicated than the installation of a radon mitigation system or testing 10 schools in a school district. If this 5-firm person regulation for the targeted radon industry was challenged legally, the regulation would be overturned as "burdensome to the radon industry", a restriction of business growth and no supporting evidence. **THE WHOLE RULE STATEMENT SHOULD BE REMOVED.** THERE SHOULD BE NO PERSONNEL FIRM EMPLOYEE LIMIT. GOOD INTENTIONS AND CONCERNS BY THE PA DEP ARE NICE, BUT NOT WHEN THEY ARE PREVENTING CAPABLE, PROFESSIONAL COMPANIES FROM GROWING AND PERFORMING RADON SERVICES, WITH AN ARBITRARY NUMBER WITH NO SUPPORTING METRICS. IF THERE IS VIOLATION OR A FAILURE OF SERVICE IN THE PERFORMANCE OF RADON MEASUREMENTS OR MITIGATION WITH SAY, 20 FIRM PERSONS UNDER ONE CERTIFIED PERSON (RESPONSIBLE), THEN THE DESIGNATED CERTIFED PERSON AND/OR OWNER TAKES RESPONSIBILITY, CONSEQUENCES AND PROPER ACTIONS TO CORRECT AND ENSURE THAT QUALITY AND VALID SERVICES ARE PROVIDED FOR THE PUBLIC AND THEIR CLIENTS. THAT IS THE PRIME DIRECTIVE OF ANY GROWING BUSINESS. THE RADON INDUSTRY IS NO DIFFERENT IN THAT PURSUIT. (20)

I strenuously object to this regulation. The proposed regulation precisely as written, and as explained by the PA DEP Radon Division, limits the size of a Radon Mitigation Company to six people and restricts five of the mitigation employees from full Certification. If more than 6 individuals, a Mitigation Company must be divided into two independent, self-governing Companies (these are separate Companies not a ratio of Certified to General Workers in a Company). It is apparent that this is unworkable. A Company with 12 mitigation individuals, must divide into 2 companies with 2 Certified Individuals. Neither Certified Individual is permitted to direct any activities of the other Certified Company's workers. This means a large project (School, Hospital, Church, Multifamily) that requires more than 5 or 6 installers must be done by 2 independent companies. This is unworkable even before accounting for illness, vacations, other commitments, etc. If any of the Company's employees miss work, they cannot be replaced by the other Company's Workers. If a Certified individual is absent for a time, the other Certified Individual cannot direct both sets of Individuals. I have experience with the rule, our Company was placed under this directive and was fined for noncompliance. The 6-person-company directive has created a series of complications and caused added costs and difficulties in meeting our commitments. Our mission is to reduce naturally occurring radiation in homes and buildings but this has entangled us with compliance complications. We have 4 Certified Individuals and 3 eligible (NRPP Tests passed and substantial experience). We would like to Certify all and organize them as distinctive department heads. Not only is the regulation unworkable, but may also be unconstitutional according to our legal advisors. We did not have the will or the money to fight this.

The intent to provide an organizational structure to radon mitigation companies, balancing certified to listed individuals is commendable, but as written these regulations are unnecessary and unworkable. Arbitrarily breaking up companies in this manner is a 'Restraint of Trade.' (23)

Response: The Department acknowledges the commentator's concerns and has removed the limitation of firm employees in the final-form rulemaking.

67. **Comment:** I would like to first mention as a member of the AARST National Board of Directors, that the EPA currently recognizes (9) ANSI/AARST National Standards of Practice, and more are currently being developed. You can view the currently recognized standards at https://www.epa.gov/radon/publications-about-radon. I am uncertain as to why the PA DEP does not utilize all of the more current ANSI/AARST Standards instead of relying on several antiquated standards.

Since 1987, when I first entered the world of radon mitigation, the EPA and DEP have been telling us that "We are saving lives." So, when I look at regulatory changes I view them as "Are these changes helping or hurting the effort to Save Lives." I fail to see how most of the proposed regulation will aid in the effort to save lives. (7)

240.308. Radon mitigation standards. – The PA DEP should adopt the consensus standards as approved by the American National Standards Institute as developed by the AARST. The ANSI-AARST standards currently in place cover radon testing and mitigation practices in

homes, schools, commercial buildings, and multifamily properties. The standards are currently recognized by the EPA as the Current Standards of Practice and are required by ANSI to be updated on a regular basis. This consensus-based process is routinely referenced by government programs across the United States. (18)

Although not included with these proposed regulations, I strongly and respectfully recommend that the PA DEP Radon Section consider adopting the ANSI AARST standards in radon measurements and radon mitigation. Some of the PA DEP Radon Section staff participated on the standards committee, along with many other state radon programs and the EPA regions. The current standards being used, especially for radon mitigation are antiquated and have not been revised in years. The adoption of these ANSI standards would ensure Pennsylvania citizens are getting the most "current best practices" for measurement and mitigation services for the second leading cause of lung cancer. The ultimate prime directive is to reduce risk, save lives and provide the professional and technical current services to all Pennsylvania citizens, workers and families. This shows that the Pennsylvania Radon Program is aligned with the current national radon standards. (20)

Response: The Department believes that the standards used in this regulation are not antiquated and provide the necessary protections to test for and mitigate radon exposure. Therefore, no change has been made in the final-form rulemaking.

68. **Comment:** I have agreed with every topic that I feel is reasonable. I believe I agree with most of the sections where I have deferred because I do not possess the knowledge, experience or expertise of a Certified Tester or Laboratory. I am deeply concerned that the overall tone of this document seems to be setting a minefield of "gotcha" traps that myself or others could step into and be punished for an inconsequential omission, or a violation, that despite my best efforts, I could be drug into by a strong-willed client. (7)

Response: The Department appreciates the comment but disagrees. The purpose of this rulemaking is to ensure radon testing is done accurately and mitigation performed according to standard protocols. The Department has no intention of setting traps. The Department has agreed to make numerous changes to the proposed rulemaking where commentators have noted hurdles or obstructions to business. In other instances, however, the balance must be maintained in favor of standardization and protection of human health.

69. **Comment:** The analysis does not come close to what it would really cost. The State fee may only be $300, but the cost of paying someone's salary, continuing education credits, travel costs and expenses to become certified wouldn't stop at $3,000; and then you have just paid to educate your mightiest potential competitor. (7)

Response: The Department has removed the proposed requirement in §§ 240.102(b)(4)(iii) and 240.112(b)(4)(iii) for radon firm employees to complete a Department-approved radon course in the final-form rulemaking. Under the final-form rulemaking, certified individuals may provide initial training and continuing education.

70. **Comment:** Back in the earlier days, about 1995 if I recall, I was involved in "workshops" on the 7th floor of the Rachel Carson Building, working as partners with the State. Our primary objective at that time was developing a "Builders System" which has now become ANSI/AARST RRNC 2.0. It felt like a partnership because it was industry and government working together as a team, for the good of Pennsylvanians, and eventually the world. I have devoted almost my entire adult life to reducing radon-induced lung cancer. Much of this new regulation seems very adversarial. Feeling now that I have to turn my attention from providing the best quality mitigation systems for my clients to looking over my shoulder and watching every step because the State I have so willingly volunteered my time through community outreach education; TV newscasts on stations that aren't in my work travel radius; volunteering nationally through AARST even before becoming a board member; and fighting diligently year after year, at my expense, in Washington DC for SIRG grants may penalize me. It really sucks. What happens if an employee was to quit when the certified individual is on vacation? Or at the International Radon Symposium, or when you are in the hospital? The entire tenor of this proposed regulation is very disturbing. It seems the intention has nothing to do with saving lives. (7)

Response: The purpose of these regulations is to ensure radon testing is done accurately and mitigation performed according to standard protocols. The Department does not believe that the best course is an adversarial one, and in that spirit, much has been removed from the proposed version that commenters felt was an undue burden.

71. **Comment:** If a firm has more than one certified individual (whether it be for a testing firm, a mitigation firm or a laboratory) and the certified individual responsible for the firm or laboratory employees can no longer serve in this capacity, then another certified individual in the same discipline should be allowed to be a replacement immediately without waiting for PA DEP approval. The PA DEP has already certified the individual for the discipline and the notification requirement to the PA DEP as written in the proposed regulation is unduly burdensome to operating a business. (16)

Response: Written Department approval has been the current practice and whenever possible, when the change of a certified individual may be anticipated, the Department works with the firm to ensure there is no lapse in the firm certification. For the Department to ensure that a correctly certified individual is in responsible charge of that firm's activities, it is vital to track and account for all changes of a firm's certified individual.

72. **Comment:** I don't understand the requirement to have a serial number on the electret ion chamber. Is there that much variation between chambers that necessitates this labeling? I assume that this requirement is based on one brand of electrets. (16)

Response: The Department agrees with the comment and has amended §§ 240.604(c)(2)(ii) and (c)(3)(v)(C), and 240.605(c)(1)(ii) and (c)(2)(v)(C), accordingly.

73. **Comment:** I am confused by the sections on voltage drift for new batches of electrets. Is this testing to be done by the manufacturer or by the client buying the electrets from the manufacturer? If this testing is to be done by the client, does the client have to wait to use the new batch of electrets until the voltage drifting testing has been completed? Are the limits on voltage drop for short-term and long-term electrets based on one manufacturer's product lines? I am confused as to how you correct for voltage drift if the voltage has drifted more than the prescribed limits. I am also concerned that the requirements for handling the electrets involve a lot of quality control and do not understand why analysis by electret ion chambers is exempt from laboratory certification. (16)

    Response: The Department has removed the proposed requirement in §§ 240.604(c)(5) and 240.606(c)(5) to do a voltage drift check in the final-form rulemaking. Electret ion chambers are exempt from laboratory certification because the level of complexity presented by these devices is much lower than other types of devices.

74. **Comment:** The requirement 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 for many certified individual testers. (16, 19)

    Response: The Department agrees with the comment and has amended §§ 240.604(c)(3)(iv), 240.605(c)(2)(iv) and (d)(2)(iv), and 240.606(c)(3)(iv), (d)(4)(iv) and (e)(3)(iv) the final-form rulemaking accordingly.

75. **Comment:** The requirement for annual calibration for AC, LS and AT is also unnecessary and burdensome to the laboratory. Calibration should be performed when there is a new batch of charcoal being used for production of AC or LS devices or a new batch of film/plastic being used for production of AT devices. All other QA measurements (daily calibration of analyzers, spikes, duplicates, blanks and proficiency tests) are satisfactory to ensure that the device calibration is in good working order. (16)

    The requirement for annual calibration for AC, LS and AT is also unnecessary and burdensome to the laboratory. Each client of the lab is also performing spikes (known) at the same rate so it is duplicated for the 50% humidity range at least. This has become so constant that professionals are simply having labs send cans directly to the chambers on their behalf and directly to the lab to avoid getting them there beyond 7 days – so the whole purpose of QA/QC is nonexistent. (19)

    Response: Annual calibration for any instruments that measure radiation concentrations has been the standard practice within the U.S. Environmental Protection Agency, the U.S. Nuclear Regulatory Commission, and the radon industry for the past 25 years. This is necessary to ensure that these devices are providing precise and accurate results.

76. **Comment:** I don't understand the requirement for laboratories to report the status of a radon mitigation system. This is burdensome for a laboratory and I suspect that many laboratories do not ask for this information from the consumer. It is difficult to get the required

information from the consumer – name (not the agent), measurement dates, test location, temperature, weather, position of the vents, closed house agreement signed. (16, 19)

Response: The Department recognizes that consumers may not always provide the laboratory with complete information. The Department has added "as available" at the end of § 240.303(1) in the final-form rulemaking so that the report forms contain all information available to the lab.

77. **Comment:** I am disappointed that it appears that the enforcement policy and associated penalty table for Chapter 240 was posted for Comment, approved for use and put into force without any notification to the regulated community. Will the enforcement policy table also be up for revision once these regulations are finalized? (19)

    Response: The Department does not plan on revising the Compliance and Enforcement Technical Guidance document at the time of this final-form rulemaking.

78. **Comment:** The Department is proposing to increase the radon certification fees based on the finding of the Report to assure that Chapter 240 fee revenue covers the Department's Radon Program costs. Are all of the current and proposed program costs necessary and required to protect the public from the unscrupulous radon professionals and the hazards of radon gas? (19)

    Response: This comment is beyond the scope of this rulemaking. Fees were the subject of a separate rulemaking that became effective on October 21, 2017.

79. **Comment:** Although the Radiation Protection Advisory Committee (RPAC) endorsed the proposed rulemaking for presentation to the Board, it appears that the radon industry was not properly represented because none of the members are certified testers or mitigators. (19)

    Response: While there is one member of the RPAC who represents the radon industry, RPAC formed a Radon Subcommittee and has engaged that subcommittee regarding this final-form rulemaking.

80. **Comment:** Why is there a fee waiver provision for local government employees or school employees performing unit installations in a school or local government building if the installation is pursuant to his or her official duties and the employee is not compensated for this service except through the employee's salary. Is there a job description that this task is already listed on or will this fee create a new job? (19)

    Response: There is no fee applied in the regulations for the exception of local government employees or school employees in the regulations. A job description for these employees is not under the purview of the Department.

81. **Comment:** There needs to be consistency regarding when a mitigation system is deemed installed. A mitigation system should be considered installed when the fan is activated. (19)

Response: Proposed § 240.303(2)(i)(C) clarifies that installation means "the date of initial fan activation." No change was made in the final-form rulemaking.

82. **Comment:** I fail to understand why the radon division suddenly changed the way radiological instruments are exchanged for use, calibrated, checked prior to use and set aside for future need. The Department suddenly changed the calibration requirement to where an instrument is required to be back to the end user by the calibration due date. This practice is inconsistent with the rest of the regulated community. Some radiological labs use a device up to the end of the month of the date a survey meter is due for calibration. (19)

    Response: The instrument may be used to the last day that its calibration sticker permits. At that point, one can notify the Department to take the unit out of service, send it back for calibration, and, when ready, notify the Department that the unit can be placed back into service. This requirement in proposed §§ 240.605(a)(1) provides for precise timing of instrument calibration and has been retained in the final-form rulemaking.

83. **Comment:** A firm should not have to pay additional costs simply to have an employee. Health Physics labs can have as many employees as they need and train them commensurate with hazard per OSHA regulations. (19)

    Response: The Department has removed the proposed limitation of firm employees in §§ 240.102(b)(4) and 240.112(b)(5) from the final-form rulemaking. The Department has also removed the proposed requirement for firm employees to pass a Department-approved radon course from §§ 240.102(b)(4)(iii) and 240.112(b)(6)(iii). This proposed requirement has been replaced with initial training requirements that can be given by the firm's certified individual or through a Department-approved course.

84. **Comment:** The ALARA Health and Safety program should also extend to the occupants of the dwelling. (19)

    Response: The Department has no regulatory authority over the occupants of a dwelling.

85. **Comment:** There is no place to report data about passive system installations and failures. This data is easily acquired. (19)

    Response: There are reporting codes for reporting passive systems into Greenport, the Department's web-based method to report radon activities. Consideration will be given to adding a code for failures.

86. **Comment:** Paragraph 240.2a(2) limits the scope of the Department's oversight of radon practitioners and systems. Specifically, it provides an exception for new construction from conforming to the RMS. This exception would seem to be in direct violation of enabling Act 147. Section 102 of the Radiation Protection Act of July 10, 1984 states: *"The General Assembly hereby determines, declares and finds that, since radiation exposure has the*

potential for causing undesirable health effects, ***the citizens of the Commonwealth should be protected from unnecessary and harmful exposure resulting from*** *use of radioactive materials,* ***radiation sources,*** *accidents involving nuclear power and radioactive material transportation."* The Act does not instruct the Department to only protect citizens who are living in existing homes and fail to protect citizens living in newly constructed homes. It is the case that major home construction companies install passive radon piping in many of the homes built throughout Pennsylvania. It is also the case that certified mitigation professionals regularly encounter passive piping installed by unskilled and untrained tradesmen that fails to function. This was found REPEATEDLY in the neighborhood in Center Valley that received much publicity for exhibiting the highest residential radon levels ever recorded. Properly installed and functioning passive systems would have provided some degree of protection for these homeowners. Thus, the Department is failing to protect the citizens of the state from exactly the behavior the statute was designed to prevent. *Question 1: Why don't citizens who buy new homes have the same protections as existing homeowners, namely, protection against radon systems that are installed by unlicensed mitigators and don't meet national or PA-DEP standards? Question 2: How does the department reconcile its un-equal protection of PA citizens with the enabling statutory language reproduced above?* (6)

Although not in the regulations: It is respectfully recommended that the PA DEP Radon Section consider requiring builders performing new construction of homes with RRNC, to at a minimum, follow the ANSI AARST RRNC standards for all new construction. The builders and responsible subcontractors would sign a statement that they have installed RRNC in accordance to the ANSI RRNC standards, or use a properly qualified and certified radon mitigator to perform the RRNC installation. The RRNC, even if installed by the builder and their associated subcontractors would have a qualified-certified AARST RRNC designated radon mitigator to inspect and sign off on all RRNC design and installations. There is already verified evidence of incorrectly installed RRNC and active ASD systems in newly constructed homes. This would ensure that homebuyers and their families are truly getting the protection against the second leading cause of lung cancer. It could even be considered as part of the occupancy requirement for new construction. Another path would be to provide a specified training and certification program for builders. Initially, it could be voluntary. This would be critical in high zone 1 radon counties. This is the real substance and "standard of care" in meeting ALARA and protection of the public and new construction. (20)

In other words, a builder, developer or architect / engineer is exempt from any regulations for RRNC (Radon-Resistant New Construction) in new homes or buildings. This is the time and place to amend what has been missing since the original regulations. Our tallies and other's comparative tallies show a 40% failure rate when builder RRNC pre-pipe is activated. Why does this happen? Because the builders are under no laws nor obligation to get the RRNC installation correctly done. The pass, seemingly, was given to allow builders to install their own system as owners of the structures. This view is distorted but understandable. Reality is that builders (or their employees) do not install this pipe! It is primarily installed by plumbers that are subcontractors. The plumbers do not have any mandates (nor guidelines) to follow.

A builder is not allowed to have the plumber do the electric in a home. If subcontractors do the RRNC installation they should be certified radon mitigation individuals following AARST/ANSI RRNC 2.0. Homeowners very often believe that the RRNC pre-pipe (regardless of how it is installed or vented) means they are safe and never have to test. We, mitigation companies, see firsthand the anger and worry these duped homeowners have when they later (usually when selling) find levels of radon that are dangerously high! Builders are long gone but we see this weekly. It's years later and may have tragic consequences. Seems rather absurd to regulate the size and structure of a mitigation company. To allow unrestricted home and office searches, mandate radon mitigator training, exams, fees continuing education and reporting all in the name of radiation protection. At the same time allow builders, plumbers and designers to have no rules at all!!! Bad policy! Not Radiation Protection. If a certified mitigation individual subcontracts from a builder can he install anything he likes as the plumber can? Can a mitigation company have a non-certified company that only does builder work? Several class action lawsuits have been brought and won against builders and developers over poor radon systems and deception involving radon system installations. Unfortunately, settlements have been sealed. This oversight is a ticking bomb and Pennsylvanians most likely have died! The time is long overdue to correct this and fulfill the mandate of radiation protection! (23)

Response: The Department agrees that new homes should be built in accordance with radon resistant new construction standards. The Department will explore removing this exemption from Chapter 240 in a future rulemaking, which will allow all stakeholders to provide input on this important issue.

87. **Comment:** In § 240.2(a)(4), it adds "Department approved." The Radon Section is attempting to control research. There is no reason they should have to approve research as long as the conditions in the original wording are satisfied. The Department has not provided justification as to why this is necessary. The original wording should remain. (2)

Response: The Department agrees and has removed this language in the final-form rulemaking.

88. **Comment:** In § 240.2(a)(4)(ii), the results may very well be valid. Validity is a function of accuracy. The original wording, that the results "...are not certified" should remain. (2)

Response: Radon tests are not certified; the tester is certified. Therefore, if a test was performed by an uncertified tester for the purpose of the research, it would be considered an invalid test. The Department retained the proposed amendment in the final-form rulemaking.

89. **Comment:** § 240.2(a)(5) – Does this mean a real estate agent who buys and gives out, but does not place or retrieve secondary devices is exempt from the regulations? Does this mean a home inspector placing and retrieving secondary devices and getting the lab's report is not exempt? (2)

Response: In the first scenario, Chapter 240 would not apply to the real estate agent. In the second scenario, yes, Chapter 240 would apply to the home inspector.

90. **Comment:** § 240.2(a)(5)(ii) – The dictionary defines purvey as to provide or supply, as in sell. What are you really trying to say? This section seems confusing. (2)

Response: Section 240.2(a)(5)(ii) provides that Chapter 240 does not apply to a person who provides, supplies or sells secondary devices.

91. **Comment:** § 240.3 – ALARA – If the Radon Section wants to define ALARA, they should further refine "economic considerations." The US NRC uses $1000 per person-rem. Does the DEP subscribe to this same evaluation criteria? And if not, what is their economic criteria? It should be stated in the regulations. (2)

Response: The definition for ALARA has been removed from Chapter 240 in the final-form rulemaking. Instead, the substance of how to pursue ALARA is discussed in § 240.305.

92. **Comment:** § 240.3 – Measurement – Your definition appears to exclude actual test results in a structure. Is this your intent? (2)

Response: Yes, test results in a structure are covered under the definition of "test."

93. **Comment:** § 240.3 – suggested additions:
AC – Activated charcoal – change to "A device used to measure radon by exposing activated charcoal to air in the area to be tested and analyzed by gamma ray spectroscopy."

Blind study – change to "A study in which the certified person's device is exposed to a specific radon concentration in an approved radon chamber that is unknown to the certified person."

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

Spiked measurement or spike – change to "A QC measurement conducted in an approved radon chamber to evaluate accuracy by exposing the detector or device to a known concentration and submitted for analysis." (18)

Response: The Department agrees with the comment as to the definitions of "AC," "LS," and "spiked measurement" or "spike," and has made the suggested changes in the final-form rulemaking. The proposed definition of blind study has been removed because it is only used once in the regulation in § 240.203(a)(5), where it is explained.

94. **Comment:** §§ 240.101(b), 240.102(b), 240.121(b), and 240.122(b) - The change in language seems to prohibit having more than one certified individual, which was clearly

permissible in the old regulations. A business may want to have more than one certified individual for various reasons, such as, someone planning to retire, numerous testers being supervised by more than one certified individual, the certified person may be sick and die, in which case the company is out of business until another person is certified by the DEP, or, if the certified person is planning to retire and the company attempts to have someone certified while the first employee is still present so that experience can be transferred - this would not be permitted. There is no valid reason why "at least" should be deleted. The Radon Section is getting into business decisions that do not impact on the purpose of these regulations. The wording, "at least one person certified to test" should be retained or added to all four sections. (2)

I strenuously object to this regulation. The proposed regulation precisely as written, and as explained by the PA DEP Radon Division, limits the size of a radon mitigation company to six people and restricts five of the mitigation employees from full certification. If more than 6 individuals, a mitigation company must be divided into two independent, self-governing companies (these are separate companies not a ratio of certified to general workers in a company). It is apparent that this is unworkable. A company with 12 mitigation individuals, must divide into 2 companies with 2 certified individuals. Neither certified individual is permitted to direct any activities of the other certified company's workers. This means a large project (school, hospital, church, multifamily) that requires more than 5 or 6 installers must be done by 2 independent companies. This is unworkable even before accounting for illness, vacations, other commitments, etc. If any of the company's employees miss work, they cannot be replaced by the other company's workers. If a certified individual is absent for a time, the other certified individual cannot direct both sets of employees. I have experience with the rule, our company was placed under this directive and was fined for noncompliance. The 6-person-company directive has created a series of complications and caused added costs and difficulties in meeting our commitments. Our mission is to reduce naturally occurring radiation in homes and buildings, but this has entangled us with compliance complications. We have 4 certified individuals and 3 eligible (NRPP Tests passed and substantial experience). We would like to certify all and organize them as distinctive department heads. Not only is the regulation unworkable but per our legal advisors may also be unconstitutional. We did not have the will or the money to fight this. The intent to provide an organizational structure to radon mitigation companies, balancing certified to listed individuals is commendable but as written, these regulations are unnecessarily, unworkable. Arbitrarily breaking up companies in this manner is a Restraint of Trade. (23)

Response: The Department acknowledges the concern and has amended the final-form rulemaking to remove the proposed requirement that only one person in a firm can be certified. The term "person" was replaced with "individual" in this final-form rulemaking in §§ 240.101(b) and 240.111(b) for consistency.

95. **Comment:** §§ 240.102(b)(2) and 240.122(b)(2) – Why can a certified individual not also be a firm employee? I am the certified individual and also an employee of my company! Again, the Radon Section is micromanaging on business decisions that have no impact on the purpose of these regulations, without any justification. If you are a corporation and not an employee, you are not covered under many insurance companies. (2)

Response: These sections have been revised in the final-form rulemaking to remove proposed language prohibiting a certified individual from being a firm employee.

96. **Comment:** §§ 240.103(a)(3), 240.113(a)(3) and 240.123(a)(3) – Why is the date of birth needed? How is the PA DEP going to use the birth date without the last four digits of the social security number? Again, the Radon Section is trying to interfere with a company's business decisions without any justification. If the Radon Section is concerned that minors are attempting to obtain employment, simply state that no one under 18 years of age may work in this field. Why can't a 16- or 17-year-old work part time as a lab technician analyzing charcoal? I certainly hope they are not trying to set a maximum age. There are federal laws that prohibit age discrimination. (2)

    Why is the date of birth required? PA DEP does not require it for the certified radon tester or the certified radon mitigator or the radon firm testing employees. (20)

    Response: These sections have been revised in the final-form rulemaking to remove the proposed date of birth requirement.

97. **Comment:** §§ 240.102 and 240.112 – I agree with only having one certified person in charge, however, I feel that listing an employee prior to performing any radon-related activity puts an unnecessary burden on an employer. I typically have them experience what field work is like firsthand before I list them. I know of no better gauge than having them on the job for a day or two. I have had an employee quit after one or two days. I have also let employees go after one or two days. It could be because they are afraid or unsafe to be on a ladder or roof, or refuse to seal a crawlspace. Some new hires do not take direction well. At that point, my focus was on finding a replacement, not on what obligation do I have to the State to make sure I don't receive a fine! I feel 10 working days would be much more appropriate. A trainee under direct supervision poses no risk to the public. A trainee under the direct guidance and supervision of the firms certified individual will learn more about safety, procedures and processes than any course of test that could ever possibly be offered. And to whom is it more important that the new employee possesses the skill and knowledge to perform up to his employers' expectation, the employer or the government? At the end of the day that radon system will have my name on it. Is the certified individuals time better spent instructing the trainee, or sitting at his computer filling out a government reporting firm? (7)

    Response: The Department agrees that 10 business days is a reasonable and has made the appropriate changes to the proposed language in the final-form rulemaking.

98. **Comment:** § 240.111 (a) and (b) – The structuring of certification that sets up two tiers of either a certified individual or a certified individual under a certified firm is problematic, causes unfair burdens to firms and leads to abuses of the system. In PA a contractor is required to have contractor certification through the Home Improvement Contractor (HIC) program. This in effect requires an individual to be a business with insurance if he wants to do home improvement in PA. The certification program should work in conjunction with

this program and needs to be structured the same way. If you are accepting money in PA for radon services, then you are doing home improvement and need to act like and be certified as a firm not an individual. I recommend that the certification program require adherence to all PA home improvement contractor requirements. I strongly recommend that all PA Radon Certification programs be structured to require each certified individual must work under a certification firm. A Certified Mitigation or Testing individual cannot do work without being associated with a certified firm. An individual can however be both a single person certified firm and the certified individual of that firm. A firm can also have multiple certified individuals working for that firm. A certified individual in the firm can have up to five noncertified but listed employees under his supervision. Reporting of jobs and testing would be done under the firm. The job or testing reporting should include a requirement that the listed certified individual responsible for the job or test is included in the report. Any problems or issues with work whether from the DEP or the homeowner would be addressed to the firm. The Firm would be required to have HIC license. (11)

Response: Requiring certified individuals to work under a certified firm is not necessary. The name, street address and telephone number of the tester are required in the report. Also, 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 has been made to the final-form rulemaking in this regard.

99. **Comment:** § 240.111(b) – I assume that the last section is eliminated because it is in [ ]. (11)

Response: Yes, the language starting with "Not everyone within" and ending with "mitigation of radon contamination" has been deleted from this section.

100. **Comment:** § 240.112(b)(5) – PA DEP has no legal right to mandate that a company cannot expand beyond one certified individual or to mandate that a company certified individual has to report jobs as if he was the sole responsibility for that job. If that is the case, then that individual would have to be have a HIC license and carry his own insurance. Change the wording to: A mitigation firm may list a maximum of five mitigation firm employees at any one time under each of the firms listed certified mitigation individuals. (11)

Response: In the final-form rulemaking, the Department has removed the proposed limits of one certified individual per firm and five firm employees from the rulemaking. 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.

101. **Comment:** § 240.112(b)(6)(iii) stipulates that any mitigation FIRM employee must provide "Proof of passing a Department-approved course on radon mitigation or passing a

Department-approved mitigation exam." The FIRM structure is often utilized for mitigation "helpers" and apprentices. If the course is relatively basic and introductory, then it is most appropriate. In this case, I endorse the department's change. If, however, the full radon mitigation certification course/exam must be completed, then this is a very expensive and an unnecessary burden. The department needs to clarify its intentions. *What training course/exam will the department require for new radon mitigation FIRM employees? Does it exist yet?* (6)

§ 240.112(b)(6)(iii) This is a new requirement that is not defined. According to this section a mitigation employee must take a course and pass an exam?? Is this correct? Whose exam and what course must he take? (11)

Paragraph 240.112(b)(6)(iii) stipulates that any mitigation FIRM employee must provide "*Proof of passing a Department-approved course on radon mitigation or passing a Department-approved mitigation exam.*" I considered this proposed regulation unrealistic, burdensome, and a real threat to the radon mitigation industry business.

1. It is agreed that every mitigation installer worker should have proper training, including the safe operation of all equipment, proper use of PPE, OSHA health and safety practices, OSHA SDS education/awareness, and general education of radon risk and causal mechanics the radon lung cancer risk. This can be done in a 4-8-hour training and repeating training every 6 months. This course be NRPP approved and thus PA DEP approved. Each worker would provide signature of attendance, just like they do in the nuclear power industry.
2. Training every worker taking the full 3-5-day radon training provided by radon regional training centers and then each worker taking the exam and passing it is unnecessary.
3. The radon worker, radon gopher does not do radon design or select the fan size or determine the proper air flow. That is done by the certified radon mitigation "responsible person". The radon mitigation worker(s) will core holes in the floor, dig out the appropriate amount dirt and rock for suction pit. They will cut PVC pipe, put together and route the pipe as directed. You do not need a full 3 day training course and passing exam to properly do these actions.
4. This would cause any radon mitigator with firm employee workers to invest huge amount of money into their personnel that is not needed. What would stop that worker that was sent to a 3-5 day training course and supporting costs (hotel, meals, transportation) from deciding to quit and start his own company? Nothing. Even non-compete agreements that a mitigation firm owner would have a worker sign are not really binding. This would be considered a major threat to his business to train all workers to the level of a PA DEP certified mitigation person. This goes against basic business principles.
5. This regulation is anti-business.
6. What about the radon mitigation company secretary? She or he is a firm employee. Would they also need to be fully trained and pass an exam? (20)

§ 240.112 Since this regulation has changed for Mitigation Firm Employees, shouldn't there be more information on the newly required "exam or test." (23)

Response: The Department has removed the proposed requirement for firm employees to pass a Department-approved radon course. This proposed requirement has been replaced in the final-form rulemaking with initial training requirements that may be given by the firm's certified individual or through a Department-approved course. These amendments are in §§ 240.102(b)(6) and (b)(7), and 240.112(b)(6) and (b)(7).

102. Comment: § 240.112(7)(c) – Change wording to: A firm shall 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). All certified mitigation individuals and mitigation firm employees shall be familiar with these programs and abide by the requirements of these programs. (11)

Response: Section 240.112(c) was not revised in the final rulemaking because the Department believes the current language sufficiently explains the requirement to have health and safety and continuing education programs. The cross-reference to §§ 240.305 and 240.306 explains the requirements of those programs.

103. Comment: § 240.113 – It is the responsibility of the radon mitigation firm to track their employees, including their WLM tracking, with an individual employee file. If you are tracking mitigators, why not track the radon testers? Each of these trained persons enters into homes and buildings. Where is security differential? There is none. The PA DEP needs to provide viable supporting logistics to request this information. This regulation is inconsistent and discriminatory, besides being invasive. It should be totally removed. (20)

Response: Radon testers are much less susceptible to exposure than radon mitigators; therefore, it is unnecessary for testers to track it. Therefore, no change has been made to § 240.112(c).

104. Comment: § 240.114 – I'm not sure I understand this amendment. (7)

Response: Proposed § 240.114(b) clarifies that a late fee will be charged if a renewal application is postmarked after the certification expiration date. The proposed language remains in the final-form rulemaking.

105. Comment: Section 240.122(b) – The work experience should be spelled out. This would prevent the Radon Section from making up requirements at their whim. It appears the Radon Section wants to tie everything down as it applies to radon testing and mitigation industry but doesn't like to be tied down so that they are forced to follow strict requirements. (2)

Response: Work experience is addressed in § 240.122(a)(3) and is included to allow flexibility for a person without a bachelor's degree to become a certified individual. No change has been made to § 240.112(a)(3).

106. Comment: § 240.132(1) – Which states does PA have reciprocal agreements with? (11)

Response: Pennsylvania has not entered into any reciprocal agreements.

107. Comment: § 240.142 – My employees have their badges with them at all times, but asking to wear them in attics and crawlspaces means that I will be asking the Department for replacements at a much higher rate of frequency! I am also concerned that if an employee would like a day off, he could simply tell me his badge was lost. The last time I lost my badge, I had a vendor call me and tell me that it was found in their parking lot, and all I had done was load a few boxes into the trunk of my car. I view this requirement as a headache waiting to happen and feel it puts an undue burden on me as an employer. If the wording was changed to "Presented upon request" I would agree with it. (7)

Response: The Department agrees and has removed the proposed requirement to wear the badges in the final-form rulemaking.

108. Comment: § 240.203 (relating to conditions of certification) – Clarify this section and add the requirement for testing and laboratory individuals to pass blind studies conducted by the Department. This blind testing ensures accurate testing is being performed by the certified community with a percent error of less than or equal to +/- 25% of the reference value. Any studies conducted by the Department could be considered biased because the handlers of the devices have not participated in proficiency testing, have not taken a national exam and obtained certification. (19)

Response: The Department agrees that "testing and laboratory" should be added to § 240.203(a)(5) and has made the appropriate changes in the final-form rulemaking. In regards to biased studies done by the Department, Department employees have participated in proficiency testing when it was conducted by the EPA, have taken the five-day Rutgers course and the exam, and are exempt from certification according to the regulations. Performing blind studies is one of the best ways to ensure the public is receiving accurate test results.

109. Comment: § 240.203 – change to "Certified individuals shall pass blind studies conducted by the Department. Blind studies will be conducted in an approved radon chamber that has no conflict of interest with parties being subjected to blind testing. The individual measurement results of the blind study must achieve an individual RPE of less than or equal to +/- 25% of the RV. (18)

Response: The Department does not believe that conflict of interest will play a role in blind studies. If a certified individual believes that a failed blind study is invalid and suspects a conflict of interest, the certified individual can bring it to the Department's attention. Therefore, the requested change has not been made in the final-form rulemaking.

110. Comment: § 240.203(2) – Paragraph 240.203(2) stipulates, *"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."*

This clause in the rulemaking document would seem to be based on section 305 of the Radiation Protection Act of July 10. In this section the ACT is clearly concerned with radiation sources. Since radon mitigators and testers do not use such sources, it would seem to be inappropriate to maintain such an invasive policy. It would be more appropriate to specify a notification period. Note that the ACT does provide for the department to secure a search warrant should probable cause exist. That should be the mechanism for "surprise" searches. (6)

Paragraph 240.203(2) stipulates, "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 radon industry, both radon testers and radon mitigators do not use or have possession of radioactive sources. There are radon measurement systems that do have radioactive check sources, but the majority, more than 99% of the radon industry do not use these instruments. Some charcoal canister laboratories and radon chambers may have radioactive sources, but again, the majority of the radon industry does not. It seems, the standard audit process and violation process the PA DEP Radon Section has followed in notifying radon testing and mitigation firms should stay in place. There is no need for the PA DEP to draw a warrant to enter unannounced into a radon services firm. There is no threat to the public or surround environmental resources. THIS REGULATION SHOULD BE COMPLETELY REMOVED. The process of violations, audits and enforcement are very well defined already. This regulation is considered an extreme, unduly, and overbearing exercise of power. There is no threat to the public or danger to the environmental resources. This regulation borders on the violation of the 14th Amendment. (20)

So, the regulations allow the Department access to home, workplace or other premises. **"The Department and its agents and employees will… Enter the premises of a licensee or registrant for the purpose of making an investigation…"** Radon Companies are reducing naturally occurring radiation levels in homes but do not use devices that incorporate radioactive sources such as other Companies regulated by the Bureau of Radiation Protection. Allowing searches that waive the Fourth Amendment of the U.S. Constitution (A search or seizure is generally unreasonable and illegal without a warrant). This seems unnecessary for Radon Companies so if it is deemed necessary by the Department, the regulation should note the rational. (23)

Response: The Supreme Court of the United States has consistently held that, in the context of the Fourth Amendment, privacy interests are weakened for property employed in a "closely regulated" industry. *See New York v. Burger*, 482, U.S. 691 (1987). "Certain industries have such a history of government oversight that no reasonable expectation of privacy…could exist for a proprietor over the stock of such an enterprise." *Id.* 700 (citing *Marshall v. Barlow's, Inc.*, 435 U.S. 307, 313 (1987)). Courts look to "the pervasiveness and regularity of regulation of an industry and the effect of that regulation upon an owner's expectation to privacy." *Id.* 701.

Section 305 of the Radiation Protection Act also provides support for this provision, Section 2 of the Radon Certification Act requires the Department to implement a certification program to "protect property owners from unqualified or unscrupulous consultants or firms." 25 P.S. § 7110.305 and 63 P.S. § 2002. Section 2 of the Radon Certification Act indicates the General Assembly's intent to create a regulatory scheme for certified radon service providers.

The language in § 240.203(a)(2) allows the Department to reasonably inspect the regulated community to ensure compliance with the Radon Certification Act, the regulations promulgated thereunder, and the terms of the individual's certification. Therefore, no change has been made to the proposed language in the final-from rulemaking.

111. **Comment:** § 240.204 – I would like to agree, however, this year I did not receive my renewal packet until it was about 30 days from expiration. I know that was probably due to a changeover in DEP personnel, but technically I would have been in violation, and it was not with my control. (7)

Response: It is the responsibility of the certified individual to make a timely application for certification renewal. The Department attempts in all cases to process applications efficiently.

112. **Comment:** § 240.205 – Agree with the principle, however, the wording should be more specific. (7)

Response: The Department believes the language in § 240.205, as proposed, is clear and has therefore not amended it in the final-form rulemaking.

113. **Comment:** § 240.302 – I thought this was covered earlier. I recommend changing the wording to "Should" and "Upon request." What happens if you are called by a Realtor to view a vacant property or a home's owner who gives you access when there is no one present to present your ID? The way it is worded, you will be in violation and it is not within our control. (7)

Response: This section requires photo identification to be presented upon request. In the scenario described in the comment, a request has not been made for production of the identification, so the individual would not be in violation. Therefore, no change to this section, as proposed, has been made in the final-form rulemaking.

114. **Comment:** § 240.303 – I have concerns about changing the existing reporting method. There are frequent times that it is hard to get people to retest right away. Reasons range from real estate transactions that are delayed, home improvements taking place where the new owners will not be capable of maintaining closed house conditions until the renovations are completed, to people who refuse to test until cooler weather because they don't have or choose not to use air conditioning and will not test during that time. It doesn't matter what my guarantee states. I've been told that "radon levels are higher in the Winter, and you just

want me to test now so it will pass. If it flunks in January and you don't honor your guarantee, I'll take you to court" (expletives' omitted). In the 30 years I have been mitigating I have heard just about everything under the sun, and holding a Mitigator responsible for something that is well beyond any reasonable expectation of their control is an extremely unfair burden. (7)

Response: The Department revised § 240.303(4) in the final-form rulemaking by removing proposed language that required testing after system installation and by adding that the postmitigation test shall be reported in accordance with the 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."

115. **Comment:** § 240.303(3) – "If a secondary tester..." Which certified individual – the secondary tester or the certified individual of the laboratory? This should be clearly spelled out. (2)

Response: The Department revised this section in the final-form rulemaking to change "secondary tester" to "certified tester" and "certified individual" to "certified laboratory" to clarify who should be reporting to the client.

116. **Comment:** § 240.303(4) – Radon monitors sold over the internet are commonplace. Homeowners use these monitors to measure their own radon levels and loan the monitors to family members and friends. The homeowner is not required to perform a certified radon test. A homeowner also has the right to hire a certified radon contractor to install a radon system at his house no matter what radon level he has or how a radon level was determined. The DEP should not require an approved radon test prior to mitigation. This section implies the radon mitigation firm is performing the radon testing. (11)

Response: The Department has removed the proposed requirement for a test to be performed prior to a mitigation system installation in § 240.303(4) of the final-form rulemaking.

117. **Comment:** § 240.305 – Even using the highest measured concentration, which does not exist during the time of mitigation because venting the home by opening basement doors and windows is probably in the Workers Safety Program of every mitigator in the State, in 30 years I have never reached more than a fraction of the exposure limits. I view exposure tracking as a totally worthless waste of time and feel the language should be deleted from any regulation. Have you ever seen any exposure tracking that has ever reached 50% of the limit? I seriously doubt it! So why don't you remove this unnecessary burden and let us focus on something a little more productive? (7)

Response: Exposure tracking for radiation exposure is standard practice for anyone dealing with radioactive materials. The time it takes to record the pre-mitigation radon level and then use the time in the building to calculate one's exposure should not be burdensome. No change to § 240.305 has been made in the final-form rulemaking in this regard.

118. Comment: § 240.305 – This appears to indicate that only mitigators have to evaluate the radon exposure, as it should be since it is extremely unlikely that any tester would exceed 1, let alone 4 WLM/year. Is that the case? (2)

Response: Yes, only mitigators are required to track their radon progeny exposure.

119. Comment: § 240.306 – What does the last sentence mean? If a person is certified as both a tester and a laboratory, are 16 or 32 hours required? (2)

Response: The Department has revised § 240.306 in the final-form rulemaking to require 16 hours of continuing education regardless of the concurrent certifications.

120. Comment: § 240.308 – There are several radon mitigation standards and these standards have different requirements. A certified mitigation firm needs to define which standard they will use. This section is important because it defines the minimum mitigation system requirements that have to be followed no matter which standard is used. It is important therefore that this section include any significant minimum requirements that are not included in any of the other mitigation standards. One critical component that is part of the PA DEP RMS is the necessity of a certified radon mitigator to inspect a building prior to any mitigation work being done to define all aspects of the job that needs to be done in order to abide by the appropriate radon mitigation standards. A certified radon mitigator must take a course that reviews and defines all the mitigation requirements and pass an exam demonstrating at least a reasonable knowledge of those requirements. PA DEP RMS specifies that a mitigation installation cannot be started based on the decision of what needs to be done by a mitigation employee who has not passed the written exam or attended the 3-day mitigation class. At the end of the system installation the certified mitigator must inspect at least one-fifth of all jobs the mitigation firm employees perform that he was not on site for. At least one of the radon mitigation standards approved by DEP does not include this requirement. If PA DEP does not include this requirement, non-certified mitigators will be able to install hundreds of radon mitigation systems without a single inspection by a certified mitigator who has been trained in the requirements of radon mitigation standards.

I strongly recommend that the inspection requirements prior to and after mitigation as specified in the PA DEP RMS be included in this document. Imagine if the building code requirements for all construction in the State of PA would now be based on the honor system and building inspections were no longer required. That is what the new guidance is proposing. (11)

Response: The Department agrees and has added new § 240.308(a) to the final-form rulemaking, which requires a thorough visual inspection by the certified individual prior to mitigation.

121. Comment: § 240.308(a)(6) – This section needs a rewrite to include additional language to allow option of extending the termination point higher than a nearby vertical wall. There are many times that a roof changes height by 1 to 2 feet. Guidance should allow the termination

to be next to a roof change in height as long as it is above the higher roof if it is within 10' of the height change. Revise to: The termination point must be 10 feet or more horizontally from a vertical wall that extends above the roof or higher than the vertical wall. (11)

Response: The Department agrees with this comment and clarified this section in the final-form rulemaking accordingly. Proposed § 240.308(a)(6) was renumbered as § 240.308(b)(5) in the final-form rulemaking. Additionally, upon further consideration the Department believes 5 feet is more reasonable than the 10 feet proposed in subsection (a)(6) and has made this change in renumbered subsection (b)(5) in the final-form rulemaking.

122. Comment: § 240.308(b)(1) – These days there are lots of egress window wells with ladders in the well built in basements. A mitigator could define the floor of the large window well as grade and therefore install the fan in the egress window well. Add this language clarification to prevent this from happening. Revise to: (1) Below grade, in a window well or egress window well, or in the heated or cooled space in the building. (11)

Response: The Department agrees and has revised § 240.308 in the final-form rulemaking to prevent the installation of a fan in an egress window well. Proposed subsection (b)(1) was renumbered as subsection (c)(1) in the final-form rulemaking.

123. Comment: § 240.308(c)(1)(iii) – Foundation walls require water-proofing on the outside of the wall. We have yet to experience an elevated radon level in a building due to foundation cracks. The requirement to seal foundation walls without any science or personal experience of effectiveness is not justified.

Expansion and control joints often have vapor barrier under the cracks which provides an air seal. Our experience is that sealing the perimeter slab to foundation crack even if small can double to ten-fold increase sub-slab negative pressure. Center expansion joints typically do not give us anywhere as much pressure field change indicating they typically don't need to be sealed. If the vapor barrier is known to exist, then these cracks do not need to be sealed. When the suction hole is installed it can be determined that there is or is not a vapor retarder under the slab.

Revise to: (iii) Openings ~~or cracks in the foundation or~~ at expansion or control joints that have no vapor retarder membrane installed under the slab. (11)

Response: During an inspection it is not possible to know if there is a vapor membrane under the slab after the slab is poured. However, the proposed language in proposed § 240.308(c)(1)(iii) was revised to "Expansion or control joints" in the final-form rulemaking. Proposed subsection (c) was renumbered as subsection (d) in the final-form rulemaking. New subparagraphs (iv) "Openings around utility penetrations of the foundation walls" and (v) "Sump pits that allow entry of soil gas or that allow conditioned air to be drawn into a sub-slab depressurization system" were added to § 240.308(c)(1) in the final-form rulemaking to clarify the Department's concerns with foundations.

124. Comment: § 240.308(c)(3) – In almost every house that has a basement that is used even for storage or any slab that has finished walls there are "other openings or cracks that are inaccessible." The present wording of this section would require mitigators to provide written statements for every home that has a work bench or boxes blocking a perimeter crack. This is excessive.

Revise to: If the mitigator and homeowner determine that the perimeter channel drain cannot be sealed for water control reasons, ~~or that other openings or cracks are inaccessible,~~ then the mitigator may leave those areas unsealed and shall provide the following written statements to the homeowner: (11)

Response: The Department agrees that the proposed language in § 240.308 may be overly burdensome. Therefore, the section has been revised as suggested in the final-form rulemaking. Proposed subsection (c) was renumbered as subsection (d) in the final-form rulemaking.

125. Comment: § 240.308(c)(3)(i) and (ii) – What is an increased heating and cooling penalty? Replace penalty with cost. Most homeowners do not care if the efficiency of a radon system is reduced (ex. use of a larger than required fan). Homeowners are concerned if the effectiveness of the system is reduced. I would think the PA DEP would also be more concerned with system effectiveness. Change "decrease the efficiency" to "reduce the effectiveness." (11)

Response: The Department agrees and has revised § 240.308 as suggested in the final-form rulemaking. Proposed subsection (c) was renumbered as subsection (d) in the final-form rulemaking.

126. Comment: § 240.308(d)(1)(ii) and (iii) – The system label should only have the certified firm's ID. The owner needs to contact the firm if there are issues with the system not the original installer who may no longer work for the firm.

Revise (ii) to: The name and certification number of the mitigation certified firm.
Revise (iii) to: The contact number of the mitigation certified firm. (11)

Response: A firm may not always be performing the mitigation. Therefore, the revision to § 240.308 in the final-form rulemaking requires the name and certification number of the mitigation certified individual or firm in subparagraphs (ii) and (iii) to be listed on the mitigation system. Proposed subsection (d) was renumbered as subsection (e) in the final-form rulemaking.

127. Comment: § 240.309 – change (7) to "Multifamily building tests. Multifamily building tests shall be performed in accordance with ANSI/AARST MAMF-2017, "Protocol for Conducting Measurements of Radon and Radon Decay Products in Schools and Large Buildings," or its most recent version as determined by the Department. (18)

Response: The Department appreciates the correction and has made the suggested change in subsection (a)(7) in the final-form rulemaking. Proposed § 240.309 was renumbered as § 240.310 in the final-form rulemaking.

128. Comment: § 240.309 – By accepting ANSI standards you will increase the operating costs as these documents will continuously be revised and may require an associated exam and more costs. (19)

Response: The only ANSI/AARST standards that the Department currently requires relate to the testing and mitigation of multifamily buildings. The Department believes the cost associated with complying with these standards is outweighed by the benefit these standards provide for addressing radon issues in multifamily buildings. Proposed § 240.309 was renumbered as § 240.310 in the final-form rulemaking.

129. Comment: § 240.309(a)(4)(iv)(G) – Testing companies have no control over whether the mitigation system is operating or not, and we are typically under a time limit to test. If the system is not operating, it will usually result in an elevated measurement, thereby requiring additional remedial action or, at least having the person responsible for the house turning it back on. We are there to test under current conditions. (2)

Response: This comment concerns proposed § 240.309(a)(4)(v)(G). The Department has revised this provision in the final-form rulemaking by adding "If the system is not functioning, the client must be notified immediately." Proposed § 240.309 was renumbered as § 240.310 in the final-form rulemaking.

130. Comment: § 240.309(a)(4)(viii) – In many cases in real estate transactions, the property is vacant and we are retained by a third party national organization in another state, by a home inspector, or by a real estate agent. We have no control over whether the instructions are given to the person controlling the building. The sentence should end with "...control the building." (2)

Response: The Department agrees with the recommendation and has made the suggested revision in § 240.310(a)(4)(viii) in the final-form rulemaking. Proposed § 240.309 was renumbered as § 240.310 in the final-form rulemaking.

131. Comment: § 240.309(a)(6)(i) – "...secured against movement..." You cannot secure something against movement! The most you can do is employ an anti-tampering device that shows the device was moved. Most homeowners do not like driving nails and screws into their furniture. And even that does not secure it from movement unless you nail the furniture to the floor. The sentence should be rewritten to reflect reality. (2)

Response: The Department has revised this provision in § 240.310(a)(6)(i) in the final-form rulemaking to remove "secured against movement" in the final-form rulemaking. The section only requires an anti-tampering device. Proposed § 240.309 was renumbered as § 240.310 in the final-form rulemaking.

132. Comment: § 240.309(a)(6)(iv) – What if the building owner refuses to have these notices posted – what do we do? (2)

Response: The certified tester should document the refusal. The documentation does not need to be reported to the Department but must be available during an inspection. No change has been made to the final-form rulemaking. Proposed § 240.309 was renumbered as § 240.310 in the final rulemaking.

133. Comment: § 240.309(a)(10)(iii) – The guidance implies that if 30 days have passed you can no longer do a post mitigation test. Change the wording to require the test within 30 days but not disallow the test after 30 days.

Revise to: The post mitigation test shall be completed no ~~may not be performed sooner than 24 hours or~~ later than 30 days following the completion of and activation of the mitigation system or an alteration to an existing system. The test shall be initiated no sooner than 24 hours after the system activation. (11)

Response: The Department has added language regarding unforeseen circumstances in the final-form rulemaking to clarify when subparagraph (iii) would apply. This amendment provides flexibility in conducting postmitigation tests. Proposed § 240.309 was renumbered as § 240.310 in the final-form rulemaking.

134. Comment: §§ 240.309(b)(1)(vi) and 240.309(b)(2)(vi) – Does this apply to charcoal canisters with respect to the manufacturer and model? The manufacturer and model of the radon canister is of minimal interest to the client, especially if only one type of canister is used. (2)

Response: Yes, both the NRPP and NRSB websites show all devices by manufacturer and model number. Having this information on a report form can ensure the device in question is properly listed. Proposed § 240.309 was renumbered as § 240.310 in the final-form rulemaking.

135. Comment: § 240.309(b)(1)(xiii) – "...severe weather conditions" needs to be defined. (2)

Response: The proposed phrase "severe weather condition" has been replaced with "unusually severe storms or periods of high winds" in § 240.310(b)(1)(xiii) in the final-form rulemaking. Proposed § 240.309 was renumbered as § 240.310 in the final-form rulemaking.

136. Comment: § 240.309(b)(2)(v) and (viii) – As an analyzing lab, we can only provide the information back to the client if the client provides the information to us. Some clients want to keep some of this information private for legal reasons. (2)

Response: The Department has revised this section in the final-form rulemaking to add "as available" to § 240.310(b)(1) to account for these situations. Proposed § 240.309 was renumbered as § 240.310 in the final-form rulemaking.

137. Comment: §§ 240.604, 240.605 and 240.606 – Multiple references are found in Chapters 240.604-240.606 to the RPD tracking control charts as described in EPA 402-R-92-003, May 1993. Updated documents have been produced through the consensus-based process described above and published as ANSI-AARST National Standards. Additional work on quality assurance is ongoing and will be references in future editions of these standards. Referencing the most current version of the ANSI-AARST standards will ensure that the most common consensus-based products are referenced by the DEP and used by the certified radon community.

Make this change – "The RPD will be tracked using control charts from ANSI/AARST Standard MAH-2014 "Protocol for Conducting Measurements of Radon and Radon Decay Products in Homes", Appendix A.

Make this change – "If the plotted RPD result falls outside of the warning level, ANSI/AARST Standard MAH-2014 "Protocol for Conducting Measurements of Radon and Radon Decay Products in Homes." Appendix A. (18)

Response: The Department determined that, even though it is currently using the EPA standard(s), the warning and control limit numbers are the same as found in ANSI/AARST.

138. Comment: I agree with §§ 240.1, 240.2, 240.3, 240.101, 240.141, 240.201, 240.202, 240.304, 240.306 and 240.308 (but I thought these were already pretty clear), 240.501, 240.502, 240.603. (7)

Response: The Department appreciates the comment.

139. Comment: I defer to folks with certified devices for § 240.143. §§ 240.203, 240.307, 240.601, 240.602, 240.604, 240.605, 240.606, and Appendix B I defer because I do not possess the knowledge, experience or expertise of a Certified Tester or Laboratory.

§§ 240.121 through 240.124 – I defer to the opinion of Certified Laboratories. (7)

Response: The Department acknowledges the comment.

140. Comment: Appendix C – A complete and utter waste of time. (7)

Response: Tracking for radiation exposure is standard practice for anyone dealing with radioactive materials and is an appropriate method to protect worker health and safety. The Department has retained proposed Appendix C of Chapter 240 in this final-form rulemaking.

IRRC Comments

141. Comment: *Advances* in *equipment technology* - The Preamble states the EQB has not updated its regulations since 2009. Allegheny Health Network commented that "the rapid technological changes occurring in diagnostic images, including computerization and automation, require additional flexibility in these proposed regulations to allow appropriate responses to these ever-accelerating changes and improvements." Allegheny Health Network suggests relying more on the Qualified Medical Physicist (QMP) expertise and is concerned that detailed regulations will quickly become outdated and irrelevant. Another comment describes equipment that self-calibrates. In other instances, commentators describe computer controlled technology that incorporates internal controls to shut down the equipment if it is not used safely. In light of the public comments, we are concerned that, despite an allowance for exemptions such as § 215.31, portions of the proposed regulatory scheme will quickly become outdated. We recommend that the EQB reconsider the regulatory scheme of using prescriptive requirements and, where possible and appropriate, provide flexibility to accommodate advances in technology that are presently occurring and are certain to occur in the future. The EQB should also consider whether more reliance on the QMP might better accommodate advances in technology and better implement safety. (24)

Response: The Department agrees that there have been advances in technology. Article V, however, accommodates those advances. In general, 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. Besides the noted § 215.31 (relating to granting exemptions), which authorizes DEP to grant exemptions from Article V and thereby provides flexibility to address advances in technology, other sections in Article V 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. With respect to "prescriptive requirements" the Department strives to write regulations as performance based; however, certain requirements are not likely to change because they are basic operations. For example, radiographic devices will always use adjustments to kVp, mAs, half-value layer, exposure rate, and the like. Regarding reliance on QMPs as technology advances, the Department anticipates that the waiver requests discussed above will necessitate QMP involvement to ensure new technologies are being implemented safely.

142. Comment: *Department of Health regulations* – Regulatory Analysis Form (RAF) 13 asks the promulgating agency: "Will the regulation affect any other regulations of the

promulgating agency or other state agencies? If yes, explain and provide specific citations." The response to RAF 13 explains the Department of Environmental Protection's (Department) authority and states that "The Department of Health may have regulations regarding radiation. However, DEP's radiological health regulations would supersede them." Why didn't the response include citations to the Department of Health regulations that address radiology including 28 Pa. Code Chapters 127 (relating to radiology services) and 565 (relating to laboratory and radiology services)? While RAF 13 explains that the Department's regulation would supersede Department of Health regulations, the regulated community must comply with both regulations. How was the development of this regulation coordinated with the Department of Health to make sure there are no conflicts? We recommend that the EQB provide in the final regulation submittal an explanation of how it coordinated its regulation with the Department of Health regulations to make sure there are no conflicts for the regulated community. (24)

Response: DOH has regulations regarding radiation sources in 28 Pa. Code Chapters 51 (relating to general provisions), 127 and 565 that could be affected by this rulemaking. DOH is currently working on a regulatory update. DEP and DOH have held several meetings and have been working together to ensure DOH's regulations are consistent with DEP's regulations.

143. **Comment:** *Definitions* – Commentators identified several terms that are defined, but not used in the regulation. As an example, our search for the defined phrase "Medical reportable event for radiation-producing diagnostic or interventional X-ray procedures" did not find this term used in the body of either the proposed regulation or the existing regulation. In other instances, such as the terms "ALARA – as low as reasonably achievable" and "Blind study" defined in § 240.3, these terms are only used once in the proposed regulation (§§ 240.305 and 240.203(a)(5), respectively). It would be clearer to include an explanation of these terms in those sections rather than defining them in § 240.3. Therefore, we ask the EQB to review all of the proposed definitions to eliminate terms not used in the body of the regulation, make sure defined terms are used consistently in the body of the regulation, and consider whether definitions are needed for terms in instances where the terms are only used once. (24)

Response: The defined phrase "medical reportable event for radiation-producing diagnostic or interventional X-ray procedures" remains in the final-form rulemaking to distinguish the difference between the two types of reportable events that are discussed in Chapter 219. One type is for radiation-producing machine therapy and the other is for diagnostic or interventional procedures. "Medical reportable event for radiation-producing machine therapy" is defined in existing § 219.3 and applies to sections that are not part of this final-form rulemaking. The definition of "medical reportable event for radiation-producing diagnostic or interventional X-ray procedures" clarifies § 219.229. Section 219.229 is included in this final-form rulemaking and only covers diagnostic or interventional procedures. The title of § 219.229 has be revised in the final-form rulemaking to "diagnostic or interventional procedure medical reports" to avoid confusion and to clarify the types of reportable events that are covered by this section. The proposed term "blind study" is a common term used in all types of scientific studies, but has been removed from the definitions proposed in § 240.3 and is

explained in § 240.203(a)(5) in the final-form rulemaking. The proposed term "ALARA" in § 240.3 has been removed in the final-form rulemaking. Instead, the substance of how to pursue ALARA is discussed in § 240.305. The Department reviewed all of the proposed definitions to make sure terms are used consistently in the body of the regulation and to consider which definitions should be removed from the rulemaking.

144. **Comment:** *Preamble* – In our review of regulations, we refer to the Preamble for an explanation of the amendments, including the need for the amendment. The Preamble to the proposed amendments does not include all amendments and also does not explain why certain amendments are needed. For the final regulation, the Preamble should be amended to include these explanations. (24)

Response: The Order in the final-form rulemaking includes all amendments made to the final-form rulemaking and reasons for them.

145. **Comment:** *Compliance Costs* – The Preamble explains costs imposed by the regulation including costs relating to Qualified Medical Professionals and radon certification. However, the response to RAF 18 states there are no costs or adverse effects associated with the proposed rulemaking. How are these explanations consistent with each other? Furthermore, commentators believe the proposed regulation imposes operational costs, supervisory costs and compliance costs relating to outdated regulations. We ask the EQB to review and amend the responses in the Preamble and the RAF for the final regulation. (24)

Response: The response to question 18 in the RAF states how the benefits outweigh the costs that may be encountered. The RAF and Order associated with the final-form rulemaking have been updated from the proposed rulemaking. Also, the cost for a Qualified Medical Physicist (QMP) is associated with the cost to achieve certification with a recognized organization or board. The Department does not address Qualified Medical "Professionals" in its regulations. In retrospect, the Preamble associated with the proposed rulemaking should not have included costs regarding QMPs, just as the Department does not include costs to be a licensed physician, a medical radiologist or a radiologic technologist. With regards to the benefits outweighing costs associated with radon certification, the benefits of the radon certification amendments include adding clarity to the application and reporting requirements and make it easier for the regulated community to understand what is required during each process. The benefits of the amendments to the radon testing and mitigation protocols and quality assurance and quality control requirements include ensuring that radon services provided to the public will protect the public's health and welfare from the dangers of radon.

146. **Comment:** *Business Days* – Several provisions require notice to the Department within a specific time period such as five days or 10 days. Commentators asked that these time periods be business days rather than calendar days. We agree. (24)

Response: The specific time periods have been revised to "business days" in the final-form rulemaking.

147. Comment: § 219.3. Definitions. - clarity – *Medical Reportable event for radiation-producing diagnostic or interventional X-ray procedures* - If this definition is retained in the final regulation, we have two comments. First, Paragraph (i) specifies a dose of "3 Gy (300 rad)." Commentators questioned this dose and believe it is too low. The EQB should explain why 3 Gy is the appropriate dose. Second, this definition uses the phrase "unintended dose." The phrase "unintended dose" is defined in § 221.2. Should this definition also be included in § 219.3? (24)

Response: The 3 Gy limit is recommended by NCRP as an appropriate substantial radiation dose limit. However, the Department has considered this concern and changed the dose to 15 Gy in the final-form rulemaking based on recommendations of The Joint Commission—a national health care accreditation body—and the Department's discussions with RPAC. A limit of 15 Gy still maintains the importance of a good quality assurance program. Regarding "unintended dose," this term addresses diagnostic or interventional X-ray, and is therefore more appropriately placed in Chapter 221 (relating to x-rays in the healing arts).

148. Comment: § 219.229. Other medical reports. - clarity – *Subsection (b)* - The phrase "medical event" is used in this subsection. However, it is not clear what constitutes a "medical event" that would require reporting. Should this subsection use the defined term "Medical reportable event for radiation-producing diagnostic or interventional X-ray procedures"? (24)

Response: This phrase has been revised in the final-form rulemaking to include "medical <u>reportable</u> event."

149. Comment: § 221.2. Definitions. – Protection of the public health. – *QMP - Qualified medical physicist* - The American Association of Physicists in Medicine (AAPM) commented that this definition is insufficient to ensure that individuals providing the designated medical physics services are qualified to do so. AAPM provides suggestions for amending the definition. We recommend that the EQB consider incorporating AAPM's suggested revisions into the final regulation, or explain why it is not in the public interest to do so. (24)

Response: AAPM's definition is a restricted definition. The Department believes the individuals providing the medical physics services are already qualified to do so. The Department solicited advice from the RPAC and other reputable organizations in determining appropriate qualifications. It would not be reasonable to say the individuals already performing these services are not qualified to do so. Therefore, the proposed definition has not been changed in the final-form rulemaking and will continue to allow equivalent qualifications.

150. Comment: §§ 221.11 and 221.16 require continuing education, but the regulation does not specify the number of hours. We recommend adding the required number of hours in the final regulation. (24)

Response: The Department has not codified the number of hours due to confusion that often occurs when applying educational units or contact hours to continuing education

requirements. The radiation safety training must be documented to satisfy the regulation.

151. Comment: § 240.2. Scope. – Protection of the public health; Clarity; Reasonableness; Implementation procedures. – The Preamble explains that there are two proposed amendments to this section: Proposed amendments to § 240.2 (relating to scope) revise certification exceptions from the building that the person occupies to the building in which the person resides for clarity. A new certification exception is proposed to be added to clarify existing requirements for employees of local governments and schools who perform radon testing. Several public comments were submitted on this section. Some comments addressed proposed amendments and some addressed existing language that was not proposed for revision. For example, S.W.A.T. Environmental of Pennsylvania believes existing language in Paragraph (a)(2) violates the statute and does not adequately protect the public health. A.B.E. Radiation Measurements Laboratory's comments address concerns with amendments to §§ 240.2(a)(4), (a)(4)(ii) and (a)(5). There appears to be concerns and confusion with § 240.2, which sets the scope for all of Chapter 240, relating to Radon Certification. We recommend that the EQB review this entire section and work with the regulated community to clarify the scope of Chapter 240. (24)

Response: The Department has reviewed this section and worked with the regulated community through the RPAC's Radon Subcommittee on this final-form rulemaking. For concerns related to §§ 240.2(a)(2), 240.2(a)(4)(ii), and 240.2(5) see responses to comment # 86, 88, and 89 . These responses clarify the Department's position on these subsections. The proposed phrase "Department-approved" was removed from § 240.2(a)(4) in the final-form rulemaking.

152. Comment: § 240.3. Definitions. –Clarity; Reasonableness. – *ALARA - as low as reasonably achievable* - The definition of this term 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." These phrases are subjective and do not set a clear standard for compliance. What would meet the standard of every reasonable effort? What economic considerations must be considered? What constitutes a societal concern that must be considered? It may be clearer to delete ALARA from § 240.3 and specify the practices that must be followed in § 240.305, which appears to be the only section of the regulation where ALARA is referenced. (24)

Response: The proposed definition for ALARA has been removed from Chapter 240 in the final-form rulemaking. Instead, the substance of how to pursue ALARA is discussed in the § 240.305 in the final-form rulemaking.

153. Comment: § 240.101. Requirements for radon testing certification. – Need; Reasonableness; Economic impact. – *Subsection (b)* – This subsection is amended from allowing "at least one person certified to test" to "one individual certified to test." Commentators explained the new language presents problems when a single person is not available due to illness, quitting or retirement. We agree that the new language is unnecessarily restrictive. We recommend maintaining the existing language. Alternatively, the EQB should explain the need for, reasonableness and economic impact of precluding a firm from employing more than one

individual who is certified to test. This same concern applies to similar amendments or language proposed for Subsections (b) in §§ 240.102, 240.121 and 240.122. (24)

Response: The Department acknowledges the concern and has amended the final-form rulemaking to remove the proposed requirement that only one person in a firm can be certified. The term "person" was replaced with "individual" in this final-form rulemaking in §§ 240.101(b) and 240.111(b) for consistency.

154. Comment: § 240.102. Prerequisites for radon testing certification. – Need; Reasonableness; Economic impact; Less costly and less intrusive alternatives. – *Need for less intrusive alternatives to requiring written approval from the Department* – We have several concerns with this section of the regulation as set forth in the following discussion. Our concerns relate to the following criteria found in the RRA. Economic impact including: adverse effects on prices of services and costs to the private sector; need for the regulation; reasonableness of requirements; and, whether a less costly or less intrusive alternative method of achieving the same goal of the regulation has been considered for regulations impacting small business. We ask the EQB to carefully consider these criteria in its responses to the comments on this section, as well as similar provisions in §§ 240.112 and 240.122 cited at the conclusion of this comment.

Subparagraph (b)(1)(ii) – This provision states certification 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." The proposed amendment replaces a relatively simple notice to the Department with an indefinite time period during which the firm would be out of business while waiting for written approval from the Department. The Preamble description does not include this proposed amendment. Therefore, the EQB has not provided an explanation of the need for the amendments and it is not clear whether the economic impact of this amendment is included in the EQB's cost analysis of this regulation.

In determining whether the regulation is in the public interest, the criteria in the RRA require us to consider whether a less costly and less intrusive alternative method of achieving the goal of the regulation has been considered for regulations impacting small business. A firm may lose its certified individual on very short notice and may find a new certified individual quickly. Under existing regulation, this process could potentially be completed in a day, particularly because it is in the firm's business interest to do so. The regulation fails to specify a time period for the Department to respond. For these reasons, we recommend deleting this amendment. Alternatively, the EQB should explain the costs imposed by the amendment, how those costs are justified and how it considered less costly and less intrusive alternatives, including retaining the existing regulation. (24)

Response: Written Department approval has been the current practice and, whenever possible, when the change of a certified individual may be anticipated, the Department works with the firm to ensure there is no lapse in the firm certification. The proposed requirements, retained in the final-form rulemaking, codify this practice. This practice ensures that qualified individuals are supervising the firm's activities. This amendment does not impose any new cost on firms because firms are not, and never have been, permitted to operate without a certified individual. The benefit to the public of having adequately trained certified individuals supervising firm activities outweighs any loss of

business incurred by the firm in this scenario. For the Department to ensure that a correctly certified individual is in responsible charge of that firm's activities, it is vital to track and account for all changes of a firm's certified individual.

Paragraph (b)(2) – This paragraph adds a new requirement that the firm's certified individual may not also be a testing firm employee. What is the reason for this requirement? The Preamble does not include this addition and therefore does not explain the need for it. A commentator questioned why this provision was added. We agree that the EQB has not provided an explanation of the need for, reasonableness and economic impact of adding this provision. We recommend deleting it unless the EQB can provide justification for adding it. (24)

Response: The Department has deleted the proposed language prohibiting a certified individual from being a firm employee in the final-form rulemaking.

Paragraph (b)(3) – This provision requires a notice by the firm's certified individual to invalidate an employee's Department listing. Why wouldn't notice be the responsibility of the firm owner? (24)

Response: The certified individual is the person in responsible charge of the firm's radon-related activities and is therefore responsible for notifying the Department of this change.

Paragraph (b)(4) – This paragraph states a testing firm may list a maximum of five testing firm employees at one time. The Preamble states this limit is to "ensure adequate responsible charge by the certified individual." We agree with several commentators who do not believe the EQB has provided adequate support for the need for, reasonableness and economic impact of this provision. Therefore, we recommend deleting this provision. Alternatively, if the EQB retains a limit in the final regulation, it should explain its authority to impose a limit, provide support for the need for a limit including supporting data, explain how the limit was determined, provide an analysis of the economic impact of the limit on businesses, and explain why the limit is in the public interest. (24)

Response: The Department has deleted this proposed requirement in the final-form rulemaking.

Paragraph (b)(7) – Should the Department's written approval be to the firm's owner rather than the firm's certified individual? (24)

Response: The Department's written approval is appropriately sent to the firm's certified individual because the certified individual is the person in responsible charge of the firm's radon-related activities, as noted in response to the question concerning § 240102(b)(3), above.

Subsections 240.112(b) relating to radon mitigation certification and 240.122 (b) relating to laboratory certification – These concerns with Subsection 240.102(b) also apply to similar requirements in Subsections 240.112(b)(1)(ii), (2), (3), (5) and (7), relating to radon mitigation certification and 240.122(b)(1)(ii), (2), (3) and (6) relating to laboratory certification. (24)

Response: The Department's response above regarding § 240.102(b) also applies to these sections.

155. Comment: § 240.103. Radon testing application contents. – Need. – *Paragraph (a)(3)* – This paragraph requires the applicant's date of birth. Commentators questioned the need for the date of birth. We also question how the Department will use the applicant's date of birth. Is the intent to limit the age of an applicant? The EQB should explain the need for this requirement. The same questions apply to Paragraphs 240.113(a)(3) and 240.123(a)(3). (24)

Response: The proposed requirement to provide a date of birth has been removed in the final-form rulemaking.

156. Comment: § 240.306 – Clarity; Need; Reasonableness; Economic impact. – A commentator questions the last sentence of this section which states continuing education hours may only be used for one certification period for each certification activity. If a person is certified as both a tester and a laboratory, are 16 or 32 hours of continuing education required? The explanation of this amendment is not clear in the Preamble. We recommend that the EQB clearly establish in the regulation the number of continuing education hours required. Furthermore, if it is the EQB's intent to require 32 hours for those certified in two areas, the EQB should explain why the continuing education hours should not apply to both certifications. (24)

Response: The Department has revised the proposed language in § 240.306 in the final-form rulemaking to require 16 hours of continuing education regardless of the concurrent certifications.

157. Comment: § 240.308. Radon mitigation standards. – Reasonableness; Feasibility; Clarity. – *Subsection (a)* – We have three concerns. First, this subsection states a terminal discharge must meet "all" of the seven requirements listed. However, the requirements then describe different discharge scenarios, such as vent pipes attached to the side of the building and vent pipes that penetrate the roof. Would a vent pipe typically be attached to the side of a building and penetrate the roof? If not, the discharge would not meet "all" of the seven requirements. We recommend rephrasing Subsection (a). Second, Paragraph (6) requires a termination point to be 10 feet or more horizontally from a vertical wall that extends above the roof. Could the termination point also comply by extending above the vertical wall that extends above the roof? Third, Subsection (a) uses the term "conditioned spaces," whereas Subsection (b) uses the term "heated or cooled space of a building." Is there a difference? If so, the EQB should explain the difference in the regulation. If not, the same terminology should be used in both subsections.

Subsection (c) – In Subparagraph (3)(i) should the word "cost" be used rather than "penalty"? In Subparagraph (3)(ii) would the "efficiency" of the radon mitigation system be decreased or the "effectiveness"? (24)

Response: Proposed § 240.308(a), which has been renumbered as § 240.308(b) in the final-form rulemaking, has been revised and rephrased to address the different requirements for different discharge scenarios. The Department agrees with the recommendations in the comment and has revised § 240.308(b)(1) and clarified

§ 240.308(b)(5) in the final-form rulemaking. Additionally, the Department believes 5 feet is more reasonable than 10 feet and has made this revision in the final-form rulemaking. The phrase "heated or cooled space of a building" has been revised to "conditioned space of a building" and the term "penalty" has been revised to "cost" in the final-form rulemaking. Proposed § 240.308(a)(7) was renumbered as § 240.308(b)(6) and expanded to clarify that the termination point 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.

158. **Comment:** § 240.309(a)(4)(v)(G) – This provision states the mitigation system must be functioning during the test period. A commentator questioned what to do if the mitigation system isn't working. The final regulation should address the situation where a mitigation system is not working. (24)

Response: The Department has revised this proposed section in the final-form rulemaking by adding "If the system is not functioning, the client must be notified immediately." The Department notes that § 240.309 was renumbered as § 240.310 in the final-form rulemaking.

159. **Comment:** § 240.309(a)(6)(i) – This subparagraph requires testing devices to be "secured against movement by employing anti-tampering methods." This requirement is vague and it is not clear what actions would be required to comply. This provision should be rewritten to provide clear direction on how to comply. (24)

Response: The Department has revised this section in the final-form rulemaking to remove "secured against movement." The section now only requires an anti-tampering device. Section 240.309 was renumbered to § 240.310 in the final-form rulemaking.

160. **Comment:** Miscellaneous Clarity. – Should the definition of "General supervision" in § 221.2 state "by a licensed practitioner" rather than "of a licensed practitioner"? In Paragraphs 221.65(1) and (3), the phrasing of the exemption is not clear. Would these paragraphs be clearer by stating "the CT system is exempt from Section..."? Paragraph 221.204(c)(1) requires surveys in certain circumstances. A timeframe to complete the surveys should be added. Should § 223.22 also include research on animals? (24)

Response: For the definition of "general supervision" in § 221.2, the Department's intent is to remain consistent with the applicable phrasing in the term "supervision" defined by the Department of State in 49 Pa. Code § 25.142 (relating to definitions). Furthermore, the phrase "of a licensed practitioner" is similar to "of a QMP," which is used several times in the final-form rulemaking. The Department considered the comment related to proposed §§ 221.65(1) and (3) and has, in the final-form rulemaking, combined the two provisions into one paragraph that begins "CT systems identified in this section are exempt from..." The type of CT system must be identified because there are different types of CT systems, and only the X-ray attenuation systems are exempt. Section 221.204(c) was revised in the final-form rulemaking to state "CT X-ray systems shall have a survey performed at the time of installation..." The survey need not be repeated unless there is a change in the facility or equipment. Because §

223.1 addresses research on animals, research on animals need not be added to § 223.22.

Jefferson.

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December 14, 2017

The Honorable Patrick McDonnell, Secretary
Department of Environmental Protection
P. O. Box 2063
Harrisburg, PA 17105-2063

Dear Secretary McDonnell:

I am writing to inform you of actions taken by the Radiation Protection Advisory Committee (RPAC) at its October 19, 2017 meeting.

At the RPAC meeting, the RPAC completed review of the final proposed Radiological Health Regulations as presented by the Department, specifically proposed final regulations in Chapter 215 General Provisions, Chapter 216 Registration of Radiation-Producing Machines and Radiation-Producing Machine Service Providers; Chapter 217 Licensing of Radioactive Material; Chapter 218 Fees; Chapter 219 Standards for Protection Against Radiation; Chapter 220 Notices, Instructions, and Reports to Workers, Inspections and Investigations; Chapter 221 X-rays in the Healing Arts; Chapter 223 Veterinary Medicine; Chapter 225 Radiation Safety Requirements for Industrial Radiographic Operations; Chapter 227 Radiation Safety Requirements for Analytical X-ray Equipment, X-ray Gauging Equipment, Electron Microscopes, and X-ray Calibration Systems; Chapter 228 Radiation Safety Requirements for Particle Accelerators; Chapter 230 Packaging and Transportation of Radioactive Material; and Chapter 240 Radon Certification.

The Committee voted unanimously to concur with the Department's recommendation to present the final rulemaking amendment to the Environmental Quality Board, for consideration for adoption and publication as final rulemaking.

If you have any questions regarding this action, please call me at 215.955.7813 or email me at John.Keklak@jefferson.edu.

Sincerely,

John Keklak, CHP
Chair

c: George Hartenstein, PA DEP
David Allard, PA DEP
Joseph Melnic, PA DEP RPAC Liaison

pennsylvania
DEPARTMENT OF ENVIRONMENTAL PROTECTION

July 16, 2018

David Sumner
Executive Director
Independent Regulatory Review Commission
333 Market Street, 14th Floor
Harrisburg, PA 17120

Re: Final Rulemaking: Radiological Health (**#7-499**)
Final-Omitted Rulemaking: U.S. Nuclear Regulatory Commission Consistency Rule **(#7-550)**

Dear Mr. Sumner:

Pursuant to Section 5(a) of the Regulatory Review Act, please find enclosed copies of one final-form rulemaking and one final-omitted rulemaking for review by the Independent Regulatory Review Commission (IRRC). The Environmental Quality Board (Board) adopted these rulemakings at its June 19, 2018 meeting.

The **Radiological Health (#7-499)** final-form rulemaking amends Chapters 215-221, 223-228, 230, 232, and 240 to establish and maintain adequate radiation protection standards and oversight due to significant technological advances in the use of radiation sources, based on standards set by current recognized accrediting bodies and national organizations. Further, this rulemaking clarifies radon certification application requirements and reporting requirements for certified radon service providers. The rulemaking also amends testing and mitigation protocol requirements and quality assurance and quality control requirements to provide greater detail regarding program design and goals. Amendments included in this rulemaking also remove Agreement State transitional language and outdated requirements.

The Radiation Protection Act (RPA), 35 P.S. §§ 7110.101-7110.703, requires the Department of Environmental Protection (Department) to establish and maintain a comprehensive program of radiation protection including registration, licensing, regulation and control of radiation, radiologic procedures, radiation sources and users of radiation sources. The Radon Certification Act (RCA), 63 P.S. §§ 2001-2014, requires the Department to establish and implement a program of certification of persons who perform radon testing or carry out radon mitigation activities.

Changes to Radiological Health chapters from the proposed rulemaking include:

- reversing units of radiation doses to be consistent with PA and national standards;
- raising peak skin dose from 3 gray (Gy) to 15 Gy for dose criteria in the definition of "medical reportable event for radiation-producing diagnostic or interventional X-ray procedures";
- clarifying exemptions, evaluation intervals, Computed Tomography Dose Index ($CTDI_w$) definition, and CT X-ray systems when surveys need to be performed;

- clarifying the distance appropriate persons may be from the radiation-producing device in a veterinary medicine facility during radiographic exposure; and
- eliminating Agreement State transitional language.

Changes in Chapter 240 (Radon) from the proposed rulemaking include:

- clarifying the types of radon testing devices;
- deleting Department approval for scientific research;
- deleting definitions for terms either used once or not at all in the regulations;
- clarifying definitions;
- deleting the limit on the number of firm certified individuals and employees and a firm's certified individuals' disallowance to also be firm employees;
- adding a demonstration that a certified individual will maintain adequate span of control of employees;
- changing the requirement for firm employees to pass a Department-approved course or exam for initial training and continuing education requirements;
- deleting the birth date requirement;
- deleting the requirement to wear a Department-issued identification badge while performing services;
- adding a requirement that a building owner or occupant is to receive test results:
- clarifying reporting requirements to the client and post-mitigation tests;
- deleting the need to perform radon tests prior to mitigation installation;
- deleting duplicative continuing education requirements;
- clarifying mitigation standards;
- adding a requirement to notify the client of malfunctioning mitigation system during the test period;
- clarifying the use of anti-tampering devices;
- clarifying testing timeframe requirements;
- deleting unnecessary tracking of serial numbers, calculating control and warning levels, and electret voltage drift testing.

These amendments affect approximately 11,000 x-ray machine registrants, 825 radioactive materials licensees, 150 accelerator licensees, 325 service providers, and approximately 600 radon service providers.

A small number of registrants will be affected by the new requirement to use a qualified medical physicist (QMP). Most registrants already employ the services of a QMP, or a person with the same qualifications. All registrants and licensees will be affected by the requirement to have a written directive (prescription) by a licensed physician before the administration of any radiation source. Many of the requirements in the final-form rulemaking reflect current industry practices due to Medicare and the insurance industry requirements and therefore are not expected to impose additional requirements on the regulated community.

The public and businesses could be affected by the radon regulations if they use or provide radon mitigation services. The increased requirements for businesses are merely a codification of long-standing guidance documents published by the Department and U.S. Environmental Protection

Agency (EPA) and are considered standard practice. Other amendments in this rulemaking eliminate some current requirements of the radon industry such as testing prior to mitigation and unnecessary equipment checks and tests.

Users of radiation sources are required to comply with radiation protection standards that would not only protect employees but also the public. The final-form rulemaking ensures that trained professionals are operating these radiation sources so that both the patient and the operator are adequately protected. Because the requirements reflect current practices. this rulemaking is not expected to result in additional costs to the regulated community.

This final-form rulemaking clarifies the radon certification application and reporting requirements, making it easier for the regulated community to understand what is required during each process. Most of the new provisions will reduce the burden on businesses in both paperwork and operations, such as eliminating unnecessary equipment checks. The elimination of the requirement to pay certification fees a second time to reinstate a previously withdrawn application saves the firm or individual anywhere from $450 to $1,125. Benefits to the public include greater consistency in the services provided, improved indoor air quality with subsequent health benefits, and increased home value. Documentation requirements added in Chapter 240 in this final-form rulemaking regarding initial and ongoing training of employees by the certified individual replaced the more restrictive and costly requirement that was proposed for employees to take an approved course or exam. The documentation requirement to show how a certified individual will maintain oversight and responsibility of employees replaces the more restrictive and costly previously proposed requirement of limiting the number of firm employees.

The proposed rulemaking was adopted by the Board on October 18, 2016, and published with a 45-day public comment period on May 13, 2017. A webinar was held for the Radiological Health chapters on May 31, 2017. A separate webinar was also held on that date for Chapter 240 (Radon). Further outreach and implementation support will be provided by regional inspectors and technical staff.

Common themes raised in comments are as follows. Concerns were raised regarding the dose criteria in the definition of "medical reportable event for radiation-producing diagnostic or interventional X-ray procedures." The Department revised the dose criteria as suggested.

Several commentators requested that continuing education hours be codified. The final-form rulemaking was not revised to accommodate this request due to the confusion often occurring when applying education units or contact hours to continuing education requirements.

Several commentators recommended not limiting the number of radon firm certified individuals and employees. These limits were removed as suggested.

A concern was raised regarding firm employees being required to complete a Department-approved course or exam. These requirements have been revised to allow the training of the firm employees to be conducted by the certified individual.

Several commentators questioned the need to include the date of birth on applications for employees. This requirement has been deleted in the final-form rulemaking.

One commentator noted a possible overlap between the Department and the Department of Health's (DOH) regulations regarding radiology. 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.

All comments were considered and are addressed in the comment and response document that accompanies this final-form rulemaking.

The public comments and regulatory revisions were reviewed in detail with RPAC on October 19, 2017. Following discussion, RPAC members suggesting adding flexibility for the evaluation of spot films by adding "or digital acquisition modes" in § 221.35a(c). RPAC also suggested adding the term "high risk" into the definition of "FGI—fluoroscopic guided interventional procedures" to avoid unnecessary regulatory burdens for low risk FGI procedures. Both suggested amendments were made in the final-form rulemaking.

The **U.S. Nuclear Regulatory Commission Consistency (#7-550)** final-omitted rulemaking amends Chapters 215, 217, 230 and 232 (relating to general provisions; licensing of radioactive materials; packaging and transportation of radioactive material; and licenses and radiation safety requirements for irradiators) to exclude specific provisions of Title 10, Chapter I (relating to Nuclear Regulatory Commission) of the Code of Federal Regulations (CFR) from incorporation-by-reference in these chapters.

The Commonwealth and the NRC entered into an agreement in 2008 in which the Commonwealth agreed to oversee and regulate most types of radioactive materials used in this Commonwealth. As part of that agreement, the Commonwealth's radioactive materials program must remain compatible with NRC's radioactive materials program, under 42 U.S.C. § 2021(d)(2) (relating to cooperation with States). The Commonwealth meets this requirement by incorporating the appropriate NRC regulations by reference in 25 Pa. Code Article V (relating to radiological health). The NRC recently identified provisions of 10 CFR that should be excluded from the Commonwealth's incorporation-by-reference. This final-omitted rulemaking is necessary for the Commonwealth's radioactive materials program to remain compatible with NRC's program, because the citations to 10 CFR that the Board is excluding can only be implemented by the NRC.

The failure to exclude these sections from the Commonwealth's incorporation-by-reference of select Federal regulations was an oversight in the 2008 rulemaking (38 Pa.B. 2243, May 17, 2008) promulgated to support the 2008 agreement with the NRC. Examples of Federal provisions excluded by these amendments are: definitions of terms such as "construction" and "commencement of construction" dealing with national defense; provisions involving the sale and distribution of radioactive material in certain industrial devices across state lines; regulations concerning high concentration of radioactive source material or special nuclear material, such as uranium and plutonium; and provisions regarding the transportation and distribution of exempt consumer materials. The Department does not have the authority under the 2008 agreement to

implement these sections and has never enforced them. The amendments included in this rulemaking clarify the Department's and the NRC's legal authority under their respective regulations.

Review and consideration of public comments on the amendments is unnecessary because public comments could not alter the need to make these amendments. Finalizing these amendments without public notice and comment is in the public interest to ensure that the Commonwealth's regulations accurately reflect the Department's authority. Likewise, finalizing these amendments without public notice and comment is in the interest of those holding radioactive material licenses in the Commonwealth because the amendments clarify the proper authority of the Department and the NRC under the agencies' respective radioactive materials programs. No changes to any radioactive material license will result from this final-omitted rulemaking.

References to the provisions of Title 10 of the CFR being eliminated from incorporation-by-reference in this final-omitted rulemaking are outlined, by section, in the table below:

25 Pa. Code Section Amended	**10 CFR Provision Excluded from Incorporation-by-Reference**
§§ 215.1(e)(3) and 217.131(b)	§ 30.4
§§ 215.1(e)(5) and 217.151(b)	§§ 32.1(c)(1), 32.30, 32.31, and 32.32
§ 215.1(e)(9) and § 232.2(b)	§ 36.2
§ 215.1(e)(12)	§§ 40.4, 40.13(c)(5)(iv), 40.52, 40.53 and Part 40 Appendix A Criterion - 11 A-F and Criterion - 12
§ 217.171(b)	§§ 40.4, 40.13(c)(5)(iv), 40.52, 40.53
§ 215.1(e)(13)	§§ 70.4, 70.74 and Part 70 Appendix A
§ 215.1(e)(14)	§§ 71.17, 71.21, 71.70, 71.85(a), (b) and (c), 71.91(c) and (d), 71.101(a), (b), and (c)(1), 71.103(a), 71.106 and 71.135
§ 217.181(b)	§§ 70.4, 70.74 and Part 70 Appendix A
§ 230.3(b)	§§ 71.17, 71.21, 71.70, 71.85(a), (b) and (c), 71.91(c) and (d), 71.101(a), (b) and (c)(1), 71.103(a), 71.106 and 71.135

All radioactive materials licensees must comply with the Federal regulations incorporated by reference in Chapters 215, 217, 230, and 232. This final-omitted rulemaking does not add requirements: it clarifies the list of Federal regulations excluded from incorporation-by-reference because the Commonwealth does not have the authority to implement the regulations.

All Agreement States' radioactive materials programs are required to be compatible with the federal standards, under 42 U.S.C. § 2021(d)(2). This final-omitted rulemaking allows the Commonwealth to maintain this fundamental and essential compatibility. Therefore, this regulation will not put this Commonwealth nor the radioactive materials licensees in this Commonwealth at a competitive disadvantage.

The fundamental benefit of this final-omitted rulemaking is ensuring that the Commonwealth's regulations meet the requirements of NRC's Agreement State program, as required by Federal

law. *See* 42 U.S.C. § 2021(d)(2). If these amendments are not adopted, the Commonwealth will be at risk of losing the authority it assumed as an Agreement State under the 2008 agreement to regulate most types of radioactive materials used in the Commonwealth.

The amendments will create no compliance costs. No additional financial, economic or social impact will result from these amendments.

The Department presented this final-omitted rulemaking to the Radiation Protection Advisory Committee (RPAC) at its October 19, 2017 meeting. At that meeting, the RPAC recommended that the Department move forward with this final-omitted rulemaking.

The Department will provide assistance as necessary to facilitate IRRC's review of the enclosed rulemakings under Section 5.1(e) of the Regulatory Review Act.

Please contact me by e-mail at ledinger@pa.gov or by telephone at 717.783.8727 if you have any questions or need additional information.

Sincerely,

Laura F. Edinger

Laura Edinger
Regulatory Coordinator

Enclosures

0120-FM-PO0011 6/2015

pennsylvania
DEPARTMENT OF ENVIRONMENTAL PROTECTION

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF ENVIRONMENTAL PROTECTION
POLICY OFFICE

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

I.D. NUMBER: 7- 499

SUBJECT: Radiological Health

AGENCY: DEPARTMENT OF ENVIRONMENTAL PROTECTION

TYPE OF REGULATION

RECEIVED
JUL 16 2018
Independent Regulatory Review Commission

- ☐ Proposed Regulation
- ☑ Final Regulation
- ☐ Final Regulation with Notice of Proposed Rulemaking Omitted
- ☐ 120-day Emergency Certification of the Attorney General
- ☐ 120-day Emergency Certification of the Governor
- ☐ Delivery of Tolled Regulation
  - a. ☐ With Revisions
  - b. ☐ Without Revisions

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
7/16/18	Shelly K. Weaver	Majority Chair, HOUSE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY Representative John Maher
7/16/18	Richard Gilbert	Minority Chair, HOUSE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY Representative Mike Carroll
7/16/18	Patricia E Cruz	Majority Chair, SENATE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY Senator Gene Yaw
7/16/18		Minority Chair, SENATE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY Senator John Yudichak
7/16/18	K Cooper	INDEPENDENT REGULATORY REVIEW COMMISSION David Sumner
		ATTORNEY GENERAL (for Final Omitted only)
		LEGISLATIVE REFERENCE BUREAU (for Proposed only)