REVISED 12/16

Regulatory Analysis Form

(Completed by Promulgating Agency)

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

INDEPENDENT REGULATORY REVIEW COMMISSION

RECEIVED

(1) Agency

Department of Environmental Protection

(2) Agency Number:

Identification Number: 7-499

IRRC Number: 3169

(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):

Primary Contact: Laura Edinger, 783-8727, ledinger@pa.gov
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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 radiological health regulations were last updated in 2009 to provide for compatibility with the U.S Nuclear Regulatory Commission's (NRC) regulations after the Commonwealth became an NRC Agreement State. Since that time, there have been significant technological advances in the use of radiation sources prompting the need to amend the radiological health regulations to establish and maintain adequate radiation protection standards and oversight.

The proposed amendments are based on standards set by the current 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 radon certification regulations were first promulgated in 1991 and, other than minor amendments in 2004, 2008, and 2009, have not been significantly revised since that time. The proposed rulemaking would revise 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 and quality control requirements would provide greater detail regarding how these programs should be designed and what goals they should accomplish.

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

The proposed amendments to Chapters 215-221, 223, 225, 227, 228, and 230 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 proposed 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, and 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. The proposed rulemaking provides an opportunity to further clarify and fortify requirements in the regulations, most notably requirements for computed tomography, fluoroscopy and emerging technology systems, as well as radon certification.

As set forth in the proposed rulemaking, users of radiation sources would be required to comply with radiation protection standards that would not only protect and benefit employees but would also protect and benefit the general public. The proposed rulemaking would ensure that trained professionals are operating these 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 these proposed regulations. For example, the approximate 5,500 dentists, 230 hospitals, 860 clinics, 750 chiropractors, 490 podiatrists, registered with the Department performing, at a minimum, 10 scans per day results in millions of scans being done annually.

The proposed 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 the public's health and welfare from the dangers of radon. The quality assurance and quality control requirements being proposed also benefit the regulated community by eliminating certain equipment

check requirements when the equipment is not used. It also removes cross checks and duplicate tests for testers who use continuous monitors and continuous working level monitors. The proposed rulemaking would eliminate the requirement to have one year of radon testing experience prior to certification. This will benefit the regulated community by simplifying and shortening the process for an individual to become certified to test for radon. Lastly, the proposed amendments codify the exemption from laboratory certification for certified primary testers who place, retrieve, and analyze continuous monitors or electret ion chambers. Not requiring continuous radon monitor users or E-perm users who analyze their own devices to become certified as a laboratory will save those individuals approximately $400 per certification time period. These amendments would benefit approximately 600 certified radon service providers.

All Pennsylvania residents who have tested their homes for radon and subsequently taken action to reduce those high levels via 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. The homeowners also will benefit from the reduced level of radon exposure in their homes.

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. Pennsylvania residents are at particular risk since the radon levels in PA are much more significant than most other parts of the country.

(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?

This proposal will not put Pennsylvania at a competitive disadvantage. Instead, it will allow better protection during medical procedures involving radiation exposure. Many states have similar regulations.

Regarding radon regulations, Pennsylvania leads the nation in radon oversight, primarily since the state has the highest potential for harm from radon in the country. Pennsylvania has a unique geologic setting such that it has some of the highest radon levels in the country. In fact, a private home in Pennsylvania has recently been measured with the highest radon value in the country at 3,750 pCi/L. This value is over 900 times greater than the U.S. EPA guideline value of 4 pCi/L. Pennsylvania also has a wide geographic distribution of radon occurrence, and with the population of 12.5 million people there is great potential for radon exposure. While there are nine other states that have licensing or certification programs for radon testing, mitigation, and laboratory analysis; given Pennsylvania's unique geology, robust radon regulation is necessary.

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

No other state regulations will be affected. The Radiation Protection Act, Act of July 10, 1984, P.L. 688, No. 147 gives full authority to DEP regarding radiation protection.

Section 306. Conflicting laws.

Ordinances, resolutions or regulations now or hereafter in effect of the governing body of any agency or political subdivision of this Commonwealth relating to radiation or radiation sources shall be superseded by this act if such ordinances or regulations are not in substantial conformity with this act and any rules and regulations issued hereunder.

The Department of Health may have regulations regarding radiation. However, DEP's radiological health regulations would supersede them.

DEP is the only agency which has any regulatory authority over the radon industry.

(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.)

As required by section 301(c)(14) of the Radiation Protection Act, the Department provided the Radiation Protection Advisory Committee (RPAC) with an opportunity to review the proposed rulemaking and to advise the Department prior to submittal to the Board. The Radiation Protection Advisory Committee (RPAC) reviewed the proposed regulations on October 16, 2014; December 11, 2014; April 2, 2015; June 4, 2015; and July 23, 2015. At the conclusion of the July 23, 2015 meeting, the RPAC endorsed the proposed rulemaking for presentation to the Board.

The proposed Chapter 240 regulations were sent out to a select group of radon industry representatives and coordinated by the radon RPAC representative. The regulations were also sent to the PA local chapter of the American Association of Radon Scientists and Technologists (AARST) for comment. Additionally, the national director of AARST also discussed the regulations with Division staff.

(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?

The proposed regulations affect approximately 11,000 X-ray machine registrants, 825 radioactive material licensees, 150 accelerator licensees, 325 X-ray service providers and about 600 entities performing certified radon activities. All entities performing certified radon activities are considered to be small businesses. Approximately 85% of X-ray registrants are considered small businesses.

A small number of registrants will be affected by being required to use a qualified medical physicist, as newly defined in the regulatory amendments. The majority of 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. Many of the requirements in the proposed rulemaking reflect current industry practices, as discovered through Department inspections and through conversation with the RPAC members, and therefore are not expected to impose additional requirements on the regulated community.

The general public and businesses could be affected by the radon regulations if they choose to use the services offered. Benefits include an improved indoor air quality with subsequent health benefits and increased ability to sell property without the difficulties of radon testing and abatement.

(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 about 600 entities performing certified radon activities that would be required to comply with the proposed regulations. All future registrants, licensees, and certified radon service providers will also be required to 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.

Benefits

The benefit of the amendments to the radiological health regulations include the requirement for users of radiation sources to comply with radiation protection standards that would not only protect employees but would also protect the general public. The proposed rulemaking would ensure that trained professionals are operating these radiation sources so that both the patient and the operator are adequately protected from the harmful effects of overexposure to radiation.

The benefits of the proposed radon certification 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 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 protect the public's health and welfare from the dangers of radon. 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. Pennsylvania residents are at particular risk since the radon levels in this state are much more significant than most other parts of the country. The quality assurance and quality control requirements being proposed 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 proposed amendment to eliminate the requirement to have one year of radon testing experience prior to certification would benefit the regulated community by simplifying and shortening the process for an individual to become certified to test for radon. All PA residents who have tested their homes for radon and subsequently taken action to reduce those high levels via 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. The consumer of these services benefits by

having improved indoor air quality, with reduced exposure to this radioactive gas.

Financial, Economic, and Social Impacts

Other than new fees in Section 218.11(i) for electronic brachytherapy devices and Section 218.11(j) for emerging technology devices, which affects entities who have been assessed administratively since 2009, and is now proposed to be codified in regulation, there are no changes to the fee schedules in Chapter 218 and Chapter 240, Appendix A, in this proposed rulemaking. The annual fee is $1,000 for the first unit (controller) at the facility plus $100 for each additional unit at the facility. Because it is existing practice, regulated entities will not experience any additional costs as a result of this proposed rulemaking.

The proposed amendments to Section 221 (relating to X-rays in the healing arts), which require a Qualified Medical Physicist (QMP) to perform various functions, may increase costs for a small percentage of registrants. A QMP would be required to, among other things, personally evaluate or direct the evaluation of fluoroscopic, CT, and CBCT equipment, recommend imaging quality control programs, review protocols, perform or direct the performance of radiation surveys, and provide analysis of medical events. The Department is proposing to add these requirements because QMPs are trained and most often certified in health physics disciplines and their oversight of these functions would ensure adequate radiation protection standards are maintained. The vast majority of the regulated community is already employing QMPs in this capacity as it is standard industry practice, but there may be a small percentage of facilities that employ individuals that do not meet the proposed definition of QMP. The Department is proposing a "grandfathering" provision in the definition of QMP which would further reduce the impact to the regulated community by allowing individuals who meet certain requirements to continue to perform the functions of a QMP as long as they complete continuing education requirements. A QMP typically charges a minimum of $150 per hour for their services and the small percentage of registrants who will be required to obtain the services of a QMP for these functions may see an increase in their costs.

Radon Certification

The proposed amendments pertaining to reinstating previously withdrawn certifications would decrease costs for and be a benefit to the regulated community because they will no longer be required to pay certification fees to reinstate a withdrawn certification. Depending on the type of certification, this amendment would save a firm or individual anywhere from $300 to $750 when an individual or firm seeks to reinstate a withdrawn certification. *See* 25 Pa. Code Chapter 240 Appendix A (relating to Radon Certification Fee Schedule).

The proposed amendments, which would require certified firms to employ one certified individual per five firm employees, may increase costs for the regulated community. This amendment would benefit the public by protecting public health and welfare from the dangers of radon, because it would ensure that uncertified firm employees are being adequately supervised by the firm's certified individuals. This amendment may cost a certified firm an additional $300 (for mitigation individuals) or $350 (for testing individuals) every two years for each additional certified individual they are required to employ. *See* 25 Pa. Code Chapter 240 Appendix A (relating to Radon Certification Fee Schedule).

There are no social impacts associated with the proposed rulemaking.

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

There are no adverse effects associated with the proposed rulemaking.

The benefits of the proposed rulemaking include protecting employees and the general public by requiring compliance with current radiation protection standards. The proposed rulemaking would ensure that trained professionals are operating radiation sources so that both the patient and the operator are adequately protected. The benefit of maintaining adequate radiation protection standards outweigh the cost that a small percentage of registrants may encounter when procuring the services of a QMP to perform a limited number of functions as outlined in the proposed rulemaking.

This amendment would benefit the public by protecting public health and welfare from the dangers of radon, because it would ensure that uncertified firm employees are being adequately supervised by the firm's certified individuals.

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. Pennsylvania residents are at particular risk since the radon levels in PA are much more significant than most other parts of the country.

(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.

A small percentage of registrants will have an added cost of approximately $300 to obtain the services of a QMP. A QMP typically charges a minimum of $150 per hour, at approximately 2 hours per year.

Depending on the type of certification, the amendment relating to reinstating a previously withdrawn certification application would save a firm or individual anywhere from $300 to $750 (the certification fees are stated in Appendix A).

The proposed amendments which would require certified firms to employ one certified individual per five firm employees may increase costs for the regulated community by $300 (certification fee for mitigation individual) or $350 (certification fee for testing individual) every two years for each additional certified individual they are required to employ.

(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.

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

(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	$40,500	$33,300	$40,500	$33,300	$40,500	$33,300
Local Government	0	0	0	0	0	0
State Government	0	0	0	0	0	0
Total Costs	$40,500	$33,300	$40,500	$33,300	$40,500	$33,300

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 DEP 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	FY -2	FY -1	Current FY
Radiation Protection Fund	$11,113,000	$11,018,000	$11,628,000	$14,953,000

(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.

The proposed amendments, which would require certified firms to employ one certified individual per five firm employees, may increase costs for approximately seven small businesses. This is the number of firms that have more than five employees. This amendment may cost a certified firm an additional $300 every two years for each additional certified individual they are required to employ. *See* 25 Pa. Code Chapter 240 Appendix A (relating to Radon Certification Fee Schedule).

Another option considered for, but not incorporated in, this rulemaking was to require all radon testers and mitigators to be individually certified. While this would have ensured that each individual was properly trained, it would have added an extra cost burden to companies with multiple employees performing radon activities.

For example, the costs for a hypothetical firm with one certified individual and five employees would be $1,150 for the firm plus $400 for the employees, or $1,540. The cost for the same

scenario above, but each individually certified, would be $350 per individual multiplied by six individuals, or $2,100. These cost analyses do not include course work and exams which would be more costly for all employees being individually certified.

The proposed amendments included in this rulemaking reasonably ensure that only qualified testers and mitigators are performing this work while not placing undue burden on small businesses.

(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 needed to be developed.

(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 since the majority of the amendments are current industry radiation protection practices and are based on suggested state regulations (SSRs).

The alternative regulatory provisions for the radon certification amendments would add more cost to the regulated industry. These entities are all considered small businesses. See the alternative method explained in #24. Other amendments are not burdensome since they 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.

The 45-day reporting requirement for radon testers, laboratories, and mitigators remains the same. After the radon-related activity is complete the industry has 45 days to report to the Department. This reporting is done online and multiple reports can be done as one upload instead of entering each report individually.

Performance standards for small businesses were not considered to replace design or operation standards required by the proposed rulemaking because the risk level remains the same for small businesses who operate radiation-producing machines or small businesses who perform radon services. The exemption

of small businesses from all or any part of the requirements contained in the proposed rulemaking was also not considered for this same reason.

(28) If data is the basis for this regulation, please provide a description of the data, explain in detail 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.

The primary intention of the radon certification regulations is stated in the Act (Act 1987-43), "... to protect property owners from unqualified or unscrupulous consultants and firms by requiring the Department of Environmental Resources to establish and carry out a program of certification of persons who perform radon progeny testing or carry out remedial radon measures". All data is subsequent to this primary intent. Radon testing and mitigation data is generated by the radon industry and that data is reported to the Department 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). These amendments are also based on DEP's expertise and experience.

To date, there are approximately 1.5 million radon test results and about 185,000 radon mitigations reported. The testing data highlights the severity of the impact of radon in Pennsylvania. Mitigation data shows that remedial measures are effective at reducing these high radon levels.

In Pennsylvania, the average basement radon concentration is 7 pCi/L and the average first floor concentration is 3.5 pCi/L. The U.S. 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 is greater than 4 pCi/L). They have designated 17 PA counties as Zone 2, which is the intermediate designation (predicted average level is 2 to 4 pCi/L), and only one PA 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 U.S. EPA's website, www.epa.gov.

Pennsylvania also has about 6,000 test results greater than 100 pCi/L, which is 25 times greater than the U.S. EPA guideline of 4 pCi/L.

This radon test data supports the continued need for a strong regulatory arm to assure that 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: N/A

C. The expected date of delivery of the final-form regulation: Quarter 4, 2017

D. The expected effective date of the final-form regulation:	Quarter 1, 2018
E. The expected date by which compliance with the final-form regulation will be required:	Quarter 1, 2018
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.

This regulation will be reviewed in accordance with the sunset review schedule published by the Department to determine whether the regulation effectively fulfills the goals for which it was intended.

pennsylvania
DEPARTMENT OF ENVIRONMENTAL PROTECTION

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF ENVIRONMENTAL PROTECTION
BUREAU OF RADIATION PROTECTION

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.
     - **The maximum firm employees that can be DEP-listed at one time is five.**
   - 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 employee is employed by the firm. DEP has adopted the common law federal Internal Revenue Service definition of employee.~~ 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:
       * Enclose a list of all firm employees who will be performing radon activities, including each employee's educational background and related experience.
       * 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.

* ~~Each testing, mitigation, & laboratory employee must fill out the appropriate Employee Form(s).~~ For each mitigation employee submit proof of passing either a DEP-approved radon mitigation exam or course.

* For each testing employee, submit proof of having passed a DEP approved radon measurement exam.

☐ All mitigation and laboratory employees are free. The first testing employee is free. Each additional testing employee is $100

☐ 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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2.12 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. The maximum number of testing firm employees per testing firm certification is five.

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)

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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. The maximum number of mitigation firm employees per mitigation firm certification is five.

_____

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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2.2 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 $100 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).

☐ ~~**Experience**~~
~~Submit a description of at least one year of professional radon measurement experience:~~

- ~~either as a DEP-listed testing employee, certified individual or from another state/country, or~~
- ~~one year's equivalent experience in procedural compliance or quality control.~~

~~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 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.

☐ ~~**Workers, Health and Safety Program** Specify the following:~~

~~2. How you will maintain exposure to radon progeny as low as reasonably achievable.~~
~~3. How you will track employee exposures, including all equations.~~
~~4. A statement that permanent records of employee exposure will be maintained and that the OSHA export limit of 4 WLM/yr will not be exceeded.~~
~~5.~~1. ~~A copy of your exposure tracking record. See Section 2.6 (Page 49) for an example of this form.~~

☐ **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. $100 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. $100 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 $100 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: The maximum testing firm employees that can be DEP-listed at one time is five.

☐ **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).

☐ **Department-approved Exam Results for Each Testing Firm Employee**
Submit proof of passing a Department-approved measurement exam result for each firm employee that is to be listed with our Department to perform radon testing. For Department-approved exams see Section 4.1 (Page 75).

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

☐ **Testing Employee Fee**
Submit $100 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.

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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 $100 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 Mitigation Protocols Form**
Complete and submit the completed form in Section 2.7 (Page 50).

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

☐ **Workers, Health and Workers Safety, Program**
Complete, sign, and submit the recommended Mitigation Health and Safety Plan enclosed as Section 2.5 (Page 47) and Section 2.6 (Page 49), of this document. (If you submit your own Mitigation Health and Safety Plan all the "shalls" in Section 12 of the *Pennsylvania Mitigation Standards* must be included.)

☐ **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: The maximum mitigation firm employees that can be DEP-listed at one time is five.

☐ **Employee Information**
- List each firm employee(s) who will be performing radon mitigation activities on the General Application
- Submit ~~each employee's educational background and related experience.~~proof of having passed a DEP-approved exam or course for each employee.

☐ **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.

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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)
- ☐ $100 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)
- ☐ $100 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: The maximum testing firm employees that can be DEP-listed at one time is five.

☐ *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 $100 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) The maximum testing firm employees that can be DEP-listed at one time is five.

☐ **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 $100 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 $100 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.

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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 month 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 Mitigation Protocols Form**
Complete and submit the completed form in Section 2.7 (Page 50)

☐ **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: The maximum testing firm employees that can be DEP-listed at one time is five.

☐ ***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.) The maximum testing firm employees that can be DEP-listed at one time is five.

☐ **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 $100 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 $100 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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Acknowledgement Testing Form

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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, (b) have passed the DEP approved testing exam, and (c) are listed with DEP as employees of a certified radon testing firm. ~~All employees shall have a minimum of four hours of initial training in radon testing. 25 Pa. Code §240.306 (if applicable).~~
4. ~~Exercising due diligence to ensure that all radon testing activities are conducted in accordance with the following DEP-approved protocols: (All recommendations referenced in these documents are requirements and at a minimum the "lowest livable level" must be tested for any real estate transaction performed in Pennsylvania.)~~

~~EPA 402-R-92-004 – Indoor Radon and Radon Decay Product Measurement Protocols, July 1992~~
~~EPA 402-R-92-003 – Protocol for Radon and Decay Product Measurements in Homes, June 1993~~
~~EPA 402-R-92-014 – Radon Measurement in Schools, July 1993~~

5. 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.
6. 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.
7. 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.
8. 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).
9. 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).
10. 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).
11. 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).
12. 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) _____

13. 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.

14. 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.

15. Ensuring that I will be in responsible charge of no more than five ~~radon-related services~~DEP-listed firm employees ~~for certified firms~~ at any time.

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

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

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

    - ~~Documentation of each measurement containing the items as outlined in 4.3.5 Measurement Documentation of the *EPA Protocols For Radon and Radon Decay Product Measurements in Homes*, EPA 402-R-93-003, June 1993 shall be maintained for a minimum of 5 years.~~
    - ~~All quality assurance documentation (including calibration records, QC measurements, QC charts and QA reports) shall be maintained for a minimum of 5 years.~~
    - ~~Permanent records of all exposure tracking records shall be maintained.~~

19. 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.

20. 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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BUREAU OF RADIATION PROTECTION

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. Cross Checks – Shall be performed semi-annually between calibrations (if available, use active instrument calibrated within 3 months that reads in the same units, if not use an RMP-listed device). I will retain all radon-related QA records and radon test result documentation for a minimum of five (5) years.~~

3.2. **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) _____

4.3. 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) _____

~~5.~~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

~~6.~~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. Initially, the control chart is established using a warning level of plus and minus 20% and control limits of plus and minus 30%. These control and warning levels shall be adjusted once the Relative Percent Error (RPE) of at least 20 spike results have been calculated. The standard deviation of the 20 or more spikes shall now be calculated and the warning and control limits shall now be re-established on new control charts. Individual control charts shall be established for different radon concentration ranges, such as 4 to 20 pCi/L, 20 to 50 pCi/L, and 50 to 100 pCi/L. All subsequent spike RPE values shall now be plotted on the newly established control charts.

   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

Electret Voltage Drift: For shipments of 20 electrets or fewer, a minimum of one electret shall be set aside from each new shipment and evaluated for voltage drift. For shipments of more than 20 electrets, at a minimum five percent (5%) of the electrets or 10 electrets, whichever number is smaller, shall be evaluated. The electrets shall be kept covered with protective caps in a low radon environment. For short-term and long-term electrets an initial and a final voltage reading shall be made. For short-term electrets, the final voltage shall be taken after four weeks, and for long term electrets the final voltage shall be taken after three months. If the short-term voltage loss is greater than six volts per month or if the long term voltage loss is greater than 12 volts do not test with this shipment until voltage loss is corrected.

All electret voltage drift shall be documented on a form which contains at a minimum the following:

- Specify short or long term electret
- Date new shipment received
- Electret serial numbers
- Initial voltages & dates
- Final voltages & dates
- Reader serial number
- 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

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

By: Amy M. Elliott
(Deputy Attorney General)

APR 07 2017
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 OCTOBER 18, 2016

BY Patrick McDonnell

TITLE PATRICK MCDONNELL
ACTING CHAIRMAN

EXECUTIVE OFFICER CHAIRMAN OR SECRETARY

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

BY Marisa H. Z. Lehr

NOV 17 2016
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 PROPOSED RULEMAKING

DEPARTMENT OF ENVIRONMENTAL PROTECTION
ENVIRONMENTAL QUALITY BOARD

Radiological Health

25 Pa. Code, Chapters 215-221, 223, 225, 227, 228, 230, and 240

PROPOSED RULEMAKING
ENVIRONMENTAL QUALITY BOARD
[25 Pa. Code, Chapters 215-221, 223, 225, 227, 228, 230, and 240]
Radiological Health

The Environmental Quality Board (Board) proposes to amend portions of 25 Pa. Code Article V (relating to radiological health) to read as set forth in Annex A. The proposed rulemaking would amend Article V to include clarification and guidance relating to radiation safety, update the standards for protection against radiation, and amend requirements for radon certification.

This proposed rulemaking was adopted by the Board at its meeting on October 18, 2016.

A. Effective Date

This proposed rulemaking will be effective upon final-form publication in the *Pennsylvania Bulletin*.

B. Contact Persons

For further information, contact Joseph Melnic, Chief, Division of Radiation Control, P.O. Box 8469, Rachel Carson State Office Building, Harrisburg, PA 17105-8469, (717) 783-9730, 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. Information regarding submitting comments on this proposal appears in Section J of this preamble. Persons with a disability may use the AT&T Relay Service by calling 1-800-654-5984 (TDD users) or 1-800-654-5988 (voice users). This proposal is available electronically through the Department of Environmental Protection's (Department) website at www.dep.pa.gov (select Public Participation, then select Environmental Quality Board).

C. Statutory Authority

The proposed amendments to Chapters 215-221, 223, 225, 227, 228, and 230 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 proposed 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.

D. Background and Purpose

The Board last updated its radiological health regulations in 2009 to provide for compatibility with the U.S Nuclear Regulatory Commission's (NRC) regulations after the Commonwealth became an NRC Agreement State. Since that time, there have been significant technological advances in the use of radiation sources prompting the need to amend the radiological health regulations to establish and maintain adequate radiation protection standards and oversight.

The proposed amendments are based on standards set by the current 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 radon certification regulations were first promulgated in 1991 and, other than minor amendments in 2004, 2008, and 2009, have not been significantly revised since that time. The proposed rulemaking would revise 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 and quality control requirements would provide greater detail regarding how these programs should be designed and what goals they should accomplish.

As required by section 301(c)(14) of the Radiation Protection Act, the Department provided the Radiation Protection Advisory Committee (RPAC) with an opportunity to review the proposed rulemaking and to advise the Department prior to submittal to the Board. Beginning in 2014, the Department and the RPAC worked together over five RPAC meetings to develop this proposed rulemaking. On July 23, 2015, the RPAC endorsed the proposed rulemaking for presentation to the Board.

E. Summary of Regulatory Requirements

The following summary outlines the regulatory requirements that have been affected by the proposed regulations and describes the basis for the amendments.

Chapter 215 – General Provisions

§ 215.12 (Inspections and investigations) – The proposed rulemaking would include a mechanism whereby the Department can secure or lock-down a radiation source device that is abandoned or poses a threat to public health, safety, or the environment.

§ 215.14 (Availability of records) – This section would be amended to clarify the scope of records relating to radiation sources prohibited from public access in order to protect public health, safety, and the environment.

§ 215.22 (Prohibited uses) – The proposed rulemaking would expand this section's prohibition on use of non-medical human use devices in order for the Department to determine efficacy of a procedure.

§ 215.24 (Human use) – The proposed rulemaking would amend this section to apply the same X-ray operator requirements to all medical facilities for consistency throughout the regulated community.

§ 215.31 (Granting exemptions) – These amendments would add clarity and reaffirm fee requirements in order to prevent regulatory confusion.

Chapter 216 – Registration of Radiation-Producing Machines and Radiation-Producing Machine Service Providers

§ 216.1 (Purpose and scope) – This amendment proposes the inclusion of licensing requirements for electronic brachytherapy devices. This is a new modality that was not previously addressed in the regulations.

§ 216.2 (Registration of radiation-producing machines) – This amendment would clarify notification requirements for registrants. Specifically, a change in name was added to the notification requirements, and radiation safety officer was replaced with the individual responsible for radiation protection; a requirement was added to have a written inventory that includes the type and location of all devices; and a current schedule that includes the date and location where mobile services are to be performed.

§ 216.2a (Registration of radiation-producing machine service providers) – This amendment would delete transitional language from when service provider registration went into effect, and it would exempt in-house service providers.

§ 216.2b (Reporting and recordkeeping requirements for registered radiation-producing machine service providers) – This amendment would clarify that radiation-producing machine service providers are not exempt from the radiation protection requirements in Chapter 219.

§ 216.3 (Exemptions) – This amendment proposes to make electronic brachytherapy operations exempt from registration but require licensure. X-ray tubes require registration; however, when tubes are used for electronic brachytherapy a higher degree of oversight is necessary. This is due to a higher dose being administered in these procedures.

Chapter 217 – Licensing of Radioactive Material

Amendments to a number of sections propose to delete the transitional language used when Pennsylvania became an Agreement State in 2008.

§ 217.143 (Certain measuring, gauging or controlling devices) – The proposed rulemaking would add three radioisotopes to this section that are not referenced by 10 CFR 31.5. The U.S. NRC unintentionally omitted these three isotopes.

Chapter 218 – Fees

§ 218.1 (Purpose and scope) – This amendment would clarify that this section also applies to electronic brachytherapy license holders. Electronic brachytherapy is a new modality not previously addressed in the regulations.

§ 218.11 (Registration, renewal of registration and license fees) – This amendment would address emerging technologies and include a fee for electronic brachytherapy devices at $1,000 annually for the first unit (controller) at a facility and $100 for each additional unit at that facility.

§ 218.11a (Special provisions for calculating fees during Agreement State transition period) – The proposed rulemaking would delete this obsolete section.

Chapter 219 – Standards for Protection Against Radiation

§ 219.3 (Definitions) –The proposed rulemaking would clarify the medical reportable event definition for radiation-producing machine therapy by including actual criteria. A new definition is added for medical reportable events involving radiation-producing diagnostic or interventional X-ray procedures.

§ 219.6 (Effects of incorporation of 10 CFR Part 20) – This amendment would exempt the Radiation Exposure Information and Reporting System (REIRS) requirement. The REIRS requirement remains the responsibility of the U.S. NRC.

§ 219.229 (Other medical reports) – The proposed rulemaking would include additional requirements for reporting medical events. Such as interventional radiology, a modality not previously addressed in the regulations.

Chapter 220 – Notices, Instructions, and Reports to Workers; Inspections and Investigations

§ 220.10 (Effects of incorporation of 10 CFR Part 19) – This amendment would delete transitional language that is obsolete.

Chapter 221 – X-Rays in the Healing Arts

§ 221.1 (Purpose and scope) – This amendment would include licensee in the scope.

§ 221.2 (Definitions) – The proposed rulemaking would add definitions to support the addition of terms noted in §§ 218.11 through 221.205: "Air Kerma," "Air Kerma Rate," "CBCT," "CINE," "CR," "CT," "Certified components," "DDR," "DLR," "Dose length product," "DR," "Electronic brachytherapy," "Emerging technology," "FGI," "Health physics," "High-risk procedure," IORT," "Kerma," Medical physics," "Low-risk procedure," "Performance phantom," "Radiological physics," "QE," "QMP," "SRDL," "Unintended dose." In addition, for clarity, all forms of supervision are defined, such as, "Direct," "General" and "Personal." The

rulemaking would also amend the definition of the term "image intensifier" as an image receptor rather than a device.

§ 221.11 (Registrant responsibilities) – The proposed rulemaking would clarify continuing education requirements and expand the quality assurance program. This includes clarifying how often continuing education should occur, and adding diagnostic reference levels; image quality; and, artifacts to be addressed by the quality assurance programs. These amendments will ensure adequate radiation protection.

§ 221.16 (Training, competency and continuing education) – This proposed section would add specific training for X-ray operations, competency in the operation, and continuing education requirements for registrants and licensees. Continuing education requirements include biological effects of radiation, quality assurance and quality control, and radiation safety.

§ 221.21 (Diagnostic equipment requirements) – This amendment would require that new equipment comply with FDA requirements, which will prevent any business, foreign or domestic, from selling non-certified devices.

§ 221.25 (Beam quality) – The proposed rulemaking would update Table II, X-ray tube voltage, to current FDA standards.

§ 221.35a (Fluoroscopic X-ray systems) – The proposed rulemaking would limit who can operate a fluoroscopic X-ray system for clinical purposes to licensed practitioners; radiologist assistants; registered technologists; and students-in-training. The amendment adds equipment evaluations such as entrance exposure rates; maximum air kerma rates; and high contrast resolutions. The amendment adds requirements for fluoroscopic-guided interventional procedures, such as written procedures; records of policies and procedures; radiation output; and, peak skin dose.

§ 221.57 (Facilities using CR or DR) – This new section would add quality control program requirements for the relatively new imaging methods of computed radiography (CR) and digital radiography (DR). These requirements address exposure indicators, image quality control program, phantom image evaluation, and manufacturer specifications.

§ 221.61 (Radiation therapy simulation systems) – The proposed rulemaking would clarify the oversight requirements for simulation systems. Requirements for simulation systems are not as arduous as diagnostic systems, therefore, these systems only need to comply with certain radiological health regulations.

§ 221.63 (Therapy imaging guidance systems) – This new section would add technical requirements for procedures using this new type of guidance system, such as quality control procedures and methods addressing radiation safety.

§ 221.64 (CBCT) – This new section would add quality control and evaluation requirements for cone beam computed tomography (CBCT) in order to address radiation safety. Radiation

measurements for these units must be evaluated annually, and as soon as practical following any component repair. The operator shall have instructions on performing routine quality control.

§ 221.65 (X-ray attenuation systems) – This new section would clarify the restrictions needed for this type of computed tomography (CT) system. These systems function differently than diagnostic systems and are required only to comply with §§ 221.202-221.205 unless they are exempted by other means.

§ 221.71 (Equipment requirements) – This amendment would clarify the requirements that apply to electronic brachytherapy. This is a new modality previously not addressed in the regulations and are exempt from certain equipment requirements.

§ 221.201 (Definitions) – The proposed rulemaking would add eight definitions applicable to CT X-ray systems, such as, "Alert value," "CT dosimetry phantom," "$CTDI_{100}$," "$CTDI_{vol}$," "$CTDW_{w}$," "Dose profile," "Modulation transfer function," and "notification value." The proposal deletes the definition of MSAD (multiple-scan average dose), an obsolete term, and revises the definitions of CT number and CTDI (computed tomography dose index).

§ 221.202 (Equipment requirements) – The proposed rulemaking would require accreditation of all diagnostic CT X-ray systems, and safety information necessary for these potentially high-risk systems be maintained and readily accessible to the operators in order to address radiation safety.

§ 221.204 (Performance evaluations, routine QC and surveys) - This amendment would delete obsolete requirements and add performance evaluation requirements for CT X-ray systems to be performed by or under the direction of a QMP; changing performance evaluation procedures to routine quality control procedures; and adding requirements for radiation protection survey and records management in order to address radiation safety.

§ 221.205 (Operating procedures) – The proposed rulemaking would add the requirement for operators to be appropriately trained in the specific techniques and modalities they will be utilizing.

Chapter 223 – Veterinary Medicine

§ 223.1 (Purpose and scope) – The proposed rulemaking would clarify that these safety requirements also apply to radiation sources being used in research on animals.

§ 223.22 (Sealed and unsealed sources) – This amendment would add unsealed sources to the scope of this section because unsealed sources are now being used in animal therapy.

§ 223.31 (Registrant responsibilities) – This new section would add responsibilities of the registrant, including responsibilities such as adequate instruction, written safety procedures, a quality assurance program, and continuing education in order to satisfy radiation safety requirements.

Chapter 225 – Radiation Safety Requirements for Industrial Radiographic Operations

§ 225.3a (Effect of incorporation of 10 CFR Part 34) – The proposed rulemaking would delete obsolete transitional language.

§ 225.4a (Radiation safety program) – The proposed rulemaking would add monitoring report requirements. These are individual monitoring reports required by 10 CFR 20.2206(a)(2).

§ 225.81 (Permanent radiographic installations) – This amendment would rectify an incorrect reference to 10 CFR 34.52 and require that records of tests performed for permanent radiographic installations be retained for five years as opposed to the current three years. This proposed change in records retention requirements was suggested by the RPAC to promote consistency throughout the radiological health regulations.

Chapter 227 – Radiation Safety Requirements for Analytical X-ray Equipment, X-ray Gauging Equipment, Electron Microscopes and X-ray Calibration Systems

§ 227.11a (Equipment requirements) – This amendment would add requirements for hand-held devices in new subsection (i) in order to address radiation safety. This is a new modality not previously addressed in the regulations.

Chapter 228 – Radiation Safety Requirements for Particle Accelerators

§ 228.11a (Licensee responsibilities) – The proposed rulemaking would add qualification requirements for operators of accelerators used in the healing arts in order to address radiation safety. This includes operators who need additional instruction including certification in the applicable specialty.

§ 228.21a (Notification and license requirements) – This amendment would delete an outdated requirement and increase the time in which to file an application for a specific license from 30 to 90 days after the initial order is issued to obtain any or all parts of an accelerator.

§ 228.35 (Operating procedures) – The proposed rulemaking would reduce the requirement for testing interlocks from quarterly to annually. Testing interlocks quarterly can be damaging to the accelerator because it forces a quick shutdown to the machine. The regulated community has recommended the need for no more than an annual test, and the Department's inspection records confirm that an annual test is sufficient to ensure that the interlocks are functioning properly. The proposed rulemaking would also require records to be maintained for five years instead of the current four years. This proposed change in records retention was suggested by the RPAC to promote consistency throughout the radiological health regulations. In addition, paragraph (g)(5) would be renumbered as subsection (h) and clarifies that the subsection refers to both medical and non-medical accelerator operations.

§ 228.36 (Radiation monitoring requirements) – The proposed rulemaking would change this annual check to daily testing to reflect current industry practice. The original rulemaking inadvertently required annual testing.

§ 228.61 (Leakage radiation to the patient area) – This amendment changes 'Existing Equipment' to 'Equipment manufactured or installed prior to July 17, 2004, must meet'. And changes 'shall' to 'must'.

§ 228.72 (Selection of radiation type) – This amendment would clarify that the section refers to devices capable of X-ray therapy or electron therapy, or both.

§ 228.73 (Selection of stationary beam therapy or moving beam therapy) – This amendment would clarify that the section refers to devices capable of stationary beam therapy, or moving beam therapy, or both.

§ 228.75 (Calibrations) – The proposed rulemaking would include the addition of Flattening Filter Free (FFF) mode for calibration of a therapy beam.

Chapter 230 – Packaging and Transportation of Radioactive Material

§ 230.15 (Packaging and transportation of unlicensed material) – The proposed rulemaking would add a new section to address unlicensed material, such as TENORM, and the requirement to adhere to US Department of Transportation regulations.

Chapter 240 – Radon Certification

A majority of amendments to this section codify current radon testing and mitigation protocols and standards being implemented by radon service providers.

§ 240.1 (Description of regulatory structure) – The proposed rulemaking would delete reference to Subchapter F (relating to interim certification), which is proposed for deletion.

§ 240.2 (Scope) – The proposed rulemaking would revise certification exceptions from the building that the person occupies to the building in which the person resides for clarity and adds a new certification exception to clarify existing requirements for employees of local governments and schools who perform radon testing.

§ 240.3 (Definitions) – The proposed rulemaking would add 42 definitions applicable to Chapter 240-Radon Certification, such as "AC – activated charcoal," "ALARA—As Low As Reasonably Achievable," "AT---alpha track," "Alteration," "Blind Study," "Calibration," "CRM," "CWLM," "Certification year," "Certified individual," "Client," "Control limit," "Diagnostic test," "Duplicate measurements," "Electret ion chamber," "Electret reader," "Electret voltage drift," "Field blank," "Firm employee," "Firm owner," "Laboratory," "LS," "Lowest livable level," "MV," "Measurement," "Mitigator," "Multifamily building," "Nonreported test," "pCi/L," "QA," "QC," "RPD," "RPE," "RV," "Secondary device," "Secondary tester," "Sigma level," "Spiked measurement," "Tester," "WLM," "WLM/yr,"and "Warning level." The proposed rulemaking also amends seven existing definitions for clarity and standardization, such as "Firm," "Laboratory analysis," "Person," "Primary device," "Primary tester," "Test," and "WL".

§ 240.101 (Requirements for radon testing certification) – The proposed rulemaking would clarify the language of this section. Including adding that testers reading/analyzing their own continuous monitors or electrets are not required to become certified in radon laboratory analysis. This requirement is in place because of the ease of reading/analyzing these test devices due to advancements in technology. This also clarifies that prior to performing radon testing activities, a person shall obtain either a radon testing individual certification or Department-listing as an employee of a testing firm.

§ 240.102 (Prerequisites for radon testing certification) – The proposed rulemaking would remove the one-year radon testing experience requirement as it has proven to be prohibitive to persons becoming certified and is not necessary for the protection of the public. It would clarify that it is the firm owner and the certified individual that is responsible to inform the Department of the loss of the certified individual. It would clarify that a certified firm may only have one certified individual in responsible charge of a firm at a time to ensure clear lines of responsibility for accountability. It codifies the limit on number of testing firm employees to a maximum of five to ensure adequate responsible charge by the certified individual. It specifies the requirements for testing firm employee applications to include a completed application form, an ID card photograph, proof of passing an approved exam, and the appropriate fee.

§ 240.103 (Radon testing application contents) – This amendment would clarify language, add ID photograph and date of birth to the application requirements to ensure proper identity tracking of testers. It adds the requirement to notify the Department of any changes to the application within 10 days of each change to ensure compliance with the requirement to perform all radon activities in accordance with the application.

§ 240.104 (Application filing deadline) – The proposed rulemaking would specify when a testing individual renewal applicant can be assessed a late application fee and clarifying that this late fee will not be assessed on any firm renewal applications.

§ 240.111 (Requirements for radon mitigation certification) – The proposed rulemaking would clarify that a certified firm may only have one certified individual in responsible charge of a firm at a time to ensure clear lines of responsibility for accountability. It also clarifies that prior to performing radon mitigation activities a person shall obtain either a radon mitigation individual certification or Department-listing as an employee of a mitigation firm.

§ 240.112 (Prerequisites for radon mitigation certification) – The proposed rulemaking would clarify the language of this section, adding that it is the firm owner and the certified individual's responsibility to notify the Department of the loss of the certified individual. It codifies the limit on the number of mitigation firm employees to a maximum of five to ensure adequate responsible charge by the certified individual. It specifies the requirements for mitigation firm employee applications to include a completed application form, an ID card photograph, and proof of passing an approved exam or course.

§ 240.113 (Radon mitigation application contents) – This amendment would clarify language, add ID photograph and date of birth to the application requirements to ensure proper identity tracking of the mitigators. It adds the requirement to notify the Department of any changes to the

application within 10 days of each change to ensure compliance with the requirement to perform all radon activities in accordance with the application.

§ 240.114 (Application filing deadline) – The proposed rulemaking would specify when a mitigation individual renewal applicant can be assessed a late application fee and clarifying that this fee will not be assessed on any firm renewal applications.

§ 240.121 (Requirements for radon laboratory certification) – The proposed rulemaking would provide clarifying language to this section. It also clarifies that prior to performing radon laboratory activities a person shall obtain either a radon laboratory individual certification or Department-listing as an employee of a laboratory firm.

§ 240.122 (Prerequisites for radon laboratory certification) – The proposed rulemaking would clarify the language of this section, adding that it is the firm owner and the certified individual's responsibility to inform the Department upon the loss of the certified individual. It clarifies that a certified firm may only have one certified individual in responsible charge of a firm at a time to ensure clear lines of responsibility for accountability. It specifies the requirement for each laboratory firm employee applicant to submit a completed and signed laboratory firm employee application as provided by the Department, and the applicant must receive written approval prior to conducting radon laboratory activities as a firm employee. It also clarifies the limits of each laboratory employee's listing.

§ 240.123 (Radon laboratory application contents) – This amendment would clarify language, add applicant's date of birth to ensure proper identity tracking and also add the requirement to notify the Department of any changes to the application within 10 days of each change to ensure compliance with the requirement to perform all radon activities in accordance with the application.

§ 240.124 (Application filing deadline) – The proposed rulemaking would specify when a laboratory individual renewal applicant can be assessed a late application fee. Therefore, clarifying that this fee will not be assessed on any firm renewal applications.

§ 240.132 (Limited radon practice in this Commonwealth) – The proposed rulemaking would simply make a grammar change to give it a more direct approach.

§ 240.133 (Certification application contents) – The proposed rulemaking would clarify the language of this section by adding date of birth requirements for individual applicants, and adding the requirement to notify the Department of any changes to the application within 10 days of each change.

§ 240.141 (Withdrawal of applications and certifications) – This new section would specify the requirements for withdrawing an individual and/or firm certification application or an individual certification and the process for re-instating a previously withdrawn individual and/or firm certification. This includes that certification fees are not refundable for a withdrawal of any certification application. Also, that previous individual and/or firm certifications may be reinstated upon written request by the individual for an individual certification and by the firm

owner for a firm certification for only the remainder of that certification period at no additional fees.

§ 240.142 (Testing and mitigation identification cards) – This new section requires each mitigation and testing individual and each mitigation and testing firm employee to obtain a Department ID card and these ID cards are to be worn prominently and will be presented to the client upon request. This is being added to ensure the public has proper and current proof of certification at all times.

§ 240.143 (Adding or removing devices from certification) – This new section explains that written requests signed by the certified individual must be submitted to add or remove testing and/or lab devices. The Department's written response letter will contain the add or remove date, so that all parties are clear on exactly when a device has been added or removed from a certification.

§ 240.201 (Criteria for issuance or denial of certifications or course provider applications) – This amendment would revise the section title and subsections (a) and (b) to add reference to requirements for course provider's applications to ensure proper accountability and transparency about who is providing this educational service to the certified community.

§ 240.202 (Terms of certification) – The proposed rulemaking would clarify the language of this section by changing 'other radon-related activity' to 'laboratory analysis.'

§ 240.203 (Conditions of certification) – The proposed rulemaking would clarify the language of 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.

§ 240.204 (Certification renewal) – The proposed rulemaking would add that a certification renewal application needs to be submitted at least 30 days prior to the expiration of the current certification, and that the submittal of the renewal application does not extend that expiration date. It would add any individual certification application postmarked prior to one year after the expiration of the previous certification is considered a renewal application subject to the late application fee. And an individual certification application postmarked one year or more after the expiration of the previous certification is considered an initial application subject to the initial application fee, but not the late application fee.

§ 240.205 (Certification modification) – The proposed rulemaking would clarify the language of this section by adding that certifications may be subject to the amendment, revision, or modification by the Department for a violation.

§ 240.301 (Advertising) – The proposed rulemaking would clarify the language of this section and add the requirement to include the valid certification number of the certified individual in advertisements to ensure proper accountability and enforcement capability.

§ 240.302 (Required client information) – The proposed rulemaking would revise the section title and clarify the language of this section and adding the requirement that the tester, mitigator or laboratory shall present to the client a current Department-issued photo ID card.

§ 240.303 (Reporting of information) – The proposed rulemaking would clarify what information is to be reported to the Department by the primary certified testing, mitigation, or laboratory individual. It also clarifies that if no radon-related activities are performed during a 45-day period, a report of no activity must be submitted to the Department by the end of that 45-day period in a Department-approved format. The Department currently collects this information through DEP's Greenport which has greatly minimized tracking and entry time, however, it has shown the data requirements needed to be clarified. This proposed rulemaking would also change the requirement of reporting the results in writing within 45 days to 10 days after testing or laboratory analysis to the owner or occupier of the building, and changes 'the owner or occupier of the building' to 'client'.

§ 240.304 (Quality assurance program) – This section would be reserved and the content moved to new § 240.603 (relating to quality assurance program).

§ 240.305 (Health and safety program) – The proposed rulemaking would clarify the language of this section and add requirements for radon mitigators to track exposure and retain these records for 5 years. The requirement for testers and laboratories to track exposure was removed because statistics prove their exposure is not even a fraction of the limit due to the short duration of their exposure. However, there is still the possibility that mitigators may reach or exceed the exposure limits.

§ 240.306 (Continuing education program) – The proposed rulemaking would clarify the language of this section and specify that continuing education credit hours may only be used for one certification period for each certification activity to prevent the use of continuing education credits being used for more than one certification period.

§ 240.307 (Radon measurement proficiency program) – The proposed rulemaking would revise the section title and clarify the language of this section as well as the applicability of this requirement to initial primary tester and laboratory applicants only. This was changed to an initial applicant requirement only. Renewal applicants are not required to repeat this operator's proficiency requirement since they are operating these devices regularly as part of their certification.

§ 240.308 (Radon mitigation standards) – This amendment would revise the section title and content of the section to provide specific requirements for mitigation system installations including fan/fan discharge location, sealing, labeling, and information required to be provided to the client. This section is to provide codification of requirements in the Pennsylvania Radon Mitigation Standards to ensure proper enforcement of these standards.

§ 240.309 (Testing protocols) – This new section provides specific requirements for radon testing to codify the following EPA guidance to ensure proper enforcement capability.

"Protocols for Radon and Radon Decay Product Measurements in Homes," EPA 402-R-92-003, May 1993

Radon Measurement in Schools (EPA 402-R-92-014)

And the following ANSI standard:

ANSI/AARST MAMF-2010 *Protocol for Conducting Radon and Radon Decay Product Measurements in Multifamily Buildings*

These additions include placement criteria; closed house conditions; short-term, post mitigation, real estate, multifamily, school, and commercial building testing; and testing of new construction and buildings under construction. This section will also specify that the result must be given to the client within 10 working days and the information to be included on the Result Report Form provided to the client. The information contained on the radon test result report form is the only information the client receives about that test. In order to fully understand that result data such as location of test, calibration due date, test start and end date and time, type of device used, complete address of test location, the average and individual results of co-located devices, radon health risk info, and if applicable the name and certification number of the lab must be included to have a meaningful test result. Just reporting the result as a number in pCi/L is not sufficient or adequate.

§ 240.401 (Inspection) – The proposed rulemaking would correct minor grammatical errors.

§§ 240.501 (Scope) and 240.502 (Reapplication when this chapter is adopted as final) – The proposed rulemaking would delete these sections, which are now obsolete.

Sections 240.601 – 240.606 are proposed to be added as new Subchapter G, Quality Assurance Requirements.

§ 240.601 (Scope) – This section would apply quality assurance (QA) requirements to testers and laboratories and their devices. This new section would clarify that the requirements do not apply to testing performed only for diagnostics, because diagnostic testing is used only for performance of internal quality assurance.

§ 240.602 (General requirements) – This section would require QA records to be retained for five years and require the certified individual to be responsible for the QA requirements regardless of who performs the QA activity.

§ 240.603 (Quality assurance program) – This section is existing language proposed to be relocated from § 240.304.

§ 240.604 (Quality assurance requirements for testing using primary devices) – This section specifies all QA requirements for each primary testing device (continuous monitors, electret ion chambers and continuous working level monitors). It states specific requirements for each of these devices and their- frequency, logging requirements and control limits.

§ 240.605 (Quality assurance requirements for testing using secondary devices) – This section would include all QA requirements for each secondary testing device (activated charcoal,

continuous monitor, working level monitors, alpha track detectors, and electret ion chambers). It states the specific requirements for each of these devices and their frequency, logging requirements and control limits.

§ 240.606 (Quality assurance requirements for laboratories) – This section would specify all QA requirements for each laboratory device (activated charcoal, continuous monitors, working level monitors, alpha track detectors, and electret ion chambers). It states the specific requirements for each of these devices and their- frequency, logging requirements and control limits.

APPENDIX B (Non-interference Agreement for Real Estate Radon Testing) – The proposed rulemaking would add this appendix to specify the minimum requirements for testing non-interference requirements maintained during a real estate transaction. The conditions are necessary to ensure valid radon test results

APPENDIX C (Radon Exposure Tracking Record)—The proposed rulemaking would add this appendix to specify the template that must be used by radon mitigation service providers as part of their health and safety program in order to track radon exposure of employees pursuant to § 240.305 (relating to health and safety programs). Tracking radon exposure is necessary to ensure that employees do not exceed recommended exposure limits.

F. Benefits, Costs and Compliance

Benefits

As set forth in this proposal, users of radiation sources would be required to comply with radiation protection standards that would not only protect employees but would also protect the general public. The proposed rulemaking would ensure that trained professionals are operating these radiation sources so that both the patient and the operator are adequately protected.

The proposed amendments to the radon certification regulations would 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 protocols and quality assurance and quality control requirements would ensure that the radon services provided to the public will protect the public's health and welfare from the dangers of radon. The quality assurance and quality control requirements being proposed 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 proposed amendments would eliminate the requirement to have one year of radon testing experience prior to certification, which would benefit the regulated community by simplifying and shortening the process for an individual to become certified to test for radon. Lastly, the proposed amendment codifies the exemption from laboratory certification for certified primary testers who place, retrieve, and analyze continuous monitors or electret ion chambers.

Compliance Costs

The proposed amendments to Section 221 (relating to X-rays in the healing arts), which require a Qualified Medical Physicist (QMP) to perform various functions, may increase costs for a small percentage of registrants. A QMP would be required to, among other things, personally evaluate or direct the evaluation of fluoroscopic, CT, and CBCT equipment, recommend imaging quality control programs, review protocols, perform or direct the performance of radiation surveys, and provide analysis of medical events. The Department is proposing to add these requirements because QMPs are trained and most often certified in health physics disciplines, and their oversight of these functions would ensure adequate radiation protection standards are maintained. The vast majority of the regulated community is already employing QMPs in this capacity as it is standard industry practice, but there may be a small percentage of facilities that employ individuals that do not meet the proposed definition of QMP. The Department is proposing a "grandfathering" provision in the definition of QMP, which would further reduce the impact to the regulated community by allowing individuals who meet certain requirements to continue to perform the functions of a QMP as long as they complete continuing education requirements. A QMP typically charges a minimum of $150 per hour for their services, and the small percentage of registrants who will be required to obtain the services of a QMP for these functions may see an increase in their costs.

The proposed amendments to the radon certification regulations pertaining to reinstating previously withdrawn certifications would decrease costs for and be a benefit to the regulated community because they will no longer be required to pay certification fees to reinstate a withdrawn certification. Depending upon the type of certification, this amendment would save a firm or individual anywhere from $300 to $750 when an individual or firm seeks to reinstate a withdrawn certification. See 25 Pa. Code Chapter 240 Appendix A (relating to Radon Certification Fee Schedule).

The proposed amendments to the radon certification regulations requiring certified firms to employ one certified individual per five firm employees may increase costs for the regulated community. This amendment would benefit the public because it would ensure that uncertified firm employees are being adequately supervised by the firm's certified individuals. Based on the current fee schedule, this amendment may cost a certified firm an additional $300 every two years for each additional certified individual they are required to employ.

Compliance Assistance Plan

Outreach and support will be provided by regional inspectors and technical staff of the Department's Radiation Control Division. The majority of changes clarifying references and definitions are self-explanatory. Assistance will be offered to explain acceptable requirements for addressing new technologies.

Paperwork Requirements

The proposed rulemaking would change various records retention requirements to a five-year records retention period. This change was suggested by the RPAC to promote consistency

throughout the radiological health regulations. These records do not need to be in paper format and may be stored electronically.

G. Pollution Prevention

Pollution prevention is not applicable to this proposed rulemaking.

H. Sunset Review

The Board is not establishing a sunset date for these regulations, since 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.

I. 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 this proposed rulemaking to the Independent Regulatory Review Commission (IRRC) and the Chairpersons of the House and Senate Environmental Resources and Energy Committees.

Under Section 5(g) of the Regulatory Review Act, IRRC may convey any comments, recommendations or objections to the proposed rulemaking within 30 days after the close of the public comment period. The comments, recommendations or objections must specify the regulatory review criteria which have not been met. The Regulatory Review Act specifies detailed procedures for review, prior to final publication of the rulemaking, by the Department, the General Assembly and the Governor of comments, recommendations or objections raised.

J. Public Comments

Interested persons are invited to submit written comments, suggestions, support, or objections regarding the proposed rulemaking to the Board. Comments, suggestions, support, or objections must be received by the Board by June 26, 2017. In addition to the submission of comments, interested persons may also submit a summary of their comments to the Board. The summary may not exceed one page in length and must also be received by the Board by June 26, 2017. The one-page summary will be distributed to the Board and available publicly prior to the meeting when the final-form rulemaking will be considered.

Comments including the submission of a one-page summary of comments may be submitted to the Board online, by e-mail, by mail or express mail as follows.

Comments may be submitted to the Board by accessing the Board's online comment system at http://www.ahs.dep.pa.gov/eComment.

Comments may be submitted to the Board by e-mail at RegComments@pa.gov. A subject heading of the proposed rulemaking and a return name and address must be included in each transmission.

If an acknowledgement of comments submitted online or by e-mail is not received by the sender within 2 working days, the comments should be retransmitted to the Board to ensure receipt. Comments submitted by facsimile will not be accepted.

Written comments should be mailed to the Environmental Quality Board, P. O. Box 8477, Harrisburg, PA 17105-8477. Express mail should be sent to the Environmental Quality Board, Rachel Carson State Office Building, 16th Floor, 400 Market Street, Harrisburg, PA 17101-2301.

PATRICK MCDONNELL,
Acting Chairperson
Environmental Quality Board

PROPOSED RULEMAKING
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.

* * * * *

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

The following Department records [**are not available for public inspection**] **may not be disclosed to the public or to any 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 non-medical use without prior written approval of the Department.**

(1) A person requesting the Department to approve the non-medical 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 non-medical 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:

* * * * *

(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)] **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 listed 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).

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

§ 216.1. Purpose and scope.

* * * * *

(b) A person possessing an accelerator as defined in § 228.2 (relating to definitions) **or a person performing electronic brachytherapy as defined in § 221.2 (relating to**

definitions) is exempt from the requirements of § 216.2 (relating to registration of radiation-producing machines).

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

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

(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:

* * * * *

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

(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.

* * * * *

§ 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.

* * * * *

(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 performance standards for ionizing radiation-emitting products).

§ 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).

* * * * *

(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:

* * * * *

(4) **[Accelerators are exempt from registration.]**Accelerators**, which are [shall be]** 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.

* * * * *

(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)]**<u>**(b)**</u>(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, 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 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.*] <u>**[Reserved].**</u>

[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 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) 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) or more of radium-226 shall also comply with 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 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, 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 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 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 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 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:

* * * * *

(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:

Type Facility	*Annual Administrative Fee*	*Annual Fee per X-ray Tube or Radiation Generating Device*
Dentists, podiatrists, veterinarians	$100	$50
Hospitals	$725	$50
Other Facilities	$350	$50

* * * * *

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

* * * * *

(e) An initial application for a license or reciprocity shall be accompanied by a check payable 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.

* * * * *

(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]** __have__ the following meaning, 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 (300 rad).__

__(ii) An unintended dose, other than skin dose, in a single procedure exceeding 5 times the facility's established protocol and 0.5 Gy (50 rad) to any organ.__

__(iii) A dose to the wrong patient or wrong site for the entire procedure and exceeding 0.5 Gy (50 rad) 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 multi-fraction 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 shall be directed to the Department, **__except as required in 10 CFR 20.2206 (relating to Radiation Exposure Information and Reporting System (REIRS))__ [and, for NRC licenses, to the NRC until agreement state status is in effect].**

* * * * *

Subchapter M. REPORTS

§ 219.229. Other medical reports.

__(a)__ Within 30 days of the determination by a physician of either actual or suspected acute or long-term functional damage to an organ or a physiological system of a patient exposed to **__radiation from a__[therapeutic or]** diagnostic **[radiation]__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 event, the registrant or licensee shall:

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

(2) Provide a written report, including the analysis of the medical 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 event as part of the patient's permanent medical record.

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

§ 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 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 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:

* * * * *

Air kerma **– Kerma in air (see definition of Kerma).**

Air kerma rate **– Air kerma per unit time.**

* * * * *

[*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 (see also DR) **– 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. Computed radiography systems may use cassettes to house the phosphor, or it may be integrated into a digital radiography 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.

***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).**

* * * * *

DDR - Direct digital radiography (see also CR and DR) **– 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.**

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.**

DR - Digital radiography **– An X-ray imaging method (or radiography) which produces a digital rather than film projection image. It includes both CR and DDR.**

DRL - Diagnostic reference level**—An investigational level, set as a standard by a recognized body (e.g., ACR, AAPM, NCRP, 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.**

* * * * *

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) = CTDIvol (mGy) x 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 shall meet the applicable parts of Title 25 pertaining to registration and use.**

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

* * * * *

FGI - Fluoroscopic-guided interventional procedures – **An interventional diagnostic or therapeutic procedure performed via percutaneous or other access routes, usually with local anesthesia or intravenous sedation, which uses external ionizing radiation in the form of fluoroscopy to localize or characterize a lesion, diagnostic site, or treatment site; to monitor the procedure; and to control and document therapy.**

* * * * *

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.**

* * * * *

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 energies of less than 1 million electron volts (MeV) that could exceed skin doses of 200 rads (2 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.

* * * * *

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 (Gy).**

* * * * *

Medical physics – **An application of physics that addresses the needs of medicine or healthcare. 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.

* * * * *

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

* * * * *

Performance phantom – A device specifically approved by the QMP/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.

* * * * *

QE – Qualified Expert – A qualified expert 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 the following credentials:

(A) Is 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) must 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 noted in the medical physics definition, under the supervision of a QMP who is qualified to practice in the same subfield(s), 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 date of adoption of this proposal.) 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 and/or subfields in which the individual practices. As of (Editor's Note: The blank refers to the date of adoption of this proposal.), an individual who qualifies as a QMP under this subsection must meet the continuing education requirements in subparagraph (ii)(C).

* * * * *

Radiological physics **– See health physics.**

* * * * *

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.**

* * * * *

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

* * * * *

ADMINISTRATIVE CONTROLS

§ 221.11. Registrant responsibilities.

* * * * *

(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 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 two years.

(2) Continuing education for all other (low-risk) procedures shall occur, at a minimum, every four 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 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; **diagnostic reference levels;** 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 handheld during the exposure **unless specifically designed to be handheld**.

(n) Any 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 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 DAP (dose-area product) values, CTDI 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(s) to be used.

(xvii) Fluoroscopic and fluorographic outputs of each mode of operation on the system(s) 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 all 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 outlined above, the continuing education shall include facility and X-ray unit-specific methods to manage patient dose.

(2) Documentation of continuing education shall 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 date of adoption of this proposal.) 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 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.]

* * * * *

§ 221.35a. Fluoroscopic X-ray systems.

(a) *General requirements.* Fluoroscopic X-ray systems **[shall]** **must** use an image intensifier[,] and, in addition to the requirements of § § 221.1—221.34a, **[shall]** **must** 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 shall be limited to:

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

(2) A Department-recognized radiologist assistant (RA) 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 (ARRT) 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 these evaluations shall include:

(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 cineradiography (CINE), when available. Measurements shall be performed with a calibrated dosimetry system per manufacturer recommendations not to exceed 2 years and records maintained for 5 years for inspection by the Department. These 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 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 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 availability and accuracy of technique indicators and integrated radiation dose displays.

(7) An evaluation of any changes that may impact patient and personnel protection devices.

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

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

(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 shall include 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 shall include other information necessary to estimate the radiation dose to the skin in accordance with established protocol or the following, as necessary:

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

(b) CT units used solely for therapy simulations **[shall] must** comply with § § 221.202(**[f]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 must be evaluated annually and as soon as practical after any component repair or change which, in the opinion of the QMP, may affect the performance of the CBCT unit:

(1) Beam alignment. The X-ray field in the plane of the image receptor shall not exceed beyond the edge of the image receptor by more than 2 percent 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 shall be aligned with the center of the image receptor to within 2 percent of the SID.

(2) A performance evaluation shall be performed by or under the direct supervision of a QMP. 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 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 performing routine QC, including the use of the CBCT phantom(s); a schedule of routine QC appropriate for the system; allowable variations set by the QMP, if required, for the indicated parameters; and 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.

§ 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 below:

(1) Section 221.202(a) (relating to equipment requirements) 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) 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.

* * * * *

(k) When a control panel may energize more than one X-ray tube, the following requirements shall be met:

(1) It must be possible to activate only one X-ray tube at one time.

(2) There must be an indication at the control panel identifying which X-ray tube is energized.

(3) There must be an indication at the tube housing assembly when that tube is energized.

(l) There must be a means of determining the SSD to within 5 millimeters.

(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 (e.g., $CTDI_{vol}$ (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.**

* * * * *

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

CT number - The number used to represent the X-ray attenuation associated with each elemental area of the CT image**[.]:**

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

where:

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

μ_x = Linear attenuation coefficient of the material of interest.

μ_w = Linear attenuation coefficient of water.

CTDI—Computed tomography dose index—

(i) The integral of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan.

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

where:

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

D(z) = Dose at position z.

T = Nominal tomographic section thickness (cm).

N = Number of tomograms produced in a single scan.

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

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

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

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

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,

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

CTDWw - Weighted Computed Tomography Dose Index– **The estimated average $CTDI_{100}$ across the field of view (FOV). 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 or 32 cm acrylic phantom. $CTDI_w$ uses $CTDI_{100}$ and an f-factor for air (0.87 rad/R or 1.0 mGy/mGy).

* * * * *

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

* * * * *

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

[*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 x K x L x E)/(T x 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]

* * * * *

Notification value **- A dose index value (e.g. $CTDI_{vol}$ (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.**

* * * * *

§ 221.202. Equipment requirements.

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

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

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

[(b)](d) *Tomographic plane indication and alignment.* * * *

[(c)](e) *Status indicators and control switches.* * * *

[(d)](f) *Indication of CT conditions of operation.* * * *

[(e)](g) *Leakage radiation.* * * *

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

* * * * *

(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**.

* * * * *

§ 221.204. [Radiation measurements and p]Performance evaluations**, routine QC, and surveys.**

(a) **[***Radiation measurements***]***Performance evaluations*.

(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 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.]

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 shall 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 shall include, but not be limited to, 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 where 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 shall 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-old).

(B) Pediatric abdomen (5-year-old; 40-50 lb. (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) of this paragraph.

(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 such 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] routine QC** procedures shall include **[at least], at a minimum,** the following using the facility's performance phantom:

(i) Noise.

(ii) [Contrast scale.

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

(iv)] Mean CT number for water.

(iii) Artifact evaluation.

[(v) Acceptable tolerances.]

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

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

(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 date of adoption of this proposal.) and those systems not previously surveyed shall have a survey performed by or under the direction of a QMP. In addition, such surveys shall be performed after any change in the facility or equipment which might cause a significant increase in radiation hazard.

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

(d) ***Records.***

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

§ 221.205. Operating procedures.

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

[(a)](b) [Information]The following information shall be **readily** available **[at the control panel regarding the operation and performance evaluations of the system. The information shall include the following]to the CT operator**:

(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 **and a process for reporting deviations in protocols** including a schedule of **[performance evaluations]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) [A current]Current [technique chart] protocol information available at the control panel which specifies for each routine examination the CT conditions of operation **[and the number of scans per examination]**.

[(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

§ 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]30 (relating to rules of general applicability to domestic licensing of byproduct material) and 10 CFR Part 31 Section 31.11 (relating to 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 shall include the subjects listed in Chapter 221 Appendix A (relating to determination of competence), and 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 during the radiographic exposure. The following requirements apply to persons involved with the examination:

(1) No individual or extremity may 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, 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 in subsection (d).

(f) The registrant shall have a QA program. The QA 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 QA program shall 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 non-human imaging are exempt from §§ 221.202 – 221.205.

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, 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 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 by 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 industrial radiographic operations.

* * * * *

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 the following requirements**[.]**:

* * * * *

(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]**53 (relating to surveillance; 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 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.

* * * * *

(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) (relating to area requirements), but shall meet the requirements of subsection (f)(2) of this section and §§ 227.13a(a) and 227.14(a) (relating to operating requirements; and personnel requirements).

CHAPTER 228. RADIATION SAFETY REQUIREMENTS FOR PARTICLE ACCELERATORS

ADMINISTRATIVE CONTROLS

§ 228.11a. Licensee responsibilities.

* * * * *

(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.**

* * * * *

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.

* * * * *

(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)]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, items included in Appendix A (relating to determination of competence) **for medical accelerator operations, as well as basic radiation protection for non-medical 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]Equipment** [shall] **must** meet 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]Equipment manufactured or installed prior to July 17, 2004, [shall] must** meet 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]**__or__ electron therapy__, or both,__ **[shall]** __must__ meet the following additional requirements:

* * * * *

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

Equipment capable of **[both]** stationary beam therapy **[and]**__or__ moving beam therapy__, or both,__ **[shall]** __must__ meet the following additional requirements:

* * * * *

§ 228.75. Calibrations.

* * * * *

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

* * * * *

(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 (FFF) mode__.

* * * * *

CHAPTER 230. PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

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, 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 240. RADON CERTIFICATION

Subchapter A. GENERAL PROVISIONS

GENERAL

Sec.

GENERAL

§ 240.1. Description of regulatory structure.

* * * * *

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

(g)]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 persons except a person:

(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 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] secondary [radon testing]** devices **[, such as charcoal canisters or track etch monitors]** 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 radon testing devices.

(6) Employed by a local government or a school who performs testing for that local government or school if 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.

(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.**

***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).

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 but not limited to 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.**

***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).**

***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.**

***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 quality control value set at plus or minus three 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 four 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 quality control process which evaluates the voltage drift of each new batch of electrets received from the manufacturer of the electrets.

Field blank—A quality control 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 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.

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.

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

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 working levels.

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.**

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*—2.22 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:**

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

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

$$\text{RPE} = \{(MV - RV)/RV\} \times 100.$$

***RV—Reference value*—The known radon concentration value, in units of picocuries per liter or working level, 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 one, two or three sigma, corresponding to one, two, or three standard deviations around the mean.**

***Spiked measurement (spike)*—A quality control measurement conducted to evaluate accuracy by exposing the detector or device to a known concentration and submitted for analysis.**

Test—The act of **[examining] measuring for the presence of radon in** a **[building, soil,] building's** 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] supply**.

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

WL—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/l of Radon-222. One WL is equal to 130,000 Mev of potential 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 (2040 hours) from breathing in an atmosphere at a concentration of 1 WL for a working month of 170 hours.**

***Warning level*—A quality control value set at plus or minus two sigma.**

Subchapter B. CERTIFICATION

CERTIFICATION FOR RADON TESTING

Sec.

CERTIFICATION FOR RADON MITIGATION

CERTIFICATION FOR RADON LABORATORY

CERTIFICATION FOR PERSONS CERTIFIED IN ANOTHER STATE

OTHER CERTIFICATION PROCEDURES

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 **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] individual** certified to test **who is in responsible charge of the firm's testing activities**, and the firm shall submit an application for certification **and receive certification from the Department.**

(c) **[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.] 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 or she places and retrieves.**

(d) A person using **[passive radon monitors] secondary radon testing devices**, such as **activated** charcoal **[canisters],** 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)] Submitted a complete and accurate application to the Department, including applicable fees.

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

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

(i) The firm owner shall notify the Department in writing within 5 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 [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)].**

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

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

(6) Each testing firm employee applicant shall submit:

(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.

(iii) Proof of passing a Department-approved radon measurement exam.

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

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

(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 program]** and a continuing education program as required in **[§§240.304-240.307]** **§§ 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 **(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:

(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 in § 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 shall be subject to the penalties of 18 Pa.C.S. § 4904.**

(b) Within 10 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 may 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 **[person]** **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 or 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]**the individual has **[done the following]**:

(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.

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

(i) The mitigation firm owner shall notify the Department in writing within 5 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 [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].**

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

(3) If the mitigation 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 days of this change.

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

(4) 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) Each mitigation firm employee applicant shall submit:

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

(ii) The applicant's current photograph, in a format specified by the Department, to be used on the identification card as required in § 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.

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

* * * * *

§ 240.113. Radon mitigation application contents.

(a) An application for radon mitigation 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:

(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] The application must [shall also]** 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 in § 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 shall be subject to the penalties of 18 Pa. C.S. § 4904.**

(b) Within 10 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 may 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 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) **Completed [Taken]** 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**.

* * * * *

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

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

(i) The firm owner shall notify the Department in writing within 5 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 [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]**.

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

(3) 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 days of this change.

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

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

(5) Each laboratory firm employee applicant shall submit a completed and signed laboratory firm employee application as provided by the Department.

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

(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 program and a continuing education program as required in **[§§ 240.304—240.307]** **§§ 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 **(relating to continuing education 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:

(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] The [applicant] application** shall **[also]** include the duties assigned to the certified individual **in responsible charge of the laboratory analysis activities**.

*****

(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.

* * * * *

(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 shall be subject to the penalties of 18 Pa. C.S. § 4904.**

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

§ 240.124. Application filing deadline.

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

(b) **[and any]** **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 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:

(1) A copy of the **[certificatin]** **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.

* * * * *

(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 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.

***(Editor's Note:* Sections 240.141-240.143 are new and are printed in regular type to enhance readability.)**

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 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 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) *Re-instatement of withdrawn certifications.*

(1) The previously certified individual may submit a written, signed request to re-instate the individual's testing, mitigation or laboratory individual certification or the firm owner may request to re-instate 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 (relating to radon certification fee schedule).

§ 240.142. Testing and mitigation identification cards.

(a) 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

Sec.

§ 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 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).

* * * * *

(b) The Department may deny **the** certification **or course provider application of** **[to]** 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, mitigation or **laboratory analysis** **[other radon-related activity]** 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 the following conditions:

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

* * * * *

(4) For certification of a firm, the certified **[person]** **individual** shall **[continue to direct]** **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 individuals shall pass blind studies conducted by the Department. The individual measurement results of the blind study must achieve an individual relative percent error of less than or equal to +/- 25% of the reference value.

* * * * *

§ 240.204. Certification renewal.

(a) An application for certification renewal shall 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 the 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 set forth 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 set forth in Appendix A (relating to radon certification fee schedule). This 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

Sec.
240.301. Advertising.
240.302. **[Notice to clients] Required client information**.
240.303. Reporting of information.
240.304. **[Quality assurance program.] [Reserved.]**
240.305. Health and safety program.
240.306. Continuing education program.
240.307. **[EPA Radon Measurement Proficiency Program.] Radon measurement proficiency program.**
240.308. **[Testing and] Radon** mitigation **[protocols] standards**.
240.309. Testing protocols.

§ 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] services or products offered,**

health effects, **[or the risks to health]** 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 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).]

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 no radon-related analysis is 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 shall be identified as "diagnostic" when submitted to the laboratory. [At a minimum, these results will be retained for 2 years.] The information must include:

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

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

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

[(4)] (C) The **begin and end** date **of** each measurement **[was taken, or the mitigation performed], measurement method, and locations in the building.**

[(5)] (D) The type of house or building, the types of **[measurements] measurement devices used, the** location**s** 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.]

(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 quality assurance.

(2) *Mitigation reporting.*

(i) A mitigation certified individual shall report the mitigation activity results to the Department within 45 days of the mitigation system initial fan activation or the alteration to an existing mitigation system. If no mitigation activity is 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:

(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).

[(b)] (3) ***Reporting to client.*** Within **[45]** **10** days after testing **[, mitigation or other radon-related service]** **or laboratory analysis** is provided, the person providing radon-related services shall report in writing to the **[owner or occupier of the building] client** the results in picocuries per liter and, when appropriate, in working levels of radon measurements taken in the building. If a **[person] secondary tester** provides the service through a certified **[intermediary] laboratory**, it is the responsibility of the **[intermediary] certified individual** to report the results **to the client**.

[(c)] (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 **[EPA- or DEP-approved] Department-approved** protocols, **§ 240.308(e) (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 **[radon testing] the postmitigation test** shall be reported in accordance with this section.

§ 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 **firm employees [employes]** from exposure to radon **[during the course of their employment]**. The program shall include

records of each **[individual's]** **mitigator's** exposure to radon **during the course of his employment**. **The certified individual shall record the items on the form in Appendix C and retain the records for a period of 5 years. [Persons conducting radon-related activities]** **Testers and mitigators** shall maintain exposure to radon as low as reasonably achievable **(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] **Upon certification renewal,** the certified **[person]** **individual** 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]** **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] **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 the most recent EPA Radon/Radon progeny Measurement Proficiency Program or an alternative program approved by the Department for each radon measurement utilized]** **in a Department-approved radon measurement proficiency program for each model type**.

§ 240.308. Radon [Testing and] mitigation [protocols] standards.

(a) ***Terminal discharge.*** **To prevent reentrainment of radon, fan discharges of depressurization systems, whether fan-powered or passive, must meet the following requirements:**

(1) The termination point must be vertical, upward, outside the structure, and discharging to the atmosphere. 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) The termination point must be 10 feet or more above the ground level nearest to the point of discharge.

(5) 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 such 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) The termination point must be 10 feet or more horizontally from a vertical wall that extends above the roof.

(7) The termination point must be 10 feet or more from an opening into an adjacent structure.

(b) *Fan Location.* A radon fan used in active soil depressurization or a block wall depressurization system shall not be installed:

(1) Below grade or in the heated or cooled 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) *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 or control joint.

(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 sub-surface 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.

(ii) This technique may decrease the efficiency of the radon mitigation system.

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

(d) *Labeling.*

(1) If the mitigation system is accessible and visible, then 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 shall be legible from a distance of at least three feet and include the following information:

(i) "Radon Reduction System."

(ii) The name and certification number of the mitigation certified individual.

(iii) The contact telephone number of the mitigator.

(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 shall read "Radon Reduction System."

(e) *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 the following:

(1) A completed copy of the Radon Mitigation Project Record from "Pennsylvania Radon Mitigation Standards," 294-2309-002, October 1, 1997, Appendix A.

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

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

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

(6) A recommendation to retest at least every two years.

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

(f) ***Compliance.*** A person conducting radon **[testing or]** mitigation **[for radon contamination] 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.

(*Editor's Note:* The following section is new and is printed in regular type to enhance readability.)

§ 240.309. 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(a) (relating to reporting of information), radon testing shall be performed in accordance with 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 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.

(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 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 2 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 must 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) *Continuous radon monitor (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 the following anti-tampering procedures:

(i) Testing devices shall be secured against movement by employing anti-tampering methods.

(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 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 *Protocol for Conducting Radon and Radon Decay Product Measurements in Multifamily Buildings* or its equivalent as determined by the Department.

(8) *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) *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 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) *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.

(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.

(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 days from the completion of the test or the receipt of the test results from the laboratory. The Result Report Form must contain:

(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 N/A) 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 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 continuous radon monitor, a copy of the device printout.

(xvii) If using a continuous radon monitor or electret reader, the calibration expiration date.

(xviii) If using a continuous radon monitor 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 days after completion of test analysis. The Result Report Form must contain:

(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.

(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.

(ix) The Pennsylvania "Notice to Clients" statement as indicated in § 240.302.

(x) If using a continuous radon monitor, 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

Sec.

§ 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]

[Sec.]
[240.501. Scope.]
[240.502. Reapplication when this chapter is adopted as final.]

[§ 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.]

(Editor's Note: The following subchapter is new and is printed in regular type to enhance readability.)

Subchapter G. QUALITY ASSURANCE (QA) REQUIREMENTS

Sec.

§ 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 shall ensure 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) 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, 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 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 shall also contain 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 10^{th} 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, Exhibit B-2 and Exhibit 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, all 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 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 shall also contain 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 10^{th} 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, Exhibit B-2 and Exhibit 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 the following:

(i) The electret serial number.

(ii) The electret chamber serial number.

(iii) The initial voltage reading.

(iv) The final voltage reading.

(v) The exposure dates and times.

(vi) The test result.

(vii) The serial number of duplicate electret.

(viii) The RPD value.

(ix) The address of the building tested.

(x) The test location in the building.

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

(xii) 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) 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) In addition to the means control chart, all spikes shall be documented on a form that contains the following:

(A) The radon chamber name.

(B) The electret serial numbers.

(C) The electret chamber serial numbers.

(D) The reference value from radon chamber.

(E) The measured spike value or values.

(F) The individual RPE results.

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

(H) 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 must 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, Exhibit B-2 and Exhibit B-3.

(v) For duplicates when the average is greater than or equal to 4.0 pCi/L, 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, 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 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 the following:

(A) Whether it is a short- 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) *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 must 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 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, 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 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 shall also contain 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 10th 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, Exhibit B-2 and Exhibit 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, all 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 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 shall also contain 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 10^{th} test. This printout must 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, Exhibit B-2 and Exhibit 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 the following:

(i) The electret serial number.

(ii) The electret chamber serial number.

(iii) The initial voltage reading.

(iv) The final voltage reading.

(v) The exposure dates and times.

(vi) The test results.

(vii) The serial number of duplicate electret.

(viii) The RPD value.

(ix) The address of the building tested.

(x) The test location in the building.

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

(xii) 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 reference value 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) 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) In addition to the means control chart, all spikes shall be documented on a form that contains the following:

(A) The radon chamber name.

(B) The electret serial numbers.

(C) The electret chamber serial numbers.

(D) The reference value from radon chamber.

(E) The measured spike value or values.

(F) The individual RPE results.

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

(H) 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 must 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 1week 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, Exhibit B-2 and Exhibit B-3.

(v) For duplicates when the average is greater than or equal to 4.0 pCi/L, 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, 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 the following:

(A) The device serial numbers.

(B) The exposure dates.

(C) Each duplicate measurement result.

(D) The RPD results.

(d) *Liquid scintillation (LS), activated charcoal (AC) and alpha tracks (AT) for secondary testers.*

(1) *Data collection log.* Detector data shall be tracked on a form that contains 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 reference value 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) 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) In addition to the means control chart, all spikes shall be documented on a form that contains the following:

(A) The radon chamber name.

(B) The device serial numbers.

(C) The reference value 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 must 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, Exhibit B-2 and Exhibit B-3.

(v) For duplicates when the average is greater than or equal to 4.0 pCi/L, 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, 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 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, 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 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 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 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 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) 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) In addition to the means control chart, all spikes shall be documented on a form that contains the following:

(A) The radon chamber name.

(B) The electret serial numbers.

(C) The reference value 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 must 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, Exhibit B-2 and Exhibit B-3.

(v) For duplicates when the average is greater than or equal to 4.0 pCi/L, 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, 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 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 the following:

(A) Whether it is a short- 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 DEP-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/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) 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) In addition to the means control chart, all spikes shall be documented on a form that contains the following:

(A) The radon chamber name.

(B) The device serial numbers.

(C) The reference value 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 must 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 1week 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, Exhibit B-2 and Exhibit B-3.

(v) For duplicates when the average is greater than or equal to 4.0 pCi/L, 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, 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 the following:

(A) The device serial numbers.

(B) The exposure dates.

(C) Each duplicate measurement result.

(D) The RPD results.

(e) *Alpha tracks.*

(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 DEP-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 reference value 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) 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) In addition to the means control chart, all spikes shall be documented on a form that contains the following:

(A) The radon chamber name.

(B) The device serial numbers.

(C) The reference value 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 must 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, Exhibit B-2 and Exhibit B-3.

(v) For duplicates when the average is greater than or equal to 4.0 pCi/L, 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, 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 the following:

(A) The device serial numbers.

(B) The exposure dates.

(C) Each duplicate measurement result.

(D) The RPD results.

(Editor's Note: The following appendix is new and is 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

(Editor's Note: The following appendix is new and is printed in regular type to enhance readability.)

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 (WLM)	Cumulative Exposure[1] (WLM)	Method used to assess Exp.[2]
			÷200=		x		÷170=			
			÷200=		x		÷170=			
			÷200=		x		÷170=			
			÷200=		x		÷170=			
			÷200=		x		÷170=			
			÷200=		x		÷170=			
			÷200=		x		÷170=			
			÷200=		x		÷170=			
			÷200=		x		÷170=			
			÷200=		x		÷170=			
			÷200=		x		÷170=			
			÷200=		x		÷170=			
			÷200=		x		÷170=			
			÷200=		x		÷170=			
			÷200=		x		÷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)

Jefferson.

Department of Radiology
Office of Radiation Safety
[redacted]
T 215-955-7813
F 215-923-9039
[redacted]

February 22, 2016

The Honorable John Quigley, Secretary
Department of Environmental Protection
P. O. Box 2063
Harrisburg, PA 17105-2063

Dear Secretary Quigley:

I am writing to inform you of actions taken by the Radiation Protection Advisory Committee (RPAC) at its July 23, 2015 meeting.

At the RPAC meeting, the RPAC completed review of the draft proposed Radiological Health Regulations as presented by the Department, specifically proposed draft 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 proposed 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: Ken Reisinger, PA DEP
David Allard, PA DEP
Joseph Melnic, PA DEP RPAC Liaison

pennsylvania
DEPARTMENT OF ENVIRONMENTAL PROTECTION

April 21, 2017

David Sumner
Executive Director
Independent Regulatory Review Commission
333 Market Street, 14th Floor
Harrisburg, PA 17120

Re: Proposed Rulemaking: Radiological Health (#7-499)

Dear Mr. Sumner:

Pursuant to Section 5(a) of the Regulatory Review Act, please find enclosed a copy of a proposed regulation for review and comment by the Independent Regulatory Review Commission (Commission). This proposal is scheduled for publication in the *Pennsylvania Bulletin* on May 13, 2017, with a 45-day public comment period. The Environmental Quality Board (EQB) adopted this proposal on October 18, 2016.

This enclosed rulemaking proposes to amend 25 Pa. Code, Chapters 215-221, 223, 225, 227, 228, 230, and 240. Proposed amendments to Chapters 215-221, 223, 225, 227, 228, and 230 are necessary to establish and maintain adequate radiation protection standards and oversight. These regulatory amendments are proposed due to the significant technological advances in the use of radiation sources. Amendments are based on standards set by the current recognized accrediting bodies and national organizations such as the National Council on Radiation Protection and Measures (NCRP) and the Conference of Radiation Control Program Directors (CRCPD). This rulemaking also proposes to amend Chapter 240 to revise application and reporting requirements for certified radon service providers to add clarity to both processes. In addition, amendments to the testing protocols and quality assurance and quality control requirements would ensure that the radon services provided to the public will protect public health and welfare from the dangers of radon.

These proposed amendments will affect any individual, corporation, institution, group, or agency which uses radiation sources. There are approximately 11,000 X-ray machine registrants, 825 radioactive material licensees, 150 accelerator licensees, 325 X-ray service providers, and about 600 entities performing certified radon activities.

The Department of Environmental Protection (Department) discussed the need for regulatory revisions with its Radiation Protection Advisory Committee (RPAC) on October 16, 2014; December 11, 2014; April 2, 2015; June 4, 2015; and, July 23, 2015. RPAC provided extensive input to the amendments and, on July 23, 2015, concurred with the Department's recommendation to move the rulemaking forward for EQB consideration.

The Department will provide the Commission with the assistance required to facilitate a thorough review of this proposal. Section 5(g) of the Regulatory Review Act provides that the Commission may, within 30 days of the close of the comment period, convey to the agency its comments, recommendations and objections to the proposed regulation. The Department will consider any comments, recommendations or suggestions made by the Commission, as well as the Committees and public commentators, prior to final adoption of this rulemaking.

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

- [x] 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

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FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
4/21/17	Dan Cooper	Majority Chair, HOUSE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY Representative John Maher
4/21/17	Richard A. Kox	Minority Chair, HOUSE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY Representative Mike Carroll
4/21/17	Patti Cullen	Majority Chair, SENATE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY Senator Gene Yaw
4/21/17	Carly Simpson	Minority Chair, SENATE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY Senator John Yudichak
4/21/17	K Cooper	INDEPENDENT REGULATORY REVIEW COMMISSION David Sumner
		ATTORNEY GENERAL (for Final Omitted only)
4-21-17		LEGISLATIVE REFERENCE BUREAU (for Proposed only)

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF ENVIRONMENTAL PROTECTION
POLICY OFFICE

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

I.D. NUMBER: 7-444

SUBJECT: Radiological Health

AGENCY: DEPARTMENT OF ENVIRONMENTAL PROTECTION

TYPE OF REGULATION

- [X] 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

DESIGNATION	SIGNATURE	DATE
Majority Chair, HOUSE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY		4/21/17
Minority Chair, HOUSE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY		4/21/17
Majority Chair, SENATE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY		N/A
Minority Chair, SENATE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY		4/21/17
INDEPENDENT REGULATORY REVIEW COMMISSION		4/21/17
ATTORNEY GENERAL (for Final Omitted only)		
LEGISLATIVE REFERENCE BUREAU (for Proposed only)		4/21/17