

**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 _____, 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,” “CBCCT,” “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,” “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,” “CTDI₁₀₀,” “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

These regulations will be reviewed in accordance with the sunset review schedule published by the Department to determine whether the regulations effectively fulfill the goals for which they were intended.

I. Regulatory Review

Under Section 5(a) of the Regulatory Review Act (71 P.S. §§ 745.5(a)), on _____, 2016, 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 DATE. 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 DATE. 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