



pennsylvania
DEPARTMENT OF ENVIRONMENTAL
PROTECTION

Bureau of Radiation Protection

COMMENT AND RESPONSE DOCUMENT

RADIOLOGICAL HEALTH

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

Radiological Health

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

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

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

Public Comment Period and Public Hearings

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

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

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

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

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Acronyms used in this Comment/Response Document

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

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

COMMENTS AND RESPONSES

General Comments

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

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

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

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

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

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

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

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

Chapter 219

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Chapter 221

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

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

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

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

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

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

- 12. Comment:** As currently proposed in § 221.2, the definition of QMP provides three alternative pathways to be considered a “Qualified Medical Physicist.” The American Association of Physicists in Medicine (AAPM) believes that the pathways as proposed are insufficient to assure that individuals providing the designated medical physics services are qualified to do so. This is especially true given the complexity of modern X-ray equipment, including CT. The AAPM recommends that PA EQB consider adopting AAPM’s definition as stated in AAPM’s Professional Policy Statement² or the definition of QMP from the Conference of Radiation Control Program Directors (CRCPD) Suggested State Regulations for Control of Radiation (CRCPD SSRCR), Part F, Sec. F.2, p. 11³.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Response: During the initial development of the proposed rulemaking, the Department agreed with The Joint Commission’s stance on CT certification. The Department now realizes the concerns presented to The Joint Commission and the reasoning for the Joint Commission’s rescission. Thus, the Department will accept individuals having the applicable specialty in radiography, such as ARRT(R) or equivalent, to perform CT procedures, if the procedure is considered low-risk, as defined in § 221.2. CT procedures that are considered high-risk, for example, brain perfusion studies, will require a subspecialty in CT, such as ARRT(R)(CT) Section 221.11 has been revised as follows: “The operator or the individual who supervises the operation of a high-risk procedure shall have additional instruction, which may include certification or registration in the applicable specialty by a professional organization recognized by the Department.”

- 23. Comment:** In § 221.16 – Regarding the word “privileged” – “...registered or credentialed and privileged in the applicable specialty by a professional organization recognized by the

Department.” Privileging is a process conducted and granted by the institution, not a professional organization. Privileging may be based on professional credentials, but can vary among institutions. (8)

Response: The proposed language “registered or credentialed and privileged” was used to prevent disqualification of appropriately qualified individuals who have been granted privileges by an institution and is retained in the final-form rulemaking.

24. Comment: § 221.16 – New section on Training and Continuing Education. Will this still support the “List of Resources Satisfying initial and continuing education requirement...” that supplements the old technical guidance document #291-4200-001 (the document our policy is based off?). The “List” includes American Board of Radiology (ABR) Maintenance of Certification (MOC) participation right now. Obviously, the old technical guidance document will be N/A, but I am wondering if this “List” will be reworked into the new § 221.16. (15)

Response: The “List” will be a separate document from the technical guidance document that will be rescinded, so it will remain available.

25. Comment: § 221.16. Training, competency and continuing education. This section is duplicative of § 221.11(a)-(b). Additionally, it provides differing requirements. These two sections should be combined into one section. (22)

Response: Section 221.16 provides specific training and competency requirements and expands on the requirement for continuing education, and the requirements do not differ from the requirements in Section 221.11. Section 221.11 outlines administrative controls necessary for appropriate operations and are referenced in other subsections throughout the regulations. For these reasons, these sections are not combined in the final-form rulemaking.

26. Comment: § 221.16(a)(2) – For operators of hybrid imaging devices (PET/CT and SPECT/CT) where the CT is used for attenuation correction and localization only, is ARRT (CT) required or would other certification such as Nuclear Medicine Technology Certification Board (NMTCB) be acceptable? (10, 15)

Response: American Registry of Radiologic Technologists (ARRT) certification in Radiology is required when operating a CT that is only used for attenuation correction. Individuals certified in NMTCB must have post-primary certification in CT to perform CT procedures.

27. Comment: § 221.16(b)(1) – Continuing education required for high- and low-risk users every 2/4 years, respectively. Will more detailed guidance be provided as to number of hours or how inspectors will determine what is adequate? (15)

Response: The Department has not codified the number of hours due to confusion that often occurs when applying educational units or contact hours to continuing education

requirements. Therefore, additional guidance is not anticipated. Department staff are available to field questions that may arise regarding continuing education. The radiation safety training must be documented to satisfy the regulation.

28. Comment: 221.35a. Fluoroscopic X-ray Systems. § 221.35a (a) General requirements – The language is unnecessarily narrow citing that all fluoroscopic systems shall use an image intensifier. Because not all fluoroscopic units utilize this technology, this should also include language for flat panel detectors and future fluoroscopic detector technologies. (10)

Response: See response to Comment #15.

§ 221.35a(c) QMP evaluations – Fluoroscopic equipment shall be evaluated...under general direction of a QMP. I disagree with “At a minimum, evaluations shall include all of the following:” It is reasonable to assume that “any maintenance of the [fluoroscopic] system that may affect the exposure rate” would not affect many of the listed required evaluation tasks for fluoroscopic X-ray systems such as contrast or collimation. Instead of requiring a full evaluation after any maintenance affecting the output, the QMP should be allowed to make a determination to evaluate those components affected, e.g., only the exposure output in cases when maintenance would not also affect system contrast, collimation, or other system elements. (10)

Response: If the QMP determines that maintenance did not affect the exposure rate, then no further evaluation is necessary. However, a full evaluation is still required within 14 months from the date of the prior evaluation. Therefore, no change has been made in the final-form rulemaking.

§ 221.35a(c)(1) –No compulsory dosimetry system calibration schedule should be enforced (drop “not to exceed 2 years”). Manufacturer in-house testing of dosimeters will determine the best calibration schedule and future advances may require more or less frequent schedules. I currently see less than 2% changes between calibrations and diagnostic calibrations don’t demand the under 2% accuracy of therapy systems. I disagree with § 221.35a(c)(1) because no limits are enforced on exposure rates in acquisition, digital subtraction, or cine modes by any regulating or accrediting body, evaluation of these maximum rates is not always recommended. Considering the potential damage to the fluoroscopic tubes and detectors from maximum output operation, and that manufacturers have installed fail-safes to disable X-ray production at maximum exposure rates in these modes, evaluation of these maximum exposure rates should not be mandated. (22)

Clean up language regarding calibrated dosimetry system. I think the intention is: “a dosimetry system that has been calibrated within the prior 2 years according to manufacturer’s recommendations.” (10)

Response: The Department has changed the language to “Measurements shall be performed with a dosimetry system calibrated within 2 years preceding the measurements. Records of these output measurements shall be maintained for 5 years for inspection by the Department.” The Department has removed the proposed

language “including those that are expected to drive the system to maximum output,” in the final-form rulemaking in response to the comment.

§ 221.35a (d) Additional requirements for facilities performing FGI. Change to “...performing high-risk FGI.” These should not apply to low-risk FGI. For (iv), the review of established procedures should be established by the facility and not mandated by DEP. (2) – what is the rationale for requiring a justification for revisions of policies or procedures? This should be eliminated. The language in (d)(3)(iv) and (d)(4) is confusing. The regulation mandates recording of PSD, cumulative air kerma, or dose area product (DAP) if available on the fluoroscopic unit, if not available then four additional pieces of information must be recorded. NCRP Report 168 recommendation 13, cumulative fluoroscopy time alone can be used as a least preferred method of skin dose estimation without additional recorded information. This method can also be used if use of dose estimation from air kerma, DAP or PSD is not practical or possible but still available. This should be changed to align with nationally accepted practices of patient dose monitoring and recording. (22)

Response: The Department discussed this comment with the RPAC and amended the definition of FGI in this final-form rulemaking to only include high-risk fluoroscopic-guided interventional procedures.

29. Comment: Re § 221.35a. “Fluoroscopic X-ray systems.” Subsection (b)(4) allows for operation of a fluoroscopic system by “A medical resident, radiologist assistant or radiologic technology student in training who is under the personal supervision of a licensed practitioner working within his scope of practice.” I believe that this provision for individuals in clinical training needs to be made applicable to individuals in clinical training for any modality (CT, general radiography, etc.) and should therefore be moved to a location within the regulations that apply to all, or should be added individually to each appropriate section of the regulations. (4)

Response: The current regulations address clinical training in human use of radiation sources in § 215.24(d), which has been renumbered as § 215.24(c) and expanded in the fluoroscopy section because it addresses other students as well as personal supervision requirements. These two sections adequately address training requirements for other modalities.

30. Comment: § 221.35a(b)(1) – Operation of fluoroscopic systems: I would like clarification on “licensed practitioner working within his scope of practice.” It seems that Physician Assistants (except Radiology PAs?) can no longer be trained to utilize fluoroscopy, since their “Professional and Vocational Standards” do not cover operation of fluoroscopic equipment. Is this accurate? (15)

Response: No, it is not accurate. Currently, Physician Assistants (PAs) are licensed by the Department of State. Title 49, Subchapter G (relating to medical doctor delegation of medical services) of this Commonwealth’s regulations permits all duties specified in written agreements between the supervising physician and the Physician Assistant to be

performed. If those duties include fluoroscopic procedures, the Physician Assistant is permitted to perform them.

- 31. Comment:** § 221.35a(c)(3) – Replace “spot-film modes” with “radiographic modes.” Spot-film is an outdated term. (10, 15, 22)

Response: The term “spot-film” may be considered outdated; however, it is still relevant and a familiar term and defined appropriately in § 221.2. Therefore, the Department has not amended it in the final-form rulemaking.

- 32. Comment:** § 221.35a(c)(4) – I recommend eliminating the evaluation of the 5-minute timer. The 5-minute timer contributes to “alarm fatigue” without offering any advantage for radiation safety and protection. Its original intention may have been good but with modern radiation metrics, it has outlived its usefulness. (10)

Response: Evaluation of the 5-minute timer remains relevant for older units that are still in operation and therefore has not been eliminated in the final-form rulemaking.

- 33. Comment:** § 221.35a(c)(6) – An evaluation of the availability and accuracy of technique indicators...The only technique indicator we evaluate is kVp. I assume this is acceptable! (15)

Response: The Department expects both tube potential “kVp” and tube current “mA” to be measured as technique indicators. Exposure time or “pulse width” for a pulsed fluoroscopy system should also be evaluated.

- 34. Comment:** § 221.35a(d)(1)(ii) – This should reference monitoring dose as indicated by cumulative air kerma meter, i.e., dose to interventional reference point or other practical means. (15)

§ 221.35a(d)(1)(ii) – Monitoring actual patient dose during FGI is not practical. I recommend monitoring cumulative dose to a standard location in space (e.g., the Interventional Reference Point, or IRP). (10)

Response: Cumulative dose and actual dose are both acceptable methods for monitoring patient radiation dose during FGI procedures.

- 35. Comment:** § 221.35a(d)(4)(i) – In practice, the fluoroscopic mode may change during an FGI procedure. Some systems do not report the various modes that were used during a procedure. (10)

Response: The Department has amended proposed subsection (d)(4)(i) in the final-form rulemaking for clarity.

- 36. Comment:** § 221.57. Facilities using CR and DR. This section should be incorporated into

§ 221.11(l) referring to the QA/QC program. Section (c) provides vague tests including contrast/noise and workstation monitors; this section should be eliminated as section (b) addresses this adequately. (22)

Response: CR/DR should be and is referred to directly in the QA/QC section of § 221.11(l); however, due to the importance of systems using CR or DR, proposed § 221.57 was created specifically to address CR/DR. This entire section has been renumbered as § 221.50 in the final-form rulemaking.

37. Comment: § 221.57(a) – To implement a process to investigate consistent deviations from established exposure indicator ranges requires some method to electronically record and analyze the exposure indicator data. Some CR & DR manufacturers may not provide such capability as an integral part of their systems. This could be a great burden. I recommend that wording be added to allow an exemption from this requirement if the necessary tools are not an inherent capability of the CR or DR system. (10)

§ 221.57(a) – Establishing an acceptable range for exposure indicators can be a burdensome process. Some unit's report Exposure Index (EI), others report Radiation Exposure (REX), etc. Also, clinical factors greatly impact the exposure indicator such as collimation, patient centering, etc. While it is agreed that monitoring EI is important, we still need more support and guidance from the system manufacturers. Implementation and enforcement of this section will need more clarification from the Bureau. (15)

Response: An exemption is inherent in subsection (a), which begins with the language “When exposure indicators are available...”. If exposure indicators are not available, the registrant should still develop a means to determine if exposure values for each image are necessary for adequate radiation protection. Section 221.57 was renumbered as § 221.50 in the final-form rulemaking for proper placement in the regulation. No other changes to the section were made in the final-form rulemaking.

38. Comment: § 221.57(c) – I believe that requiring quarterly testing of CR/DR systems is unnecessary. For large institutions that may have many (hundreds) of CR image plates, this is also impractical. Most DR systems include software that forces the user to perform a self-test or calibration on a regular basis (approximately monthly). Creating a regulatory requirement to force all CR and DR users to meet this standard is extremely burdensome. (10)

§ 221.57(c) – Requiring quarterly phantom evaluations of CR/DR systems seems to be excessive. Perhaps requiring manufacturer's recommended Quality Control (QC) (with phantoms if supplied by manufacturer), or simpler evaluation for artifacts would be more reasonable. Exposure indicator consistence tracking is also difficult. (15)

Response: The Department believes strongly that quarterly testing requirements are necessary and appropriate to assure adequate radiation protection. A number of organizations such as ACR and ASRT recommend monthly checks as Best Practice

requirements. This entire section has been renumbered as § 221.50 in the final-form rulemaking. No other changes to the section were made in the final-form rulemaking.

- 39. Comment:** § 221.57(c) – Many DR systems now come with self-test procedures that analyze uniform (“flat-field”) images for sensitivity, uniformity, artifacts, and noise. These self-tests are often performed with a uniform beam filter. Its purpose is to harden the beam like a patient. Would this filter be considered a “phantom?” In addition, these self-tests do not evaluate spatial resolution or detector contrast. For electronic DR systems consisting of a matrix of fixed detector elements, the detector contrast and the detector resolution does not change over time so, testing spatial resolution on a routine basis is unnecessary. I suggest removing (2) Spatial resolution. (10)

Response: Advanced technology in newer DR systems use different techniques that perform the same function as a phantom. These advanced systems are acceptable for the evaluation requirements proposed in § 221.57, which has been renumbered as § 221.50 in the final-form rulemaking.

- 40. Comment:** § 221.63. Therapy imaging guidance systems. – § 221.63(a) The AAPM publishes guidelines on many topics including QA of CT Simulators. These guidelines clearly state that they are for guidance only and it is the responsibility of the assigned medical physicist and/or a departmental quality assurance committee to establish QA procedures that apply to a particular site. I am concerned that the way the proposed rule is worded, it can be interpreted by a PA state inspector that a site is expected to follow all of the QA procedures described in a document published by a national organization and by the device manufacturer. I suggest: “The QMP shall develop QC procedures and tolerances for therapy imaging guidance systems using nationally-recognized standards or those recommended by the manufacturer for guidance.” The same comment applies for §§ 221.64 (a)(2) and (a)(3). (9)

Response: The proposed rulemaking stipulated that it is the QMP’s responsibility to develop QC procedures. The Department will inspect against those procedures. This requirement is retained in the final-form rulemaking.

- 41. Comment:** § 221.64(a)(2) – In other areas of the proposed regulations, test intervals not to exceed 14 months are allowed, but in this section, it is 12 months. Please be consistent at 14 months. (10, 15)

Response: The Department agrees with this comment and has amended this section in the final-form rulemaking to 14 months for consistency.

- 42. Comment:** § 221.64(a)(2) CBCT. This is a higher supervisory standard than potentially high-risk fluoroscopy or CT. This also does not conform to any nationally recognized QC standard and should be changed to general supervision.

(6)(b)(1) – Not all CBCT systems have phantoms.

(c) – What is the basis for this exemption and the specific operating factors? (22)

Response: The Department agrees and has changed the supervisory standard in proposed subsection (a)(2) to “...under the direct supervision of a QMP or QE” in the final-form rulemaking. The FDA requires all CT systems to be evaluated with a phantom, and current regulation requires compliance with FDA regulations. Proposed § 221.64(c) has been changed in the final-form rulemaking to “CBCT systems are exempt from § 221.202(a) (relating to equipment requirements).”

43. Comment: § 221.64. CBCT. – Commentators are not sure of the need for § 221.64(a)(4). What is the rationale? Cone beam computed tomography (CBCT) is typically used for navigational purposes; these are not doing “typical CT scans” with typical protocols. There is no need to address deviations from existing protocols. For (b)(2), there is no need for an operator to know the full extent of the schedule for QC. They only need to know the ones they are expected to perform. (9, 22)

For (b)(4), it is not clear what is being sought here. The operator needs to evaluate the results of their QC tests and take appropriate action. Otherwise, the QC results need to be reviewed by the QMP. (9)

Response: The purpose of proposed § 221.64(a)(4) is to record deviations from established protocols. Not recording them would make it difficult to track any trends that may be occurring. As for proposed subsection (b)(2), operators should be fully aware of all routine QC, including the schedule to perform QC. As for proposed subsection (b)(4), operators need to be aware of the results of the last QC checks to determine if the QC passed or failed. These provisions are retained in the final-form rulemaking.

44. Comment: § 221.201. Definitions. Eliminate contrast scale, CTDI₁₀₀, dose profile, elemental area, MSAD (multiple scan average dose), multiple tomogram system, and noise, as they are not referred to in the regulations. (22)

Response: All terms listed, except for MSAD, are defined and referenced in various sections of the regulations. The term “MSAD” was deleted in the proposed rulemaking. No change has been made from proposed in the final-form rulemaking.

45. Comment: § 221.202. Equipment Requirements. Why is DEP requiring accreditations? If DEP is going to mandate accreditations, then there is no need for detailed CT equipment testing as the site will need to meet the accreditation testing. (22)

Response: CT accreditation is now a common requirement for medical imaging primarily due to payment under Part B of the Medicare Physician Fee Schedule. Regardless, accreditation will never replace having a good QA program. Routine QC assures the device is operating correctly and verifies safety to patients and staff.

46. Comment: § 221.202(a) – Diagnostic CT systems must be accredited by an organization “recognized by the Department.” Some more clarification is needed as to which accrediting bodies will be acceptable. (15)

Response: The current regulations address organizations recognized by the Department in § 221.11(l). The regulations also state that the Department’s guidelines and a list of recognized organizations will be maintained and made available on the Department’s website and upon request. Therefore, no change has been made.

47. Comment: § 221.202(a) – I recommend that CT scanners that are intended for non-diagnostic use (e.g., treatment planning/simulation, attenuation correction) be exempt from the accreditation requirement. I also recommend exempting CBCT for oral/maxillofacial/ENT, extremity imaging, etc. The ACR CT accreditation program does not support these types of CT devices. (10)

Response: The proposed rulemaking already limits this requirement to “diagnostic CT X-ray systems.” This limit is retained in the final-form rulemaking. Simulators, therapy imaging guidance, and attenuation correction systems are not considered diagnostic. CBCT has been exempted in § 221.64(c) in the final-form rulemaking.

48. Comment: § 221.204. Performance evaluations, routine QC and surveys. Subsection (d) reads “Records. Records of the performance evaluations and surveys shall be maintained for at least 1 year.” Please strike the words “at least” before “5 years” and “1 year.” Subjective regulations never go well for the regulated community when being inspected by the regulators. No other records retention requirements described in these proposed changes uses the term “at least” please provide consistency and strike these words in this section. (3)

Response: The term “at least” has been used consistently in the existing regulations and need not be deleted. The Department is prescribing the minimum amount of time to retain these records; however, the facilities may retain records for longer periods of time if they wish.

49. Comment: § 221.204. Radiation Measurements. CT dosimetry is in flux due to the multi-detector CT scanners which have invalidated the current CT dose testing methods. My recommendation is for the regulations to mandate the dosimetry phantom and testing protocols to meet accreditation requirements or other nationally-recognized standards so as not to be locked into the outdated current state of CT dosimetry. In (3), eliminate (i) HVL, (ii) MSAD. In (5), eliminate mR/mAs value determination for head and body. (22)

Response: The performance phantom is included in proposed § 221.202(h)(4) and therefore does not need to be duplicated elsewhere. All other provisions noted in this comment--§ 221.204(3)(i)-(ii) and §221.204(5)—were proposed for deletion.

50. Comment: § 221.204(a) – Performed under the general supervision of QMP. (22)

Response: The QMP is responsible for performance evaluation, and this requirement must stay under the direction of the QMP. Changing it to “general supervision” will not make a difference as the overall direction and control remain with the QMP. Therefore, no change has been made from the proposed rulemaking in the final-form rulemaking.

51. Comment: § 221.204(a)(3) – Requires initial performance evaluation of CT system prior to patient use. This should be consistent with requirements for X-ray, fluoroscopic, and other systems. (15)

Response: This requirement is consistent with X-ray, fluoroscopic and other systems; however, because CT systems have the potential to be high-risk, the initial performance evaluation is required. Therefore, no change has been made from the proposed rulemaking in the final-form rulemaking.

52. Comment: § 221.204(a)(4)(x) – The requirement to review and assess the dose of the specified procedures should not be mandated. The ACR and other recognized accrediting bodies do not require submission of specific protocols beyond the adult head and abdomen scans. For example, many clinics do not perform pediatric studies or brain perfusion studies and do not have these clinical protocols set-up to be evaluated. The regulation should require only a review and dose assessment of the most generic (adult head and adult abdomen) protocols. Alternatively, the regulation could either match the required reviews with those submitted for accreditation or allow the QMP to select a variety of clinically relevant protocols for annual review and assessment. (22)

Response: It remains the responsibility of the QMP to determine the protocols that are deemed appropriate. If brain perfusion, for example, is not performed, the protocol does not need to be reviewed. Therefore, no change has been made from the proposed rulemaking in the final-form rulemaking.

53. Comment: § 221.204(a)(4)(xi) – Additional clarification is required in the instruction to “review DRL.” Diagnostic reference levels are defined by national guidelines such as NCRP Report 172 as the bottom of the 75th percentile of diagnostic doses allowing for differences in populations. Specific DRLs reported in such references typically consider a national population. If it is the intent that a review of the DRLs should consider only the national populations and no other more specific populations, the section ought to specify that requirement. It is also unclear how, if at all, these DRLs should be interpreted with respect to the notification and alert levels. Furthermore, although XR-29 mandates a reduction in CT study reimbursements for scanners without the capability to set notification levels and alert levels, neither CMS nor any nationally recognized accrediting body has forbidden the operation of such scanners without these capabilities. The regulations should clarify that DRL, notification level, and alert review are only required for scanners that are XR-29 compliant. (22)

Response: The DRL is an investigational level the facility uses to review its methods. The purpose is to achieve acceptable image quality at the lowest possible dose. The

review of DRLs, notification values and alert values are important in the performance evaluation of the CT system and recommended by NCRP as well as other recognized bodies such as ACR and AAPM. Therefore, no change has been made from the proposed rulemaking in the final-form rulemaking.

- 54. Comment:** § 221.204(b)(2) – (2)(c) The procedures mention tracking noise. CT image quality measurements do not track noise without context to the signal or tube output. Because CT numbers are calculated relative to water attenuation, noise can vary greatly from several factors such as slice thickness, tube output, and reconstruction algorithm. Metrics such as CNR and SNR are better performance indicators and should replace “noise” in the regulation. (22)

Response: Noise is an important characteristic of the CT image that affects the ability to visualize anatomic structures. The current Article V (relating to radiological health) regulations require an evaluation of noise in determining performance. Therefore, no change has been made to § 221.204(b)(2) in the final-form rulemaking. CNR or SNR are acceptable indicators in evaluating noise.

- 55. Comment:** § 221.204(b)(5) specifies that all routine QC be performed only under clinical modes. This is not recommended by any CT manufacturer. These manufacturers provide specific phantoms to be run under specific CT operating modes which are to be processed by specific QC reconstruction algorithms. Only then can the resulting values be compared to manufacturer specifications. Running phantoms, protocols, or reconstruction algorithms that are not specified for QC by the manufacturer will not yield the same QC results and will cause incorrect and falsely out-of-tolerance results. (22)

Response: There has been no change to paragraph (5) in the final-form rulemaking other than changing “Performance evaluation” to “Routine QC.” Subsection (b)(5) does not require that QC be performed only under clinical modes.

- 56. Comment:** § 221.204(b)(4) – The Routine QC for CT looks like it is only required weekly? Several manufacturers recommend daily QC with their supplied phantom. We would most likely stick with this routine. (15)

Response: It is acceptable to perform routine QC at a frequency greater than what is required.

- 57. Comment:** § 221.205 (relating to operating procedures) – Add the requirement for operators to be appropriately trained in the specific techniques and modalities they will be utilizing and be certified by “certification organization.” A national certification organization that specializes in the certification and registration of medical imaging or radiation therapy technical personnel and is accredited by the National Commission for Certifying Agencies, the American National Standards Institute, the International Organization for Standardization, or another accreditation organization recognized by the board. (21)

Response: The Department does not believe this is necessary because operator requirements are specified in various sections of the regulations, including §§ 215.24, 221.35a, 221.64, and 221.205.

- 58. Comment:** § 221.205(3)(a) – This requirement states a CT system is to be operated only by an individual who has been specifically trained in its operation. During the webinar, it was stated this means that all CT techs must be specialty-certified in CT. This is not correct. There are other alternative trainings which can meet these criteria including those detailed in the newest Joint Commission diagnostic imaging standards. (22)

Response: The Department will accept individuals having the applicable specialty in radiography, such as, ARRT(R), or equivalent, to perform CT procedures if the procedure is considered low-risk, as defined in proposed § 221.2. However, high-risk procedures, for example brain perfusion studies, will require the advanced certification in CT such as ARRT(R)(CT). The Department has changed the language proposed in § 221.11(b)(1) to reflect this in the final-form rulemaking.

- 59. Comment:** § 221.205(3)(c) – It is important to note that the role of the QMP is mischaracterized in this section. Under no circumstances can the QMP forbid a physician from scanning or treating a patient if the physician feels the procedure will benefit the patient. Indeed, this is a nuanced qualification. The QMP’s role is to act as an advocate for both the safest possible use of radiation and for the best possible diagnostic quality. If the QMP feels that a scan or treatment is not appropriate due to malfunctioning equipment, his/her obligation is to cite acceptable standards of radiation use for diagnostic studies to the staff and physicians and recommend that the procedure be done on a fully functioning unit. The obligation however, ends there and any expectation that QMP ought to have a regulated list described in § 221.205(c) is inviting conflict with licensed caregivers and exposing the state and hospitals to potential litigation. (22)

Response: Section 221.205 has been implemented since 1998 under the authority of the Radiation Protection Act. The only revision to section 221.205(c), which was proposed as section 221.205(b), is changing “qualified expert” to “QMP” in the final-form rulemaking. The regulation does not forbid a physician from scanning or treating a patient. Rather, it stipulates that it is the responsibility of the QMP to determine if a device is functioning safely. If it is not, the use of the CT system on patients shall be limited by the QMP.

- 60. Comment:** General comments on the remaining Chapter 221 sections addressing fluoroscopic X-ray systems, CR/DR equipment, CBCT and CT – All testing requirements should be done by or under the general supervision of a QMP. There is no testing which must always be done by the QMP directly.

The rapid technological changes occurring in diagnostic images, including computerization and automation, require additional flexibility in these proposed regulations to allow appropriate responses to these ever-accelerating changes and improvements. I do not agree with the very prescriptive testing requirements detailed in these sections. The QMP expertise

should be fully utilized in developing appropriate written testing and QA/QC protocols, inconsistent with manufacturer, nationally-recognized recommendations and the long-accepted image quality metrics of low and high contrast resolution, SNR (signal to noise ratio) and CNR (contrast to noise ratio) and exposure metrics and indicators. There is no need for detailed DEP mandates which will quickly become outdated and irrelevant. (22)

Response: Final-form Chapter 221 does not include additional requirements that will become outdated or irrelevant. The chapter describes requirements that, left unaddressed, could result in misinterpretation of manufacturer and nationally recognized recommendations.

Chapter 223

61. Comment: § 223.1. Purpose and Scope. – The proposed change adds “research on animals” to the Veterinary Medicine section. I agree with this clarification to the rules and would like to comment on what I hope was an unintended consequence of this change. I currently use a Siemens Inveon Multimodal PET/CT unit in our facility that is under registration with the PA DEP. The PET/CT unit is manufactured as a cabinet X-ray system and is located and used in a room not dedicated entirely to the use of the PET/CT unit. Since this unit is used for research and would now be subject to the rule, per § 223.31(d), we would be required to have any personnel not directly associated with use of the X-ray to vacate the room during use of the X-ray. We have conducted exposure measurements around the cabinet X-ray unit and currently allow personnel not directly associated with the use of the PET/CT to be in the room during X-ray use without using any additional personnel shielding. Access to the room is already restricted based on the use of unsealed sources of radioactive materials in the room.

I propose that § 223.31(d) be revised as follows, to allow other personnel to be in the room if the X-ray is a cabinet X-ray or enclosed X-ray system and that § 223.31(d)(3) would not apply to use of such cabinet or enclosed X-ray systems:

(d) Only the staff, ancillary facility personnel or other persons required for the medical procedure or training may be in the room during the radiographic exposure, unless the radiographic equipment is a cabinet or enclosed X-ray system. All of the following requirements apply to persons involved in the examination:

(3) Unless the radiographic equipment is a cabinet or enclosed X-ray system, each person shall be protected... (12)

Response: This regulation applies to all veterinary medicine practitioners using radiation sources, whether for research or for animal treatment. There is no need to limit the type of equipment to be other than “a cabinet or enclosed X-ray system.” The Department agrees there may be individuals present in the room during the operation of the device and allows persons to be in the room. The final-form rulemaking adds that they cannot be within 2 meters of the device during operation.

Chapter 228

62. Comment: § 228.11a. Licensee responsibilities. – The proposed amendment adds qualification requirements for operators of accelerators used in the healing arts to address radiation safety. This includes operators who need additional instruction including certification in the applicable specialty. Does this restrict the operation of a linac by a student even if they are under the supervision of a trained and certified operator? If so, this is a bit restrictive. Also, there are times an accelerator needs to be operated by service personnel and others for testing. This does not seem to be accounted for in proposed additional language. (9)

Response: The regulations address clinical training in § 215.24(d), which has been renumbered as § 215.24(b) in the final-form rulemaking. Chapter 216 addresses the requirements for service providers.

63. Comment: § 228.36. – The proposed rule states “An independent radiation monitoring system shall be provided so that the individuals entering or present in a potential very high radiation area become aware of the existence of the hazard. Independent radiation monitors shall be tested for response daily and after each servicing or repair.” The daily testing of the Primalert is conducted as part of the morning QA when the beam is turned on. The Cs-137 check source is not utilized for the daily testing. Can you please confirm the current testing method (using beam, not check source) satisfies the daily testing requirement? (17)

Response: The regulation does not stipulate how the monitoring system should be tested, only that it must be tested. Both “beam on” or “check source” are acceptable means of testing.

64. Comment: § 228.73. Selection of stationary beam therapy or moving beam therapy. – The proposed change does not make sense in this section since the rules apply only to linacs capable of BOTH stationary AND moving beam therapy. (9)

Response: The proposed amendment was to account for linacs that may only do one type of therapy, such as an NRT Novak 7 accelerator. No change to the proposed language was made in the final-form rulemaking.

Chapter 240

65. Comment: We are often asked to bid on large jobs (schools, nursing homes, condos, etc.) where the client specifies the number of tests. We provide two bids: one for the number of tests specified in the specs, and two for what would meet EPA criteria, explaining that this is what is required. If the client specifically wants us to only test what was specified, are you saying we cannot test the number of locations specified on the purchase order? This is another form of interference in a legitimate business decision between a client and a provider of a service, where the client specifies what they want, knowing what the DEP requirements are. (2)

Response: There are certain required testing practices, such as those required for testing during real estate transactions, testing a school building, and testing in multi-family units, for which protocols require a certain number of tests to be placed in certain locations. The client cannot dictate how many or where the test kits will be placed.

66. Comment: A proposed amendment in Chapter 240 limits individuals per certified individual in a firm to five. This number is too small; this could mean only two to three job sites when the certified individual could supervise around five each day. The number of individuals should be raised to 10. (1)

§ 240.102 (b)(4) – There is absolutely no justification for this. This is strictly a business decision and no concern of the Radon Section as to how many employees a company hires. This section should be deleted. (2)

Paragraph 240.112(b)(5) – stipulates that any mitigation FIRM can have no more than 5 employees. This is overly restrictive and arguably beyond the scope of the statute's intent. Limiting the size of a given business enterprise would seem to exceed the authority of the department. *How are the citizens of the state better protected by limiting the size of a mitigation business enterprise given the ongoing obligation of the FIRM's certified individual to insure regulatory compliance?* (6)

§ 240.102 and 240.112 – I agree with most of the points, however I cannot agree to limiting the number of employees. As long as there is a single certified person in charge, there is accountability. Forcing a firm to hire a second certified individual could be the business equivalent to training a competitor who could become disgruntled and open up shop down the street and put you out of business. It could get as ugly as a divorce! I do not know that the employee limit would pass a constitutional challenge, and fear the Department may risk having the entire radon regulation thrown out depending on how the case was presented. (7)

§ 240.102 – This section does exactly the opposite of its intended purpose. By limiting the number of employees, if a company had enough work, the firm would have to be split and a second company would have to be established. This situation would create confusion between the two management teams. Employee testers (in the same company structure) would switch between companies and be uncertain who their real supervisor is. The clerical staff would be constantly confused which company they were working for and how to report to DEP and management. Confusion would be such that mistakes are inevitable. The number 5 is arbitrary and has no basis in real world company management. If the staff is properly trained and adequate levels of management exist, the number of employees is irrelevant. If the staff and supervisors are not properly trained, the company will make mistakes thereby providing poor customer service as well as accuracy and precision in all services provided. The properly supervised number of employees has nothing to do with the intent of this change. In addition, service prices will have to be raised because of doubling company costs. (13)

§ 240.102 – This limit of 5 employees is arbitrary. There are no supporting data, papers or labor performance studies in coming up with the limit of 5 persons either for testing or mitigation. It is the responsibility of the certified radon testing individual and/or owner to ensure that all persons, whether 1, 2, 5, 10, or 20 adhere to PA DEP radon regulations, company approved quality assurance and SOP program, including the EPA and AARST ANSI standards. If I have 20 radon testers working for me as the certified and responsible person, and I ensure proper personnel training, structural management, internal communication systems, and QA/QC procedures and internal audits, then I should be able to properly monitor my people with good business and QA/QC practices. Why the limit of 5? Why not 3? Why 15? This is viewed as a restriction on business and on business growth. PA DEP should show the studies and data supporting the limit of 5 persons-firm employees or eliminate this unduly restrictive and unsupported number limit of firm employees (both radon testing and radon mitigation). There are hospitals and facilities with more than 5 X-Ray machines, can you limit them to only 5 persons running 5 machines, because you are concerned about if they have the mental and organization and performance base capabilities? PA DEP has decided that they are going to restrict your business growth, because they do not trust you to have more than 5 firm employees. Where did that 5 firm persons limit come from? There are large air conditioning HVAC companies with hundreds of technicians performing HVAC business services with no lessening or failure of management and quality in the execution of their business. Surely, it is not because of the immense complexity of doing HVAC installations, both residential and commercial. What about all of the technicians and repair men and women working for a cable or phone company. The complexity of their business is no less more complex than the radon business. They have 100s of technicians performing services with no threat to the public or system installations. What if there was a medical office that performed knee replacements with 10 doctors and 20 supporting personnel, then should they also be restricted to 5 doctors and 5 supporting persons? What about a large builder with 100 employees building homes? You cannot tell me that building a house is less complicated than the installation of a radon mitigation system or testing 10 schools in a school district. If this 5-firm person regulation for the targeted radon industry was challenged legally, the regulation would be overturned as “burdensome to the radon industry”, a restriction of business growth and no supporting evidence. **THE WHOLE RULE STATEMENT SHOULD BE REMOVED.** THERE SHOULD BE NO PERSONNEL FIRM EMPLOYEE LIMIT. GOOD INTENTIONS AND CONCERNS BY THE PA DEP ARE NICE, BUT NOT WHEN THEY ARE PREVENTING CAPABLE, PROFESSIONAL COMPANIES FROM GROWING AND PERFORMING RADON SERVICES, WITH AN ARBITRARY NUMBER WITH NO SUPPORTING METRICS. IF THERE IS VIOLATION OR A FAILURE OF SERVICE IN THE PERFORMANCE OF RADON MEASUREMENTS OR MITIGATION WITH SAY, 20 FIRM PERSONS UNDER ONE CERTIFIED PERSON (RESPONSIBLE), THEN THE DESIGNATED CERTIFIED PERSON AND/OR OWNER TAKES RESPONSIBILITY, CONSEQUENCES AND PROPER ACTIONS TO CORRECT AND ENSURE THAT QUALITY AND VALID SERVICES ARE PROVIDED FOR THE PUBLIC AND THEIR CLIENTS. THAT IS THE PRIME DIRECTIVE OF ANY GROWING BUSINESS. THE RADON INDUSTRY IS NO DIFFERENT IN THAT PURSUIT. (20)

I strenuously object to this regulation. The proposed regulation precisely as written, and as explained by the PA DEP Radon Division, limits the size of a Radon Mitigation Company to six people and restricts five of the mitigation employees from full Certification. If more than 6 individuals, a Mitigation Company must be divided into two independent, self-governing Companies (these are separate Companies not a ratio of Certified to General Workers in a Company). It is apparent that this is unworkable. A Company with 12 mitigation individuals, must divide into 2 companies with 2 Certified Individuals. Neither Certified Individual is permitted to direct any activities of the other Certified Company's workers. This means a large project (School, Hospital, Church, Multifamily) that requires more than 5 or 6 installers must be done by 2 independent companies. This is unworkable even before accounting for illness, vacations, other commitments, etc. If any of the Company's employees miss work, they cannot be replaced by the other Company's Workers. If a Certified individual is absent for a time, the other Certified Individual cannot direct both sets of Individuals. I have experience with the rule, our Company was placed under this directive and was fined for noncompliance. The 6-person-company directive has created a series of complications and caused added costs and difficulties in meeting our commitments. Our mission is to reduce naturally occurring radiation in homes and buildings but this has entangled us with compliance complications. We have 4 Certified Individuals and 3 eligible (NRPP Tests passed and substantial experience). We would like to Certify all and organize them as distinctive department heads. Not only is the regulation unworkable, but may also be unconstitutional according to our legal advisors. We did not have the will or the money to fight this.

The intent to provide an organizational structure to radon mitigation companies, balancing certified to listed individuals is commendable, but as written these regulations are unnecessary and unworkable. Arbitrarily breaking up companies in this manner is a 'Restraint of Trade.' (23)

Response: The Department acknowledges the commentator's concerns and has removed the limitation of firm employees in the final-form rulemaking.

67. Comment: I would like to first mention as a member of the AARST National Board of Directors, that the EPA currently recognizes (9) ANSI/AARST National Standards of Practice, and more are currently being developed. You can view the currently recognized standards at <https://www.epa.gov/radon/publications-about-radon>. I am uncertain as to why the PA DEP does not utilize all of the more current ANSI/AARST Standards instead of relying on several antiquated standards.

Since 1987, when I first entered the world of radon mitigation, the EPA and DEP have been telling us that "We are saving lives." So, when I look at regulatory changes I view them as "Are these changes helping or hurting the effort to Save Lives." I fail to see how most of the proposed regulation will aid in the effort to save lives. (7)

240.308. Radon mitigation standards. – The PA DEP should adopt the consensus standards as approved by the American National Standards Institute as developed by the AARST. The ANSI-AARST standards currently in place cover radon testing and mitigation practices in

homes, schools, commercial buildings, and multifamily properties. The standards are currently recognized by the EPA as the Current Standards of Practice and are required by ANSI to be updated on a regular basis. This consensus-based process is routinely referenced by government programs across the United States. (18)

Although not included with these proposed regulations, I strongly and respectfully recommend that the PA DEP Radon Section consider adopting the ANSI AARST standards in radon measurements and radon mitigation. Some of the PA DEP Radon Section staff participated on the standards committee, along with many other state radon programs and the EPA regions. The current standards being used, especially for radon mitigation are antiquated and have not been revised in years. The adoption of these ANSI standards would ensure Pennsylvania citizens are getting the most “current best practices” for measurement and mitigation services for the second leading cause of lung cancer. The ultimate prime directive is to reduce risk, save lives and provide the professional and technical current services to all Pennsylvania citizens, workers and families. This shows that the Pennsylvania Radon Program is aligned with the current national radon standards. (20)

Response: The Department believes that the standards used in this regulation are not antiquated and provide the necessary protections to test for and mitigate radon exposure. Therefore, no change has been made in the final-form rulemaking.

68. Comment: I have agreed with every topic that I feel is reasonable. I believe I agree with most of the sections where I have deferred because I do not possess the knowledge, experience or expertise of a Certified Tester or Laboratory. I am deeply concerned that the overall tone of this document seems to be setting a minefield of “gotcha” traps that myself or others could step into and be punished for an inconsequential omission, or a violation, that despite my best efforts, I could be drug into by a strong-willed client. (7)

Response: The Department appreciates the comment but disagrees. The purpose of this rulemaking is to ensure radon testing is done accurately and mitigation performed according to standard protocols. The Department has no intention of setting traps. The Department has agreed to make numerous changes to the proposed rulemaking where commentators have noted hurdles or obstructions to business. In other instances, however, the balance must be maintained in favor of standardization and protection of human health.

69. Comment: The analysis does not come close to what it would really cost. The State fee may only be \$300, but the cost of paying someone’s salary, continuing education credits, travel costs and expenses to become certified wouldn’t stop at \$3,000; and then you have just paid to educate your mightiest potential competitor. (7)

Response: The Department has removed the proposed requirement in §§ 240.102(b)(4)(iii) and 240.112(b)(4)(iii) for radon firm employees to complete a Department-approved radon course in the final-form rulemaking. Under the final-form rulemaking, certified individuals may provide initial training and continuing education.

70. Comment: Back in the earlier days, about 1995 if I recall, I was involved in “workshops” on the 7th floor of the Rachel Carson Building, working as partners with the State. Our primary objective at that time was developing a “Builders System” which has now become ANSI/AARST RRNC 2.0. It felt like a partnership because it was industry and government working together as a team, for the good of Pennsylvanians, and eventually the world. I have devoted almost my entire adult life to reducing radon-induced lung cancer. Much of this new regulation seems very adversarial. Feeling now that I have to turn my attention from providing the best quality mitigation systems for my clients to looking over my shoulder and watching every step because the State I have so willingly volunteered my time through community outreach education; TV newscasts on stations that aren’t in my work travel radius; volunteering nationally through AARST even before becoming a board member; and fighting diligently year after year, at my expense, in Washington DC for SIRG grants may penalize me. It really sucks. What happens if an employee was to quit when the certified individual is on vacation? Or at the International Radon Symposium, or when you are in the hospital? The entire tenor of this proposed regulation is very disturbing. It seems the intention has nothing to do with saving lives. (7)

Response: The purpose of these regulations is to ensure radon testing is done accurately and mitigation performed according to standard protocols. The Department does not believe that the best course is an adversarial one, and in that spirit, much has been removed from the proposed version that commenters felt was an undue burden.

71. Comment: If a firm has more than one certified individual (whether it be for a testing firm, a mitigation firm or a laboratory) and the certified individual responsible for the firm or laboratory employees can no longer serve in this capacity, then another certified individual in the same discipline should be allowed to be a replacement immediately without waiting for PA DEP approval. The PA DEP has already certified the individual for the discipline and the notification requirement to the PA DEP as written in the proposed regulation is unduly burdensome to operating a business. (16)

Response: Written Department approval has been the current practice and whenever possible, when the change of a certified individual may be anticipated, the Department works with the firm to ensure there is no lapse in the firm certification. For the Department to ensure that a correctly certified individual is in responsible charge of that firm’s activities, it is vital to track and account for all changes of a firm’s certified individual.

72. Comment: I don’t understand the requirement to have a serial number on the electret ion chamber. Is there that much variation between chambers that necessitates this labeling? I assume that this requirement is based on one brand of electrets. (16)

Response: The Department agrees with the comment and has amended §§ 240.604(c)(2)(ii) and (c)(3)(v)(C), and 240.605(c)(1)(ii) and (c)(2)(v)(C), accordingly.

73. Comment: I am confused by the sections on voltage drift for new batches of electrets. Is this testing to be done by the manufacturer or by the client buying the electrets from the manufacturer? If this testing is to be done by the client, does the client have to wait to use the new batch of electrets until the voltage drifting testing has been completed? Are the limits on voltage drop for short-term and long-term electrets based on one manufacturer's product lines? I am confused as to how you correct for voltage drift if the voltage has drifted more than the prescribed limits. I am also concerned that the requirements for handling the electrets involve a lot of quality control and do not understand why analysis by electret ion chambers is exempt from laboratory certification. (16)

Response: The Department has removed the proposed requirement in §§ 240.604(c)(5) and 240.606(c)(5) to do a voltage drift check in the final-form rulemaking. Electret ion chambers are exempt from laboratory certification because the level of complexity presented by these devices is much lower than other types of devices.

74. Comment: The requirement for "...control and warning levels identified in...shall be adjusted when the RPE of at least 20 spike results has been calculated" may be too burdensome for many certified individual testers. (16, 19)

Response: The Department agrees with the comment and has amended §§ 240.604(c)(3)(iv), 240.605(c)(2)(iv) and (d)(2)(iv), and 240.606(c)(3)(iv), (d)(4)(iv) and (e)(3)(iv) the final-form rulemaking accordingly.

75. Comment: The requirement for annual calibration for AC, LS and AT is also unnecessary and burdensome to the laboratory. Calibration should be performed when there is a new batch of charcoal being used for production of AC or LS devices or a new batch of film/plastic being used for production of AT devices. All other QA measurements (daily calibration of analyzers, spikes, duplicates, blanks and proficiency tests) are satisfactory to ensure that the device calibration is in good working order. (16)

The requirement for annual calibration for AC, LS and AT is also unnecessary and burdensome to the laboratory. Each client of the lab is also performing spikes (known) at the same rate so it is duplicated for the 50% humidity range at least. This has become so constant that professionals are simply having labs send cans directly to the chambers on their behalf and directly to the lab to avoid getting them there beyond 7 days – so the whole purpose of QA/QC is nonexistent. (19)

Response: Annual calibration for any instruments that measure radiation concentrations has been the standard practice within the U.S. Environmental Protection Agency, the U.S. Nuclear Regulatory Commission, and the radon industry for the past 25 years. This is necessary to ensure that these devices are providing precise and accurate results.

76. Comment: I don't understand the requirement for laboratories to report the status of a radon mitigation system. This is burdensome for a laboratory and I suspect that many laboratories do not ask for this information from the consumer. It is difficult to get the required

information from the consumer – name (not the agent), measurement dates, test location, temperature, weather, position of the vents, closed house agreement signed. (16, 19)

Response: The Department recognizes that consumers may not always provide the laboratory with complete information. The Department has added “as available” at the end of § 240.303(1) in the final-form rulemaking so that the report forms contain all information available to the lab.

77. Comment: I am disappointed that it appears that the enforcement policy and associated penalty table for Chapter 240 was posted for Comment, approved for use and put into force without any notification to the regulated community. Will the enforcement policy table also be up for revision once these regulations are finalized? (19)

Response: The Department does not plan on revising the Compliance and Enforcement Technical Guidance document at the time of this final-form rulemaking.

78. Comment: The Department is proposing to increase the radon certification fees based on the finding of the Report to assure that Chapter 240 fee revenue covers the Department’s Radon Program costs. Are all of the current and proposed program costs necessary and required to protect the public from the unscrupulous radon professionals and the hazards of radon gas? (19)

Response: This comment is beyond the scope of this rulemaking. Fees were the subject of a separate rulemaking that became effective on October 21, 2017.

79. Comment: Although the Radiation Protection Advisory Committee (RPAC) endorsed the proposed rulemaking for presentation to the Board, it appears that the radon industry was not properly represented because none of the members are certified testers or mitigators. (19)

Response: While there is one member of the RPAC who represents the radon industry, RPAC formed a Radon Subcommittee and has engaged that subcommittee regarding this final-form rulemaking.

80. Comment: Why is there a fee waiver provision for local government employees or school employees performing unit installations in a school or local government building if the installation is pursuant to his or her official duties and the employee is not compensated for this service except through the employee’s salary. Is there a job description that this task is already listed on or will this fee create a new job? (19)

Response: There is no fee applied in the regulations for the exception of local government employees or school employees in the regulations. A job description for these employees is not under the purview of the Department.

81. Comment: There needs to be consistency regarding when a mitigation system is deemed installed. A mitigation system should be considered installed when the fan is activated. (19)

Response: Proposed § 240.303(2)(i)(C) clarifies that installation means “the date of initial fan activation.” No change was made in the final-form rulemaking.

- 82. Comment:** I fail to understand why the radon division suddenly changed the way radiological instruments are exchanged for use, calibrated, checked prior to use and set aside for future need. The Department suddenly changed the calibration requirement to where an instrument is required to be back to the end user by the calibration due date. This practice is inconsistent with the rest of the regulated community. Some radiological labs use a device up to the end of the month of the date a survey meter is due for calibration. (19)

Response: The instrument may be used to the last day that its calibration sticker permits. At that point, one can notify the Department to take the unit out of service, send it back for calibration, and, when ready, notify the Department that the unit can be placed back into service. This requirement in proposed §§ 240.605(a)(1) provides for precise timing of instrument calibration and has been retained in the final-form rulemaking.

- 83. Comment:** A firm should not have to pay additional costs simply to have an employee. Health Physics labs can have as many employees as they need and train them commensurate with hazard per OSHA regulations. (19)

Response: The Department has removed the proposed limitation of firm employees in §§ 240.102(b)(4) and 240.112(b)(5) from the final-form rulemaking. The Department has also removed the proposed requirement for firm employees to pass a Department-approved radon course from §§ 240.102(b)(4)(iii) and 240.112(b)(6)(iii). This proposed requirement has been replaced with initial training requirements that can be given by the firm’s certified individual or through a Department-approved course.

- 84. Comment:** The ALARA Health and Safety program should also extend to the occupants of the dwelling. (19)

Response: The Department has no regulatory authority over the occupants of a dwelling.

- 85. Comment:** There is no place to report data about passive system installations and failures. This data is easily acquired. (19)

Response: There are reporting codes for reporting passive systems into Greenport, the Department’s web-based method to report radon activities. Consideration will be given to adding a code for failures.

- 86. Comment:** Paragraph 240.2a(2) limits the scope of the Department’s oversight of radon practitioners and systems. Specifically, it provides an exception for new construction from conforming to the RMS. This exception would seem to be in direct violation of enabling Act 147. Section 102 of the Radiation Protection Act of July 10, 1984 states: *“The General Assembly hereby determines, declares and finds that, since radiation exposure has the*

potential for causing undesirable health effects, the citizens of the Commonwealth should be protected from unnecessary and harmful exposure resulting from use of radioactive materials, radiation sources, accidents involving nuclear power and radioactive material transportation.” The Act does not instruct the Department to only protect citizens who are living in existing homes and fail to protect citizens living in newly constructed homes. It is the case that major home construction companies install passive radon piping in many of the homes built throughout Pennsylvania. It is also the case that certified mitigation professionals regularly encounter passive piping installed by unskilled and untrained tradesmen that fails to function. This was found REPEATEDLY in the neighborhood in Center Valley that received much publicity for exhibiting the highest residential radon levels ever recorded. Properly installed and functioning passive systems would have provided some degree of protection for these homeowners. Thus, the Department is failing to protect the citizens of the state from exactly the behavior the statute was designed to prevent. *Question 1: Why don't citizens who buy new homes have the same protections as existing homeowners, namely, protection against radon systems that are installed by unlicensed mitigators and don't meet national or PA-DEP standards? Question 2: How does the department reconcile its un-equal protection of PA citizens with the enabling statutory language reproduced above?* (6)

Although not in the regulations: It is respectfully recommended that the PA DEP Radon Section consider requiring builders performing new construction of homes with RRNC, to at a minimum, follow the ANSI AARST RRNC standards for all new construction. The builders and responsible subcontractors would sign a statement that they have installed RRNC in accordance to the ANSI RRNC standards, or use a properly qualified and certified radon mitigator to perform the RRNC installation. The RRNC, even if installed by the builder and their associated subcontractors would have a qualified-certified AARST RRNC designated radon mitigator to inspect and sign off on all RRNC design and installations. There is already verified evidence of incorrectly installed RRNC and active ASD systems in newly constructed homes. This would ensure that homebuyers and their families are truly getting the protection against the second leading cause of lung cancer. It could even be considered as part of the occupancy requirement for new construction. Another path would be to provide a specified training and certification program for builders. Initially, it could be voluntary. This would be critical in high zone 1 radon counties. This is the real substance and “standard of care” in meeting ALARA and protection of the public and new construction. (20)

In other words, a builder, developer or architect / engineer is exempt from any regulations for RRNC (Radon-Resistant New Construction) in new homes or buildings. This is the time and place to amend what has been missing since the original regulations. Our tallies and other's comparative tallies show a 40% failure rate when builder RRNC pre-pipe is activated. Why does this happen? Because the builders are under no laws nor obligation to get the RRNC installation correctly done. The pass, seemingly, was given to allow builders to install their own system as owners of the structures. This view is distorted but understandable. Reality is that builders (or their employees) do not install this pipe! It is primarily installed by plumbers that are subcontractors. The plumbers do not have any mandates (nor guidelines) to follow.

A builder is not allowed to have the plumber do the electric in a home. If subcontractors do the RRNC installation they should be certified radon mitigation individuals following AARST/ANSI RRNC 2.0. Homeowners very often believe that the RRNC pre-pipe (regardless of how it is installed or vented) means they are safe and never have to test. We, mitigation companies, see firsthand the anger and worry these duped homeowners have when they later (usually when selling) find levels of radon that are dangerously high! Builders are long gone but we see this weekly. It's years later and may have tragic consequences. Seems rather absurd to regulate the size and structure of a mitigation company. To allow unrestricted home and office searches, mandate radon mitigator training, exams, fees continuing education and reporting all in the name of radiation protection. At the same time allow builders, plumbers and designers to have no rules at all!!! Bad policy! Not Radiation Protection. If a certified mitigation individual subcontracts from a builder can he install anything he likes as the plumber can? Can a mitigation company have a non-certified company that only does builder work? Several class action lawsuits have been brought and won against builders and developers over poor radon systems and deception involving radon system installations. Unfortunately, settlements have been sealed. This oversight is a ticking bomb and Pennsylvanians most likely have died! The time is long overdue to correct this and fulfill the mandate of radiation protection! (23)

Response: The Department agrees that new homes should be built in accordance with radon resistant new construction standards. The Department will explore removing this exemption from Chapter 240 in a future rulemaking, which will allow all stakeholders to provide input on this important issue.

87. Comment: In § 240.2(a)(4), it adds “Department approved.” The Radon Section is attempting to control research. There is no reason they should have to approve research as long as the conditions in the original wording are satisfied. The Department has not provided justification as to why this is necessary. The original wording should remain. (2)

Response: The Department agrees and has removed this language in the final-form rulemaking.

88. Comment: In § 240.2(a)(4)(ii), the results may very well be valid. Validity is a function of accuracy. The original wording, that the results “...are not certified” should remain. (2)

Response: Radon tests are not certified; the tester is certified. Therefore, if a test was performed by an uncertified tester for the purpose of the research, it would be considered an invalid test. The Department retained the proposed amendment in the final-form rulemaking.

89. Comment: § 240.2(a)(5) – Does this mean a real estate agent who buys and gives out, but does not place or retrieve secondary devices is exempt from the regulations? Does this mean a home inspector placing and retrieving secondary devices and getting the lab's report is not exempt? (2)

Response: In the first scenario, Chapter 240 would not apply to the real estate agent. In the second scenario, yes, Chapter 240 would apply to the home inspector.

90. Comment: § 240.2(a)(5)(ii) – The dictionary defines purvey as to provide or supply, as in sell. What are you really trying to say? This section seems confusing. (2)

Response: Section 240.2(a)(5)(ii) provides that Chapter 240 does not apply to a person who provides, supplies or sells secondary devices.

91. Comment: § 240.3 – ALARA – If the Radon Section wants to define ALARA, they should further refine “economic considerations.” The US NRC uses \$1000 per person-rem. Does the DEP subscribe to this same evaluation criteria? And if not, what is their economic criteria? It should be stated in the regulations. (2)

Response: The definition for ALARA has been removed from Chapter 240 in the final-form rulemaking. Instead, the substance of how to pursue ALARA is discussed in § 240.305.

92. Comment: § 240.3 – Measurement – Your definition appears to exclude actual test results in a structure. Is this your intent? (2)

Response: Yes, test results in a structure are covered under the definition of “test.”

93. Comment: § 240.3 – suggested additions:

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

Blind study – change to “A study in which the certified person’s device is exposed to a specific radon concentration in an approved radon chamber that is unknown to the certified person.”

LS – Liquid scintillation – change to “A device used to measure radon by exposing a small amount of AC contained within a small vial and placed in the area to be sampled and analyzed in a liquid scintillation counter.”

Spiked measurement or spike – change to “A QC measurement conducted in an approved radon chamber to evaluate accuracy by exposing the detector or device to a known concentration and submitted for analysis.” (18)

Response: The Department agrees with the comment as to the definitions of “AC,” “LS,” and “spiked measurement” or “spike,” and has made the suggested changes in the final-form rulemaking. The proposed definition of blind study has been removed because it is only used once in the regulation in § 240.203(a)(5), where it is explained.

94. Comment: §§ 240.101(b), 240.102(b), 240.121(b), and 240.122(b) - The change in language seems to prohibit having more than one certified individual, which was clearly

permissible in the old regulations. A business may want to have more than one certified individual for various reasons, such as, someone planning to retire, numerous testers being supervised by more than one certified individual, the certified person may be sick and die, in which case the company is out of business until another person is certified by the DEP, or, if the certified person is planning to retire and the company attempts to have someone certified while the first employee is still present so that experience can be transferred - this would not be permitted. There is no valid reason why "at least" should be deleted. The Radon Section is getting into business decisions that do not impact on the purpose of these regulations. The wording, "at least one person certified to test" should be retained or added to all four sections. (2)

I strenuously object to this regulation. The proposed regulation precisely as written, and as explained by the PA DEP Radon Division, limits the size of a radon mitigation company to six people and restricts five of the mitigation employees from full certification. If more than 6 individuals, a mitigation company must be divided into two independent, self-governing companies (these are separate companies not a ratio of certified to general workers in a company). It is apparent that this is unworkable. A company with 12 mitigation individuals, must divide into 2 companies with 2 certified individuals. Neither certified individual is permitted to direct any activities of the other certified company's workers. This means a large project (school, hospital, church, multifamily) that requires more than 5 or 6 installers must be done by 2 independent companies. This is unworkable even before accounting for illness, vacations, other commitments, etc. If any of the company's employees miss work, they cannot be replaced by the other company's workers. If a certified individual is absent for a time, the other certified individual cannot direct both sets of employees. I have experience with the rule, our company was placed under this directive and was fined for noncompliance. The 6-person-company directive has created a series of complications and caused added costs and difficulties in meeting our commitments. Our mission is to reduce naturally occurring radiation in homes and buildings, but this has entangled us with compliance complications. We have 4 certified individuals and 3 eligible (NRPP Tests passed and substantial experience). We would like to certify all and organize them as distinctive department heads. Not only is the regulation unworkable but per our legal advisors may also be unconstitutional. We did not have the will or the money to fight this. The intent to provide an organizational structure to radon mitigation companies, balancing certified to listed individuals is commendable but as written, these regulations are unnecessarily, unworkable. Arbitrarily breaking up companies in this manner is a Restraint of Trade. (23)

Response: The Department acknowledges the concern and has amended the final-form rulemaking to remove the proposed requirement that only one person in a firm can be certified. The term "person" was replaced with "individual" in this final-form rulemaking in §§ 240.101(b) and 240.111(b) for consistency.

95. Comment: §§ 240.102(b)(2) and 240.122(b)(2) – Why can a certified individual not also be a firm employee? I am the certified individual and also an employee of my company! Again, the Radon Section is micromanaging on business decisions that have no impact on the purpose of these regulations, without any justification. If you are a corporation and not an employee, you are not covered under many insurance companies. (2)

Response: These sections have been revised in the final-form rulemaking to remove proposed language prohibiting a certified individual from being a firm employee.

96. Comment: §§ 240.103(a)(3), 240.113(a)(3) and 240.123(a)(3) – Why is the date of birth needed? How is the PA DEP going to use the birth date without the last four digits of the social security number? Again, the Radon Section is trying to interfere with a company’s business decisions without any justification. If the Radon Section is concerned that minors are attempting to obtain employment, simply state that no one under 18 years of age may work in this field. Why can’t a 16- or 17-year-old work part time as a lab technician analyzing charcoal? I certainly hope they are not trying to set a maximum age. There are federal laws that prohibit age discrimination. (2)

Why is the date of birth required? PA DEP does not require it for the certified radon tester or the certified radon mitigator or the radon firm testing employees. (20)

Response: These sections have been revised in the final-form rulemaking to remove the proposed date of birth requirement.

97. Comment: §§ 240.102 and 240.112 – I agree with only having one certified person in charge, however, I feel that listing an employee prior to performing any radon-related activity puts an unnecessary burden on an employer. I typically have them experience what field work is like firsthand before I list them. I know of no better gauge than having them on the job for a day or two. I have had an employee quit after one or two days. I have also let employees go after one or two days. It could be because they are afraid or unsafe to be on a ladder or roof, or refuse to seal a crawlspace. Some new hires do not take direction well. At that point, my focus was on finding a replacement, not on what obligation do I have to the State to make sure I don’t receive a fine! I feel 10 working days would be much more appropriate. A trainee under direct supervision poses no risk to the public. A trainee under the direct guidance and supervision of the firms certified individual will learn more about safety, procedures and processes than any course of test that could ever possibly be offered. And to whom is it more important that the new employee possesses the skill and knowledge to perform up to his employers’ expectation, the employer or the government? At the end of the day that radon system will have my name on it. Is the certified individuals time better spent instructing the trainee, or sitting at his computer filling out a government reporting firm? (7)

Response: The Department agrees that 10 business days is a reasonable and has made the appropriate changes to the proposed language in the final-form rulemaking.

98. Comment: § 240.111 (a) and (b) – The structuring of certification that sets up two tiers of either a certified individual or a certified individual under a certified firm is problematic, causes unfair burdens to firms and leads to abuses of the system. In PA a contractor is required to have contractor certification through the Home Improvement Contractor (HIC) program. This in effect requires an individual to be a business with insurance if he wants to do home improvement in PA. The certification program should work in conjunction with

this program and needs to be structured the same way. If you are accepting money in PA for radon services, then you are doing home improvement and need to act like and be certified as a firm not an individual. I recommend that the certification program require adherence to all PA home improvement contractor requirements. I strongly recommend that all PA Radon Certification programs be structured to require each certified individual must work under a certification firm. A Certified Mitigation or Testing individual cannot do work without being associated with a certified firm. An individual can however be both a single person certified firm and the certified individual of that firm. A firm can also have multiple certified individuals working for that firm. A certified individual in the firm can have up to five noncertified but listed employees under his supervision. Reporting of jobs and testing would be done under the firm. The job or testing reporting should include a requirement that the listed certified individual responsible for the job or test is included in the report. Any problems or issues with work whether from the DEP or the homeowner would be addressed to the firm. The Firm would be required to have HIC license. (11)

Response: Requiring certified individuals to work under a certified firm is not necessary. The name, street address and telephone number of the tester are required in the report. Also, the main purpose of a firm is to allow firm employees without certification to perform the work under the direction of a certified individual as a cost savings measure to the industry because it is more expensive to require all employees to be certified. If a certified individual has no employees, the individual is not required to apply for firm certification. The individual can form a business entity if required by the Home Improvement Contractor program. Therefore, no change has been made to the final-form rulemaking in this regard.

99. Comment: § 240.111(b) – I assume that the last section is eliminated because it is in []. (11)

Response: Yes, the language starting with “Not everyone within” and ending with “mitigation of radon contamination” has been deleted from this section.

100. Comment: § 240.112(b)(5) – PA DEP has no legal right to mandate that a company cannot expand beyond one certified individual or to mandate that a company certified individual has to report jobs as if he was the sole responsibility for that job. If that is the case, then that individual would have to be have a HIC license and carry his own insurance. Change the wording to: A mitigation firm may list a maximum of five mitigation firm employees at any one time under each of the firms listed certified mitigation individuals. (11)

Response: In the final-form rulemaking, the Department has removed the proposed limits of one certified individual per firm and five firm employees from the rulemaking. The main purpose of a firm is to allow firm employees without certification to perform the work under the direction of a certified individual as a cost savings measure to the industry because it is more expensive to require all employees to be certified.

101. Comment: § 240.112(b)(6)(iii) stipulates that any mitigation FIRM employee must provide “Proof of passing a Department-approved course on radon mitigation or passing a

Department-approved mitigation exam.” The FIRM structure is often utilized for mitigation “helpers” and apprentices. If the course is relatively basic and introductory, then it is most appropriate. In this case, I endorse the department’s change. If, however, the full radon mitigation certification course/exam must be completed, then this is a very expensive and an unnecessary burden. The department needs to clarify its intentions. *What training course/exam will the department require for new radon mitigation FIRM employees? Does it exist yet?* (6)

§ 240.112(b)(6)(iii) This is a new requirement that is not defined. According to this section a mitigation employee must take a course and pass an exam?? Is this correct? Whose exam and what course must he take? (11)

Paragraph 240.112(b)(6)(iii) stipulates that any mitigation FIRM employee must provide “*Proof of passing a Department-approved course on radon mitigation or passing a Department-approved mitigation exam.*” I considered this proposed regulation unrealistic, burdensome, and a real threat to the radon mitigation industry business.

- 1.It is agreed that every mitigation installer worker should have proper training, including the safe operation of all equipment, proper use of PPE, OSHA health and safety practices, OSHA SDS education/awareness, and general education of radon risk and causal mechanics the radon lung cancer risk. This can be done in a 4-8-hour training and repeating training every 6 months. This course be NRPP approved and thus PA DEP approved. Each worker would provide signature of attendance, just like they do in the nuclear power industry.
- 2.Training every worker taking the full 3-5-day radon training provided by radon regional training centers and then each worker taking the exam and passing it is unnecessary.
- 3.The radon worker, radon gopher does not do radon design or select the fan size or determine the proper air flow. That is done by the certified radon mitigation “responsible person”. The radon mitigation worker(s) will core holes in the floor, dig out the appropriate amount dirt and rock for suction pit. They will cut PVC pipe, put together and route the pipe as directed. You do not need a full 3 day training course and passing exam to properly do these actions.
- 4.This would cause any radon mitigator with firm employee workers to invest huge amount of money into their personnel that is not needed. What would stop that worker that was sent to a 3-5 day training course and supporting costs (hotel, meals, transportation) from deciding to quit and start his own company? Nothing. Even non-compete agreements that a mitigation firm owner would have a worker sign are not really binding. This would be considered a major threat to his business to train all workers to the level of a PA DEP certified mitigation person. This goes against basic business principles.
- 5.This regulation is anti-business.
- 6.What about the radon mitigation company secretary? She or he is a firm employee. Would they also need to be fully trained and pass an exam? (20)

§ 240.112 Since this regulation has changed for Mitigation Firm Employees, shouldn’t there be more information on the newly required “exam or test.” (23)

Response: The Department has removed the proposed requirement for firm employees to pass a Department-approved radon course. This proposed requirement has been replaced in the final-form rulemaking with initial training requirements that may be given by the firm's certified individual or through a Department-approved course. These amendments are in §§ 240.102(b)(6) and (b)(7), and 240.112(b)(6) and (b)(7).

102. Comment: § 240.112(7)(c) – Change wording to: A firm shall have a health and safety program, and a continuing education program as required in §§ 240.305 and 240.306 (relating to health and safety program; and continuing education program). All certified mitigation individuals and mitigation firm employees shall be familiar with these programs and abide by the requirements of these programs. (11)

Response: Section 240.112(c) was not revised in the final rulemaking because the Department believes the current language sufficiently explains the requirement to have health and safety and continuing education programs. The cross-reference to §§ 240.305 and 240.306 explains the requirements of those programs.

103. Comment: § 240.113 – It is the responsibility of the radon mitigation firm to track their employees, including their WLM tracking, with an individual employee file. If you are tracking mitigators, why not track the radon testers? Each of these trained persons enters into homes and buildings. Where is security differential? There is none. The PA DEP needs to provide viable supporting logistics to request this information. This regulation is inconsistent and discriminatory, besides being invasive. It should be totally removed. (20)

Response: Radon testers are much less susceptible to exposure than radon mitigators; therefore, it is unnecessary for testers to track it. Therefore, no change has been made to § 240.112(c).

104. Comment: § 240.114 – I'm not sure I understand this amendment. (7)

Response: Proposed § 240.114(b) clarifies that a late fee will be charged if a renewal application is postmarked after the certification expiration date. The proposed language remains in the final-form rulemaking.

105. Comment: Section 240.122(b) – The work experience should be spelled out. This would prevent the Radon Section from making up requirements at their whim. It appears the Radon Section wants to tie everything down as it applies to radon testing and mitigation industry but doesn't like to be tied down so that they are forced to follow strict requirements. (2)

Response: Work experience is addressed in § 240.122(a)(3) and is included to allow flexibility for a person without a bachelor's degree to become a certified individual. No change has been made to § 240.112(a)(3).

106. Comment: § 240.132(1) – Which states does PA have reciprocal agreements with? (11)

Response: Pennsylvania has not entered into any reciprocal agreements.

107. Comment: § 240.142 – My employees have their badges with them at all times, but asking to wear them in attics and crawlspaces means that I will be asking the Department for replacements at a much higher rate of frequency! I am also concerned that if an employee would like a day off, he could simply tell me his badge was lost. The last time I lost my badge, I had a vendor call me and tell me that it was found in their parking lot, and all I had done was load a few boxes into the trunk of my car. I view this requirement as a headache waiting to happen and feel it puts an undue burden on me as an employer. If the wording was changed to “Presented upon request” I would agree with it. (7)

Response: The Department agrees and has removed the proposed requirement to wear the badges in the final-form rulemaking.

108. Comment: § 240.203 (relating to conditions of certification) – Clarify this section and add the requirement for testing and laboratory individuals to pass blind studies conducted by the Department. This blind testing ensures accurate testing is being performed by the certified community with a percent error of less than or equal to +/- 25% of the reference value. Any studies conducted by the Department could be considered biased because the handlers of the devices have not participated in proficiency testing, have not taken a national exam and obtained certification. (19)

Response: The Department agrees that “testing and laboratory” should be added to § 240.203(a)(5) and has made the appropriate changes in the final-form rulemaking. In regards to biased studies done by the Department, Department employees have participated in proficiency testing when it was conducted by the EPA, have taken the five-day Rutgers course and the exam, and are exempt from certification according to the regulations. Performing blind studies is one of the best ways to ensure the public is receiving accurate test results.

109. Comment: § 240.203 – change to “Certified individuals shall pass blind studies conducted by the Department. Blind studies will be conducted in an approved radon chamber that has no conflict of interest with parties being subjected to blind testing. The individual measurement results of the blind study must achieve an individual RPE of less than or equal to +/- 25% of the RV. (18)

Response: The Department does not believe that conflict of interest will play a role in blind studies. If a certified individual believes that a failed blind study is invalid and suspects a conflict of interest, the certified individual can bring it to the Department’s attention. Therefore, the requested change has not been made in the final-form rulemaking.

110. Comment: § 240.203(2) – Paragraph 240.203(2) stipulates, “*The certified person shall allow the Department, its agents and employees, without advance notice or a search warrant, upon presentation of appropriate credentials, and without delay, to have access to the person’s facilities, offices and files for inspection and examination of records.*”

This clause in the rulemaking document would seem to be based on section 305 of the Radiation Protection Act of July 10. In this section the ACT is clearly concerned with radiation sources. Since radon mitigators and testers do not use such sources, it would seem to be inappropriate to maintain such an invasive policy. It would be more appropriate to specify a notification period. Note that the ACT does provide for the department to secure a search warrant should probable cause exist. That should be the mechanism for “surprise” searches. (6)

Paragraph 240.203(2) stipulates, “The certified person shall allow the Department, its agents and employees, without advance notice or a search warrant, upon presentation of appropriate credentials, and without delay, to have access to the person's facilities, offices and files for inspection and examination of records.” The radon industry, both radon testers and radon mitigators do not use or have possession of radioactive sources. There are radon measurement systems that do have radioactive check sources, but the majority, more than 99% of the radon industry do not use these instruments. Some charcoal canister laboratories and radon chambers may have radioactive sources, but again, the majority of the radon industry does not. It seems, the standard audit process and violation process the PA DEP Radon Section has followed in notifying radon testing and mitigation firms should stay in place. There is no need for the PA DEP to draw a warrant to enter unannounced into a radon services firm. There is no threat to the public or surround environmental resources. **THIS REGULATION SHOULD BE COMPLETELY REMOVED.** The process of violations, audits and enforcement are very well defined already. This regulation is considered an extreme, unduly, and overbearing exercise of power. There is no threat to the public or danger to the environmental resources. This regulation borders on the violation of the 14th Amendment. (20)

So, the regulations allow the Department access to home, workplace or other premises. **“The Department and its agents and employees will... Enter the premises of a licensee or registrant for the purpose of making an investigation...”** Radon Companies are reducing naturally occurring radiation levels in homes but do not use devices that incorporate radioactive sources such as other Companies regulated by the Bureau of Radiation Protection. Allowing searches that waive the Fourth Amendment of the U.S. Constitution (A search or seizure is generally unreasonable and illegal without a warrant). This seems unnecessary for Radon Companies so if it is deemed necessary by the Department, the regulation should note the rational. (23)

Response: The Supreme Court of the United States has consistently held that, in the context of the Fourth Amendment, privacy interests are weakened for property employed in a “closely regulated” industry. See *New York v. Burger*, 482, U.S. 691 (1987). “Certain industries have such a history of government oversight that no reasonable expectation of privacy...could exist for a proprietor over the stock of such an enterprise.” *Id.* 700 (citing *Marshall v. Barlow’s, Inc.*, 435 U.S. 307, 313 (1987)). Courts look to “the pervasiveness and regularity of regulation of an industry and the effect of that regulation upon an owner’s expectation to privacy.” *Id.* 701.

Section 305 of the Radiation Protection Act also provides support for this provision, Section 2 of the Radon Certification Act requires the Department to implement a certification program to “protect property owners from unqualified or unscrupulous consultants or firms.” 25 P.S. § 7110.305 and 63 P.S. § 2002. Section 2 of the Radon Certification Act indicates the General Assembly’s intent to create a regulatory scheme for certified radon service providers.

The language in § 240.203(a)(2) allows the Department to reasonably inspect the regulated community to ensure compliance with the Radon Certification Act, the regulations promulgated thereunder, and the terms of the individual’s certification. Therefore, no change has been made to the proposed language in the final-form rulemaking.

111. Comment: § 240.204 – I would like to agree, however, this year I did not receive my renewal packet until it was about 30 days from expiration. I know that was probably due to a changeover in DEP personnel, but technically I would have been in violation, and it was not with my control. (7)

Response: It is the responsibility of the certified individual to make a timely application for certification renewal. The Department attempts in all cases to process applications efficiently.

112. Comment: § 240.205 – Agree with the principle, however, the wording should be more specific. (7)

Response: The Department believes the language in § 240.205, as proposed, is clear and has therefore not amended it in the final-form rulemaking.

113. Comment: § 240.302 – I thought this was covered earlier. I recommend changing the wording to “Should” and “Upon request.” What happens if you are called by a Realtor to view a vacant property or a home’s owner who gives you access when there is no one present to present your ID? The way it is worded, you will be in violation and it is not within our control. (7)

Response: This section requires photo identification to be presented upon request. In the scenario described in the comment, a request has not been made for production of the identification, so the individual would not be in violation. Therefore, no change to this section, as proposed, has been made in the final-form rulemaking.

114. Comment: § 240.303 – I have concerns about changing the existing reporting method. There are frequent times that it is hard to get people to retest right away. Reasons range from real estate transactions that are delayed, home improvements taking place where the new owners will not be capable of maintaining closed house conditions until the renovations are completed, to people who refuse to test until cooler weather because they don’t have or choose not to use air conditioning and will not test during that time. It doesn’t matter what my guarantee states. I’ve been told that “radon levels are higher in the Winter, and you just

want me to test now so it will pass. If it flunks in January and you don't honor your guarantee, I'll take you to court" (expletives' omitted). In the 30 years I have been mitigating I have heard just about everything under the sun, and holding a Mitigator responsible for something that is well beyond any reasonable expectation of their control is an extremely unfair burden. (7)

Response: The Department revised § 240.303(4) in the final-form rulemaking by removing proposed language that required testing after system installation and by adding that the postmitigation test shall be reported in accordance with the section "unless the postmitigation test is performed by someone other than the mitigator and the client does not provide the postmitigation test results to the mitigator."

115. Comment: § 240.303(3) – "If a secondary tester..." Which certified individual – the secondary tester or the certified individual of the laboratory? This should be clearly spelled out. (2)

Response: The Department revised this section in the final-form rulemaking to change "secondary tester" to "certified tester" and "certified individual" to "certified laboratory" to clarify who should be reporting to the client.

116. Comment: § 240.303(4) – Radon monitors sold over the internet are commonplace. Homeowners use these monitors to measure their own radon levels and loan the monitors to family members and friends. The homeowner is not required to perform a certified radon test. A homeowner also has the right to hire a certified radon contractor to install a radon system at his house no matter what radon level he has or how a radon level was determined. The DEP should not require an approved radon test prior to mitigation. This section implies the radon mitigation firm is performing the radon testing. (11)

Response: The Department has removed the proposed requirement for a test to be performed prior to a mitigation system installation in § 240.303(4) of the final-form rulemaking.

117. Comment: § 240.305 – Even using the highest measured concentration, which does not exist during the time of mitigation because venting the home by opening basement doors and windows is probably in the Workers Safety Program of every mitigator in the State, in 30 years I have never reached more than a fraction of the exposure limits. I view exposure tracking as a totally worthless waste of time and feel the language should be deleted from any regulation. Have you ever seen any exposure tracking that has ever reached 50% of the limit? I seriously doubt it! So why don't you remove this unnecessary burden and let us focus on something a little more productive? (7)

Response: Exposure tracking for radiation exposure is standard practice for anyone dealing with radioactive materials. The time it takes to record the pre-mitigation radon level and then use the time in the building to calculate one's exposure should not be burdensome. No change to § 240.305 has been made in the final-form rulemaking in this regard.

118. Comment: § 240.305 – This appears to indicate that only mitigators have to evaluate the radon exposure, as it should be since it is extremely unlikely that any tester would exceed 1, let alone 4 WLM/year. Is that the case? (2)

Response: Yes, only mitigators are required to track their radon progeny exposure.

119. Comment: § 240.306 – What does the last sentence mean? If a person is certified as both a tester and a laboratory, are 16 or 32 hours required? (2)

Response: The Department has revised § 240.306 in the final-form rulemaking to require 16 hours of continuing education regardless of the concurrent certifications.

120. Comment: § 240.308 – There are several radon mitigation standards and these standards have different requirements. A certified mitigation firm needs to define which standard they will use. This section is important because it defines the minimum mitigation system requirements that have to be followed no matter which standard is used. It is important therefore that this section include any significant minimum requirements that are not included in any of the other mitigation standards. One critical component that is part of the PA DEP RMS is the necessity of a certified radon mitigator to inspect a building prior to any mitigation work being done to define all aspects of the job that needs to be done in order to abide by the appropriate radon mitigation standards. A certified radon mitigator must take a course that reviews and defines all the mitigation requirements and pass an exam demonstrating at least a reasonable knowledge of those requirements. PA DEP RMS specifies that a mitigation installation cannot be started based on the decision of what needs to be done by a mitigation employee who has not passed the written exam or attended the 3-day mitigation class. At the end of the system installation the certified mitigator must inspect at least one-fifth of all jobs the mitigation firm employees perform that he was not on site for. At least one of the radon mitigation standards approved by DEP does not include this requirement. If PA DEP does not include this requirement, non-certified mitigators will be able to install hundreds of radon mitigation systems without a single inspection by a certified mitigator who has been trained in the requirements of radon mitigation standards.

I strongly recommend that the inspection requirements prior to and after mitigation as specified in the PA DEP RMS be included in this document. Imagine if the building code requirements for all construction in the State of PA would now be based on the honor system and building inspections were no longer required. That is what the new guidance is proposing. (11)

Response: The Department agrees and has added new § 240.308(a) to the final-form rulemaking, which requires a thorough visual inspection by the certified individual prior to mitigation.

121. Comment: § 240.308(a)(6) – This section needs a rewrite to include additional language to allow option of extending the termination point higher than a nearby vertical wall. There are many times that a roof changes height by 1 to 2 feet. Guidance should allow the termination

to be next to a roof change in height as long as it is above the higher roof if it is within 10' of the height change. Revise to: The termination point must be 10 feet or more horizontally from a vertical wall that extends above the roof or higher than the vertical wall. (11)

Response: The Department agrees with this comment and clarified this section in the final-form rulemaking accordingly. Proposed § 240.308(a)(6) was renumbered as § 240.308(b)(5) in the final-form rulemaking. Additionally, upon further consideration the Department believes 5 feet is more reasonable than the 10 feet proposed in subsection (a)(6) and has made this change in renumbered subsection (b)(5) in the final-form rulemaking.

122. Comment: § 240.308(b)(1) – These days there are lots of egress window wells with ladders in the well built in basements. A mitigator could define the floor of the large window well as grade and therefore install the fan in the egress window well. Add this language clarification to prevent this from happening. Revise to: (1) Below grade, in a window well or egress window well, or in the heated or cooled space in the building. (11)

Response: The Department agrees and has revised § 240.308 in the final-form rulemaking to prevent the installation of a fan in an egress window well. Proposed subsection (b)(1) was renumbered as subsection (c)(1) in the final-form rulemaking.

123. Comment: § 240.308(c)(1)(iii) – Foundation walls require water-proofing on the outside of the wall. We have yet to experience an elevated radon level in a building due to foundation cracks. The requirement to seal foundation walls without any science or personal experience of effectiveness is not justified.

Expansion and control joints often have vapor barrier under the cracks which provides an air seal. Our experience is that sealing the perimeter slab to foundation crack even if small can double to ten-fold increase sub-slab negative pressure. Center expansion joints typically do not give us anywhere as much pressure field change indicating they typically don't need to be sealed. If the vapor barrier is known to exist, then these cracks do not need to be sealed. When the suction hole is installed it can be determined that there is or is not a vapor retarder under the slab.

Revise to: (iii) ~~Openings or cracks in the foundation or~~ at expansion or control joints that have no vapor retarder membrane installed under the slab. (11)

Response: During an inspection it is not possible to know if there is a vapor membrane under the slab after the slab is poured. However, the proposed language in proposed § 240.308(c)(1)(iii) was revised to “Expansion or control joints” in the final-form rulemaking. Proposed subsection (c) was renumbered as subsection (d) in the final-form rulemaking. New subparagraphs (iv) “Openings around utility penetrations of the foundation walls” and (v) “Sump pits that allow entry of soil gas or that allow conditioned air to be drawn into a sub-slab depressurization system” were added to § 240.308(c)(1) in the final-form rulemaking to clarify the Department’s concerns with foundations.

124. Comment: § 240.308(c)(3) – In almost every house that has a basement that is used even for storage or any slab that has finished walls there are “other openings or cracks that are inaccessible.” The present wording of this section would require mitigators to provide written statements for every home that has a work bench or boxes blocking a perimeter crack. This is excessive.

Revise to: If the mitigator and homeowner determine that the perimeter channel drain cannot be sealed for water control reasons, ~~or that other openings or cracks are inaccessible,~~ then the mitigator may leave those areas unsealed and shall provide the following written statements to the homeowner: (11)

Response: The Department agrees that the proposed language in § 240.308 may be overly burdensome. Therefore, the section has been revised as suggested in the final-form rulemaking. Proposed subsection (c) was renumbered as subsection (d) in the final-form rulemaking.

125. Comment: § 240.308(c)(3)(i) and (ii) – What is an increased heating and cooling penalty? Replace penalty with cost. Most homeowners do not care if the efficiency of a radon system is reduced (ex. use of a larger than required fan). Homeowners are concerned if the effectiveness of the system is reduced. I would think the PA DEP would also be more concerned with system effectiveness. Change “decrease the efficiency” to “reduce the effectiveness.” (11)

Response: The Department agrees and has revised § 240.308 as suggested in the final-form rulemaking. Proposed subsection (c) was renumbered as subsection (d) in the final-form rulemaking.

126. Comment: § 240.308(d)(1)(ii) and (iii) – The system label should only have the certified firm’s ID. The owner needs to contact the firm if there are issues with the system not the original installer who may no longer work for the firm.

Revise (ii) to: The name and certification number of the mitigation certified firm.

Revise (iii) to: The contact number of the mitigation certified firm. (11)

Response: A firm may not always be performing the mitigation. Therefore, the revision to § 240.308 in the final-form rulemaking requires the name and certification number of the mitigation certified individual or firm in subparagraphs (ii) and (iii) to be listed on the mitigation system. Proposed subsection (d) was renumbered as subsection (e) in the final-form rulemaking.

127. Comment: § 240.309 – change (7) to “Multifamily building tests. Multifamily building tests shall be performed in accordance with ANSI/AARST MAMF-2017, “Protocol for Conducting Measurements of Radon and Radon Decay Products in Schools and Large Buildings,” or its most recent version as determined by the Department. (18)

Response: The Department appreciates the correction and has made the suggested change in subsection (a)(7) in the final-form rulemaking. Proposed § 240.309 was renumbered as § 240.310 in the final-form rulemaking.

128. Comment: § 240.309 – By accepting ANSI standards you will increase the operating costs as these documents will continuously be revised and may require an associated exam and more costs. (19)

Response: The only ANSI/AARST standards that the Department currently requires relate to the testing and mitigation of multifamily buildings. The Department believes the cost associated with complying with these standards is outweighed by the benefit these standards provide for addressing radon issues in multifamily buildings. Proposed § 240.309 was renumbered as § 240.310 in the final-form rulemaking.

129. Comment: § 240.309(a)(4)(iv)(G) – Testing companies have no control over whether the mitigation system is operating or not, and we are typically under a time limit to test. If the system is not operating, it will usually result in an elevated measurement, thereby requiring additional remedial action or, at least having the person responsible for the house turning it back on. We are there to test under current conditions. (2)

Response: This comment concerns proposed § 240.309(a)(4)(v)(G). The Department has revised this provision in the final-form rulemaking by adding “If the system is not functioning, the client must be notified immediately.” Proposed § 240.309 was renumbered as § 240.310 in the final-form rulemaking.

130. Comment: § 240.309(a)(4)(viii) – In many cases in real estate transactions, the property is vacant and we are retained by a third party national organization in another state, by a home inspector, or by a real estate agent. We have no control over whether the instructions are given to the person controlling the building. The sentence should end with “...control the building.” (2)

Response: The Department agrees with the recommendation and has made the suggested revision in § 240.310(a)(4)(viii) in the final-form rulemaking. Proposed § 240.309 was renumbered as § 240.310 in the final-form rulemaking.

131. Comment: § 240.309(a)(6)(i) – “...secured against movement...” You cannot secure something against movement! The most you can do is employ an anti-tampering device that shows the device was moved. Most homeowners do not like driving nails and screws into their furniture. And even that does not secure it from movement unless you nail the furniture to the floor. The sentence should be rewritten to reflect reality. (2)

Response: The Department has revised this provision in § 240.310(a)(6)(i) in the final-form rulemaking to remove “secured against movement” in the final-form rulemaking. The section only requires an anti-tampering device. Proposed § 240.309 was renumbered as § 240.310 in the final-form rulemaking.

132. Comment: § 240.309(a)(6)(iv) – What if the building owner refuses to have these notices posted – what do we do? (2)

Response: The certified tester should document the refusal. The documentation does not need to be reported to the Department but must be available during an inspection. No change has been made to the final-form rulemaking. Proposed § 240.309 was renumbered as § 240.310 in the final rulemaking.

133. Comment: § 240.309(a)(10)(iii) – The guidance implies that if 30 days have passed you can no longer do a post mitigation test. Change the wording to require the test within 30 days but not disallow the test after 30 days.

Revise to: The post mitigation test shall be completed no may not be performed sooner than 24 hours or later than 30 days following the completion of and activation of the mitigation system or an alteration to an existing system. The test shall be initiated no sooner than 24 hours after the system activation. (11)

Response: The Department has added language regarding unforeseen circumstances in the final-form rulemaking to clarify when subparagraph (iii) would apply. This amendment provides flexibility in conducting postmitigation tests. Proposed § 240.309 was renumbered as § 240.310 in the final-form rulemaking.

134. Comment: §§ 240.309(b)(1)(vi) and 240.309(b)(2)(vi) – Does this apply to charcoal canisters with respect to the manufacturer and model? The manufacturer and model of the radon canister is of minimal interest to the client, especially if only one type of canister is used. (2)

Response: Yes, both the NRPP and NRSB websites show all devices by manufacturer and model number. Having this information on a report form can ensure the device in question is properly listed. Proposed § 240.309 was renumbered as § 240.310 in the final-form rulemaking.

135. Comment: § 240.309(b)(1)(xiii) – “...severe weather conditions” needs to be defined. (2)

Response: The proposed phrase “severe weather condition” has been replaced with “unusually severe storms or periods of high winds” in § 240.310(b)(1)(xiii) in the final-form rulemaking. Proposed § 240.309 was renumbered as § 240.310 in the final-form rulemaking.

136. Comment: § 240.309(b)(2)(v) and (viii) – As an analyzing lab, we can only provide the information back to the client if the client provides the information to us. Some clients want to keep some of this information private for legal reasons. (2)

Response: The Department has revised this section in the final-form rulemaking to add “as available” to § 240.310(b)(1) to account for these situations. Proposed § 240.309 was renumbered as § 240.310 in the final-form rulemaking.

137. Comment: §§ 240.604, 240.605 and 240.606 – Multiple references are found in Chapters 240.604-240.606 to the RPD tracking control charts as described in EPA 402-R-92-003, May 1993. Updated documents have been produced through the consensus-based process described above and published as ANSI-AARST National Standards. Additional work on quality assurance is ongoing and will be references in future editions of these standards. Referencing the most current version of the ANSI-AARST standards will ensure that the most common consensus-based products are referenced by the DEP and used by the certified radon community.

Make this change – “The RPD will be tracked using control charts from ANSI/AARST Standard MAH-2014 “Protocol for Conducting Measurements of Radon and Radon Decay Products in Homes”, Appendix A.

Make this change – “If the plotted RPD result falls outside of the warning level, ANSI/AARST Standard MAH-2014 “Protocol for Conducting Measurements of Radon and Radon Decay Products in Homes.” Appendix A. (18)

Response: The Department determined that, even though it is currently using the EPA standard(s), the warning and control limit numbers are the same as found in ANSI/AARST.

138. Comment: I agree with §§ 240.1, 240.2, 240.3, 240.101, 240.141, 240.201, 240.202, 240.304, 240.306 and 240.308 (but I thought these were already pretty clear), 240.501, 240.502, 240.603. (7)

Response: The Department appreciates the comment.

139. Comment: I defer to folks with certified devices for § 240.143. §§ 240.203, 240.307, 240.601, 240.602, 240.604, 240.605, 240.606, and Appendix B I defer because I do not possess the knowledge, experience or expertise of a Certified Tester or Laboratory.

§§ 240.121 through 240.124 – I defer to the opinion of Certified Laboratories. (7)

Response: The Department acknowledges the comment.

140. Comment: Appendix C – A complete and utter waste of time. (7)

Response: Tracking for radiation exposure is standard practice for anyone dealing with radioactive materials and is an appropriate method to protect worker health and safety. The Department has retained proposed Appendix C of Chapter 240 in this final-form rulemaking.

IRRC Comments

141. Comment: *Advances in equipment technology* - The Preamble states the EQB has not updated its regulations since 2009. Allegheny Health Network commented that "the rapid technological changes occurring in diagnostic images, including computerization and automation, require additional flexibility in these proposed regulations to allow appropriate responses to these ever-accelerating changes and improvements." Allegheny Health Network suggests relying more on the Qualified Medical Physicist (QMP) expertise and is concerned that detailed regulations will quickly become outdated and irrelevant. Another comment describes equipment that self-calibrates. In other instances, commentators describe computer controlled technology that incorporates internal controls to shut down the equipment if it is not used safely. In light of the public comments, we are concerned that, despite an allowance for exemptions such as § 215.31, portions of the proposed regulatory scheme will quickly become outdated. We recommend that the EQB reconsider the regulatory scheme of using prescriptive requirements and, where possible and appropriate, provide flexibility to accommodate advances in technology that are presently occurring and are certain to occur in the future. The EQB should also consider whether more reliance on the QMP might better accommodate advances in technology and better implement safety. (24)

Response: The Department agrees that there have been advances in technology. Article V, however, accommodates those advances. In general, this rulemaking embodies the theory that regulatory clarity and codification of best practices can improve the quality of services to the public, instead of ratcheting numerical standards in a command-and-control fashion. The industry had moved ahead of the Commonwealth regulations in technology and safety. The Department engaged with the business community, learned about practices that had already become standard, and is codifying them in this final-form rulemaking. This process ensures that the requirements are not an unfair surprise to the industry. Some requirements are required of operators by insurance companies (including Medicare and Medicaid), and most others are standards from national organizations, such as the Joint Commission, or are contained in technical guidance documents. Besides the noted § 215.31 (relating to granting exemptions), which authorizes DEP to grant exemptions from Article V and thereby provides flexibility to address advances in technology, other sections in Article V address emerging technologies. For example, § 218.11 (relating to registration, renewal of registration and license fees) requires Department safety review and § 221.16 (relating to training, competency and continuing education) necessitates registrants to be knowledgeable with emerging technologies. With respect to "prescriptive requirements" the Department strives to write regulations as performance based; however, certain requirements are not likely to change because they are basic operations. For example, radiographic devices will always use adjustments to kVp, mAs, half-value layer, exposure rate, and the like. Regarding reliance on QMPs as technology advances, the Department anticipates that the waiver requests discussed above will necessitate QMP involvement to ensure new technologies are being implemented safely.

142. Comment: *Department of Health regulations* – Regulatory Analysis Form (RAF) 13 asks the promulgating agency: "Will the regulation affect any other regulations of the

promulgating agency or other state agencies? If yes, explain and provide specific citations.” The response to RAF 13 explains the Department of Environmental Protection’s (Department) authority and states that “The Department of Health may have regulations regarding radiation. However, DEP’s radiological health regulations would supersede them.” Why didn’t the response include citations to the Department of Health regulations that address radiology including 28 Pa. Code Chapters 127 (relating to radiology services) and 565 (relating to laboratory and radiology services)? While RAF 13 explains that the Department’s regulation would supersede Department of Health regulations, the regulated community must comply with both regulations. How was the development of this regulation coordinated with the Department of Health to make sure there are no conflicts? We recommend that the EQB provide in the final regulation submittal an explanation of how it coordinated its regulation with the Department of Health regulations to make sure there are no conflicts for the regulated community. (24)

Response: DOH has regulations regarding radiation sources in 28 Pa. Code Chapters 51 (relating to general provisions), 127 and 565 that could be affected by this rulemaking. DOH is currently working on a regulatory update. DEP and DOH have held several meetings and have been working together to ensure DOH’s regulations are consistent with DEP’s regulations.

143. Comment: Definitions – Commentators identified several terms that are defined, but not used in the regulation. As an example, our search for the defined phrase “Medical reportable event for radiation-producing diagnostic or interventional X-ray procedures” did not find this term used in the body of either the proposed regulation or the existing regulation. In other instances, such as the terms “ALARA – as low as reasonably achievable” and “Blind study” defined in § 240.3, these terms are only used once in the proposed regulation (§§ 240.305 and 240.203(a)(5), respectively). It would be clearer to include an explanation of these terms in those sections rather than defining them in § 240.3. Therefore, we ask the EQB to review all of the proposed definitions to eliminate terms not used in the body of the regulation, make sure defined terms are used consistently in the body of the regulation, and consider whether definitions are needed for terms in instances where the terms are only used once. (24)

Response: The defined phrase “medical reportable event for radiation-producing diagnostic or interventional X-ray procedures” remains in the final-form rulemaking to distinguish the difference between the two types of reportable events that are discussed in Chapter 219. One type is for radiation-producing machine therapy and the other is for diagnostic or interventional procedures. “Medical reportable event for radiation-producing machine therapy” is defined in existing § 219.3 and applies to sections that are not part of this final-form rulemaking. The definition of “medical reportable event for radiation-producing diagnostic or interventional X-ray procedures” clarifies § 219.229. Section 219.229 is included in this final-form rulemaking and only covers diagnostic or interventional procedures. The title of § 219.229 has been revised in the final-form rulemaking to “diagnostic or interventional procedure medical reports” to avoid confusion and to clarify the types of reportable events that are covered by this section. The proposed term “blind study” is a common term used in all types of scientific studies, but has been removed from the definitions proposed in § 240.3 and is

explained in § 240.203(a)(5) in the final-form rulemaking. The proposed term “ALARA” in § 240.3 has been removed in the final-form rulemaking. Instead, the substance of how to pursue ALARA is discussed in § 240.305. The Department reviewed all of the proposed definitions to make sure terms are used consistently in the body of the regulation and to consider which definitions should be removed from the rulemaking.

144. Comment: *Preamble* – In our review of regulations, we refer to the Preamble for an explanation of the amendments, including the need for the amendment. The Preamble to the proposed amendments does not include all amendments and also does not explain why certain amendments are needed. For the final regulation, the Preamble should be amended to include these explanations. (24)

Response: The Order in the final-form rulemaking includes all amendments made to the final-form rulemaking and reasons for them.

145. Comment: *Compliance Costs* – The Preamble explains costs imposed by the regulation including costs relating to Qualified Medical Professionals and radon certification. However, the response to RAF 18 states there are no costs or adverse effects associated with the proposed rulemaking. How are these explanations consistent with each other? Furthermore, commentators believe the proposed regulation imposes operational costs, supervisory costs and compliance costs relating to outdated regulations. We ask the EQB to review and amend the responses in the Preamble and the RAF for the final regulation. (24)

Response: The response to question 18 in the RAF states how the benefits outweigh the costs that may be encountered. The RAF and Order associated with the final-form rulemaking have been updated from the proposed rulemaking. Also, the cost for a Qualified Medical Physicist (QMP) is associated with the cost to achieve certification with a recognized organization or board. The Department does not address Qualified Medical “Professionals” in its regulations. In retrospect, the Preamble associated with the proposed rulemaking should not have included costs regarding QMPs, just as the Department does not include costs to be a licensed physician, a medical radiologist or a radiologic technologist. With regards to the benefits outweighing costs associated with radon certification, the benefits of the radon certification amendments include adding clarity to the application and reporting requirements and make it easier for the regulated community to understand what is required during each process. The benefits of the amendments to the radon testing and mitigation protocols and quality assurance and quality control requirements include ensuring that radon services provided to the public will protect the public’s health and welfare from the dangers of radon.

146. Comment: *Business Days* – Several provisions require notice to the Department within a specific time period such as five days or 10 days. Commentators asked that these time periods be business days rather than calendar days. We agree. (24)

Response: The specific time periods have been revised to “business days” in the final-form rulemaking.

147. Comment: § 219.3. Definitions. - clarity – *Medical Reportable event for radiation-producing diagnostic or interventional X-ray procedures* - If this definition is retained in the final regulation, we have two comments. First, Paragraph (i) specifies a dose of "3 Gy (300 rad)." Commentators questioned this dose and believe it is too low. The EQB should explain why 3 Gy is the appropriate dose. Second, this definition uses the phrase "unintended dose." The phrase "unintended dose" is defined in § 221.2. Should this definition also be included in § 219.3? (24)

Response: The 3 Gy limit is recommended by NCRP as an appropriate substantial radiation dose limit. However, the Department has considered this concern and changed the dose to 15 Gy in the final-form rulemaking based on recommendations of The Joint Commission—a national health care accreditation body—and the Department’s discussions with RPAC. A limit of 15 Gy still maintains the importance of a good quality assurance program. Regarding “unintended dose,” this term addresses diagnostic or interventional X-ray, and is therefore more appropriately placed in Chapter 221 (relating to x-rays in the healing arts).

148. Comment: § 219.229. Other medical reports. - clarity – *Subsection (b)* - The phrase "medical event" is used in this subsection. However, it is not clear what constitutes a "medical event" that would require reporting. Should this subsection use the defined term "Medical reportable event for radiation-producing diagnostic or interventional X-ray procedures"? (24)

Response: This phrase has been revised in the final-form rulemaking to include “medical reportable event.”

149. Comment: § 221.2. Definitions. – Protection of the public health. – *QMP - Qualified medical physicist* - The American Association of Physicists in Medicine (AAPM) commented that this definition is insufficient to ensure that individuals providing the designated medical physics services are qualified to do so. AAPM provides suggestions for amending the definition. We recommend that the EQB consider incorporating AAPM's suggested revisions into the final regulation, or explain why it is not in the public interest to do so. (24)

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

150. Comment: §§ 221.11 and 221.16 require continuing education, but the regulation does not specify the number of hours. We recommend adding the required number of hours in the final regulation. (24)

Response: The Department has not codified the number of hours due to confusion that often occurs when applying educational units or contact hours to continuing education

requirements. The radiation safety training must be documented to satisfy the regulation.

151. Comment: § 240.2. Scope. – Protection of the public health; Clarity; Reasonableness; Implementation procedures. – The Preamble explains that there are two proposed amendments to this section: Proposed amendments to § 240.2 (relating to scope) revise certification exceptions from the building that the person occupies to the building in which the person resides for clarity. A new certification exception is proposed to be added to clarify existing requirements for employees of local governments and schools who perform radon testing. Several public comments were submitted on this section. Some comments addressed proposed amendments and some addressed existing language that was not proposed for revision. For example, S.W.A.T. Environmental of Pennsylvania believes existing language in Paragraph (a)(2) violates the statute and does not adequately protect the public health. A.B.E. Radiation Measurements Laboratory's comments address concerns with amendments to §§ 240.2(a)(4), (a)(4)(ii) and (a)(5). There appears to be concerns and confusion with § 240.2, which sets the scope for all of Chapter 240, relating to Radon Certification. We recommend that the EQB review this entire section and work with the regulated community to clarify the scope of Chapter 240. (24)

Response: The Department has reviewed this section and worked with the regulated community through the RPAC's Radon Subcommittee on this final-form rulemaking. For concerns related to §§ 240.2(a)(2), 240.2(a)(4)(ii), and 240.2(5) see responses to comment # 86, 88, and 89 . These responses clarify the Department's position on these subsections. The proposed phrase "Department-approved" was removed from § 240.2(a)(4) in the final-form rulemaking.

152. Comment: § 240.3. Definitions. –Clarity; Reasonableness. – *ALARA - as low as reasonably achievable* - The definition of this term is vague and unreasonable because it sets a standard of "making every reasonable effort" to limit exposure and "taking into account economic considerations and other societal concerns." These phrases are subjective and do not set a clear standard for compliance. What would meet the standard of every reasonable effort? What economic considerations must be considered? What constitutes a societal concern that must be considered? It may be clearer to delete ALARA from § 240.3 and specify the practices that must be followed in § 240.305, which appears to be the only section of the regulation where ALARA is referenced. (24)

Response: The proposed definition for ALARA has been removed from Chapter 240 in the final-form rulemaking. Instead, the substance of how to pursue ALARA is discussed in the § 240.305 in the final-form rulemaking.

153. Comment: § 240.101. Requirements for radon testing certification. – Need; Reasonableness; Economic impact. – *Subsection (b)* – This subsection is amended from allowing "at least one person certified to test" to "one individual certified to test." Commentators explained the new language presents problems when a single person is not available due to illness, quitting or retirement. We agree that the new language is unnecessarily restrictive. We recommend maintaining the existing language. Alternatively, the EQB should explain the need for, reasonableness and economic impact of precluding a firm from employing more than one

individual who is certified to test. This same concern applies to similar amendments or language proposed for Subsections (b) in §§ 240.102, 240.121 and 240.122. (24)

Response: The Department acknowledges the concern and has amended the final-form rulemaking to remove the proposed requirement that only one person in a firm can be certified. The term “person” was replaced with “individual” in this final-form rulemaking in §§ 240.101(b) and 240.111(b) for consistency.

154. Comment: § 240.102. Prerequisites for radon testing certification. – Need; Reasonableness; Economic impact; Less costly and less intrusive alternatives. – *Need for less intrusive alternatives to requiring written approval from the Department* – We have several concerns with this section of the regulation as set forth in the following discussion. Our concerns relate to the following criteria found in the RRA. Economic impact including: adverse effects on prices of services and costs to the private sector; need for the regulation; reasonableness of requirements; and, whether a less costly or less intrusive alternative method of achieving the same goal of the regulation has been considered for regulations impacting small business. We ask the EQB to carefully consider these criteria in its responses to the comments on this section, as well as similar provisions in §§ 240.112 and 240.122 cited at the conclusion of this comment.

Subparagraph (b)(1)(ii) – This provision states certification is void: “...until the Department approves in writing the firm owner's written and signed request for a certified individual to be in responsible charge of that firm's radon testing activities.” The proposed amendment replaces a relatively simple notice to the Department with an indefinite time period during which the firm would be out of business while waiting for written approval from the Department. The Preamble description does not include this proposed amendment. Therefore, the EQB has not provided an explanation of the need for the amendments and it is not clear whether the economic impact of this amendment is included in the EQB's cost analysis of this regulation.

In determining whether the regulation is in the public interest, the criteria in the RRA require us to consider whether a less costly and less intrusive alternative method of achieving the goal of the regulation has been considered for regulations impacting small business. A firm may lose its certified individual on very short notice and may find a new certified individual quickly. Under existing regulation, this process could potentially be completed in a day, particularly because it is in the firm's business interest to do so. The regulation fails to specify a time period for the Department to respond. For these reasons, we recommend deleting this amendment. Alternatively, the EQB should explain the costs imposed by the amendment, how those costs are justified and how it considered less costly and less intrusive alternatives, including retaining the existing regulation. (24)

Response: Written Department approval has been the current practice and, whenever possible, when the change of a certified individual may be anticipated, the Department works with the firm to ensure there is no lapse in the firm certification. The proposed requirements, retained in the final-form rulemaking, codify this practice. This practice ensures that qualified individuals are supervising the firm’s activities. This amendment does not impose any new cost on firms because firms are not, and never have been, permitted to operate without a certified individual. The benefit to the public of having adequately trained certified individuals supervising firm activities outweighs any loss of

business incurred by the firm in this scenario. For the Department to ensure that a correctly certified individual is in responsible charge of that firm's activities, it is vital to track and account for all changes of a firm's certified individual.

Paragraph (b)(2) – This paragraph adds a new requirement that the firm's certified individual may not also be a testing firm employee. What is the reason for this requirement? The Preamble does not include this addition and therefore does not explain the need for it. A commentator questioned why this provision was added. We agree that the EQB has not provided an explanation of the need for, reasonableness and economic impact of adding this provision. We recommend deleting it unless the EQB can provide justification for adding it. (24)

Response: The Department has deleted the proposed language prohibiting a certified individual from being a firm employee in the final-form rulemaking.

Paragraph (b)(3) – This provision requires a notice by the firm's certified individual to invalidate an employee's Department listing. Why wouldn't notice be the responsibility of the firm owner? (24)

Response: The certified individual is the person in responsible charge of the firm's radon-related activities and is therefore responsible for notifying the Department of this change.

Paragraph (b)(4) – This paragraph states a testing firm may list a maximum of five testing firm employees at one time. The Preamble states this limit is to "ensure adequate responsible charge by the certified individual." We agree with several commentators who do not believe the EQB has provided adequate support for the need for, reasonableness and economic impact of this provision. Therefore, we recommend deleting this provision. Alternatively, if the EQB retains a limit in the final regulation, it should explain its authority to impose a limit, provide support for the need for a limit including supporting data, explain how the limit was determined, provide an analysis of the economic impact of the limit on businesses, and explain why the limit is in the public interest. (24)

Response: The Department has deleted this proposed requirement in the final-form rulemaking.

Paragraph (b)(7) – Should the Department's written approval be to the firm's owner rather than the firm's certified individual? (24)

Response: The Department's written approval is appropriately sent to the firm's certified individual because the certified individual is the person in responsible charge of the firm's radon-related activities, as noted in response to the question concerning § 240102(b)(3), above.

Subsections 240.112(b) relating to radon mitigation certification and 240.122 (b) relating to laboratory certification – These concerns with Subsection 240.102(b) also apply to similar requirements in Subsections 240.112(b)(1)(ii), (2), (3), (5) and (7), relating to radon mitigation certification and 240.122(b)(1)(ii), (2), (3) and (6) relating to laboratory certification. (24)

Response: The Department's response above regarding § 240.102(b) also applies to these sections.

155. Comment: § 240.103. Radon testing application contents. – Need. – *Paragraph (a)(3)* – This paragraph requires the applicant's date of birth. Commentators questioned the need for the date of birth. We also question how the Department will use the applicant's date of birth. Is the intent to limit the age of an applicant? The EQB should explain the need for this requirement. The same questions apply to Paragraphs 240.113(a)(3) and 240.123(a)(3). (24)

Response: The proposed requirement to provide a date of birth has been removed in the final-form rulemaking.

156. Comment: § 240.306 – Clarity; Need; Reasonableness; Economic impact. – A commentator questions the last sentence of this section which states continuing education hours may only be used for one certification period for each certification activity. If a person is certified as both a tester and a laboratory, are 16 or 32 hours of continuing education required? The explanation of this amendment is not clear in the Preamble. We recommend that the EQB clearly establish in the regulation the number of continuing education hours required. Furthermore, if it is the EQB's intent to require 32 hours for those certified in two areas, the EQB should explain why the continuing education hours should not apply to both certifications. (24)

Response: The Department has revised the proposed language in § 240.306 in the final-form rulemaking to require 16 hours of continuing education regardless of the concurrent certifications.

157. Comment: § 240.308. Radon mitigation standards. – Reasonableness; Feasibility; Clarity. – *Subsection (a)* – We have three concerns. First, this subsection states a terminal discharge must meet "all" of the seven requirements listed. However, the requirements then describe different discharge scenarios, such as vent pipes attached to the side of the building and vent pipes that penetrate the roof. Would a vent pipe typically be attached to the side of a building and penetrate the roof? If not, the discharge would not meet "all" of the seven requirements. We recommend rephrasing Subsection (a). Second, Paragraph (6) requires a termination point to be 10 feet or more horizontally from a vertical wall that extends above the roof. Could the termination point also comply by extending above the vertical wall that extends above the roof? Third, Subsection (a) uses the term "conditioned spaces," whereas Subsection (b) uses the term "heated or cooled space of a building." Is there a difference? If so, the EQB should explain the difference in the regulation. If not, the same terminology should be used in both subsections.

Subsection (c) – In Subparagraph (3)(i) should the word "cost" be used rather than "penalty"? In Subparagraph (3)(ii) would the "efficiency" of the radon mitigation system be decreased or the "effectiveness"? (24)

Response: Proposed § 240.308(a), which has been renumbered as § 240.308(b) in the final-form rulemaking, has been revised and rephrased to address the different requirements for different discharge scenarios. The Department agrees with the recommendations in the comment and has revised § 240.308(b)(1) and clarified

§ 240.308(b)(5) in the final-form rulemaking. Additionally, the Department believes 5 feet is more reasonable than 10 feet and has made this revision in the final-form rulemaking. The phrase “heated or cooled space of a building” has been revised to “conditioned space of a building” and the term “penalty” has been revised to “cost” in the final-form rulemaking. Proposed § 240.308(a)(7) was renumbered as § 240.308(b)(6) and expanded to clarify that the termination point be at least 12 inches above the surface of the roof for vent pipes that penetrate the roof and at least 10 feet from any openings of conditioned spaces in the structure.

158. Comment: § 240.309(a)(4)(v)(G) – This provision states the mitigation system must be functioning during the test period. A commentator questioned what to do if the mitigation system isn’t working. The final regulation should address the situation where a mitigation system is not working. (24)

Response: The Department has revised this proposed section in the final-form rulemaking by adding “If the system is not functioning, the client must be notified immediately.” The Department notes that § 240.309 was renumbered as § 240.310 in the final-form rulemaking.

159. Comment: § 240.309(a)(6)(i) – This subparagraph requires testing devices to be “secured against movement by employing anti-tampering methods.” This requirement is vague and it is not clear what actions would be required to comply. This provision should be rewritten to provide clear direction on how to comply. (24)

Response: The Department has revised this section in the final-form rulemaking to remove “secured against movement.” The section now only requires an anti-tampering device. Section 240.309 was renumbered to § 240.310 in the final-form rulemaking.

160. Comment: Miscellaneous Clarity. – Should the definition of "General supervision" in § 221.2 state "by a licensed practitioner" rather than "of a licensed practitioner"? In Paragraphs 221.65(1) and (3), the phrasing of the exemption is not clear. Would these paragraphs be clearer by stating "the CT system is exempt from Section..."? Paragraph 221.204(c)(1) requires surveys in certain circumstances. A timeframe to complete the surveys should be added. Should § 223.22 also include research on animals? (24)

Response: For the definition of “general supervision” in § 221.2, the Department’s intent is to remain consistent with the applicable phrasing in the term “supervision” defined by the Department of State in 49 Pa. Code § 25.142 (relating to definitions). Furthermore, the phrase “of a licensed practitioner” is similar to “of a QMP,” which is used several times in the final-form rulemaking. The Department considered the comment related to proposed §§ 221.65(1) and (3) and has, in the final-form rulemaking, combined the two provisions into one paragraph that begins “CT systems identified in this section are exempt from...” The type of CT system must be identified because there are different types of CT systems, and only the X-ray attenuation systems are exempt. Section 221.204(c) was revised in the final-form rulemaking to state “CT X-ray systems shall have a survey performed at the time of installation...” The survey need not be repeated unless there is a change in the facility or equipment. Because §

223.1 addresses research on animals, research on animals need not be added to § 223.22.