

PROPOSED RULEMAKING
Annex A
TITLE 25. ENVIRONMENTAL PROTECTION
PART I. DEPARTMENT OF ENVIRONMENTAL PROTECTION
Subpart D. ENVIRONMENTAL HEALTH AND SAFETY
ARTICLE V. RADIOLOGICAL HEALTH

CHAPTER 215. GENERAL PROVISIONS

RIGHTS AND RESPONSIBILITIES OF THE DEPARTMENT

§ 215.12. Inspections and investigations.

* * * * *

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

- (1) Have access to, and require the production of, books, papers, documents and other records and physical evidence pertinent to a matter under investigation.
- (2) Require a registrant or licensee to make reports and furnish information as the Department may prescribe.
- (3) Enter the premises of a licensee or registrant for the purpose of making an investigation or inspection of radiation sources and the premises and facilities where radiation sources are used or stored, necessary to ascertain the compliance or noncompliance with the act and this chapter and to protect health, safety and the environment.

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

* * * * *

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

The following Department records [~~are not available for public inspection~~] ~~may not be disclosed to the public or to any litigant absent a court order~~ unless the Department determines that disclosure is in the public interest and is necessary for the Department to carry out its duties under the act:

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

- (2) A report of investigation [, not pertaining to safety and health in industrial plants,] which would disclose the institution, progress or results of an investigation undertaken by or at the direction of the Department or other governmental agency.
- (3) Personnel, medical and similar [files] records, the disclosure of which would operate to the prejudice or impairment of a person's reputation or personal safety.
- (4) Location, identification, safeguards, security measures, or other security-related information relating to a radiation source.
- (5) A record designated as classified by a Federal or State authority.
- (6) A record exempt from disclosure under any Federal or State law or regulation or judicial order or decree.
- (7) Any other record maintained by the Department, the disclosure of which may endanger or threaten public health, safety, or preparedness.

PROHIBITIONS AND RESTRICTIONS

§ 215.22. Prohibited uses.

- (a) No person may operate or maintain within this Commonwealth [fitting] devices or machines which use [fluoroscopic,] X-ray or [radiation principles for the purpose of selling footwear through commercial outlets.] radiologic technology for human non-medical use without prior written approval of the Department.
- (1) A person requesting the Department to approve the non-medical human use of radiation shall submit written information describing the proposed use to the Department for evaluation.
- (2) The Department will consider efficacy of the device or procedure as a factor when evaluating the proposed non-medical human use of radiation.
- (b) Hand-held fluoroscopic screens may not be used.

§ 215.24. Human use.

* * * *

- (b) Auxiliary personnel employed by a licensed practitioner of the healing arts at the location at which the licensed practitioner practices or employed by a health care facility may use radiation sources in the healing arts provided those individuals comply

with the applicable requirements of 49 Pa. Code Part I, Subpart A (relating to professional and occupational affairs), located in the following chapters:

* * * * *

(c) [Auxiliary personnel employed by a health care facility regulated by the Department of Health, the Department of Public Welfare or the Federal government may only use radiation sources in the healing arts in accordance with written job descriptions and employee qualifications.]

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

EXEMPTIONS

§ 215.31. Granting exemptions.

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

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

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

§ 216.1. Purpose and scope.

* * * * *

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

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

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

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

§ 216.2. Registration of radiation-producing machines.

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

* * * * *

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

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

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

* * * * *

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

[After July 17, 2004, a]A person who engages in the business of assembling or installing radiation-producing machines or who offers to assemble or install radiation-producing machines or who is in the business of furnishing or offering to furnish radiation-producing machine servicing or services or who is in the business of selling, leasing or lending radiation-producing machines in this Commonwealth shall apply for registration of the activities with the Department prior to furnishing or offering to furnish those services.

* * * * *

(4) [A person who, on July 17, 2004, is currently in the business of providing radiation-producing machine services shall apply for registration by September 15, 2004.]X-ray registrants who employ in-house service providers are exempt from this section but are subject to the requirements of 21 CFR 1020.30 (relating to performance standards for ionizing radiation-emitting products).

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

* * * * *

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

* * * * *

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

§ 216.3. Exemptions.

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

* * * * *

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

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

CHAPTER 217. LICENSING OF RADIOACTIVE MATERIAL
Subchapter A. GENERAL

§ 217.1. Purpose and scope.

* * * * *

(c) The use of radioactive material in this Commonwealth under a license issued by the NRC is exempt from the licensing requirements of this chapter [until the Commonwealth becomes an agreement state on the date published in the *Federal Register*].

Subchapter B. GENERAL PROVISIONS FOR RADIOACTIVE MATERIAL

§ 217.131. Incorporation by reference.

* * * * *

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

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

To reconcile differences between this subchapter and the incorporated sections of 10 CFR Part 30, the following words and phrases shall be substituted for the language in 10 CFR Part 30 as follows:

* * * * *

- (5) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR shall be directed to the Department [and, for NRC licenses, to the NRC until agreement state status is in effect].

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

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

Subchapter C. GENERAL LICENSES FOR RADIOACTIVE MATERIAL

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

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

* * * * *

(5) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR shall be directed to the Department [**and, for NRC licenses, to the NRC until agreement state status is in effect**].

§ 217.143. Certain measuring, gauging or controlling devices.

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

* * * * *

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

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

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

* * * * *

(5) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR shall be directed to the Department [**and, for NRC licenses, to the NRC until agreement state status is in effect**].

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

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

To reconcile differences between this subchapter and the incorporated sections of 10 CFR Part 33, the following words and phrases shall be substituted for the language in 10 CFR Part 33 as follows:

* * * * *

(5) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR shall be directed to the Department [**and, for NRC licenses, to the NRC until agreement state status is in effect**].

Subchapter G. LICENSING OF SOURCE MATERIAL

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

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

* * * * *

- (5) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR shall be directed to the Department [and, for NRC licenses, to the NRC until agreement state status is in effect].

Subchapter H. LICENSING OF SPECIAL NUCLEAR MATERIAL

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

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

* * * * *

- (5) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR shall be directed to the Department [and, for NRC licenses, to the NRC until agreement state status is in effect].

Subchapter J. RECIPROCITY

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

To reconcile differences between this subchapter and the incorporated sections of 10 CFR Part 150 (relating to exemptions and continued regulatory authority in agreement states and in offshore waters under section 274), the following words and phrases shall be substituted for the language in 10 CFR Part 150:

* * * * *

(5) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR shall be directed to the Department [and, for NRC licenses, to the NRC until agreement state status is in effect].

CHAPTER 218. FEES

GENERAL

§ 218.1. Purpose and scope.

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

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

* * * * *

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

PAYMENT OF FEES

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

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

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

* * * * *

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

* * * * *

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

* * * * *

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

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

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

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

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

§ 218.11a. [Special provisions for calculating fees during agreement state transition period.] [Reserved].

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

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

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

CHAPTER 219. STANDARDS FOR PROTECTION AGAINST RADIATION

Subchapter A. GENERAL PROVISIONS

§ 219.3. Definitions.

The following [term]terms, when used in this subchapter, [has] have the following meaning, unless the context clearly indicates otherwise:

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

- (i) An unintended peak skin dose to the same area in a single procedure greater than 3 Gy (300 rad).**
- (ii) An unintended dose, other than skin dose, in a single procedure exceeding 5 times the facility's established protocol and 0.5 Gy (50 rad) to any organ.**
- (iii) A dose to the wrong patient or wrong site for the entire procedure and exceeding 0.5 Gy (50 rad) to any organ.**

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

- (i) An administration of a therapeutic radiation dose to the wrong individual, wrong treatment site, or using a treatment delivery intended for another individual.**
- (ii) An administration of a dose for therapy [when the result is an increase in the total expected doses inside or outside of the intended treatment volume for organs, tissue or skin that exceeds 20% of the total prescribed dose for the intended target volume.]identified in a written directive that differs from the prescribed dose for the treatment site or any other organ from the intended prescribed dose, by one of the following:**

- (A) More than 20% of the total prescribed dose.**
- (B) Exceeds 30% of the weekly prescribed dose.**
- (C) Exceeds 50% of a single fraction dose of a multi-fraction plan.**

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

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

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

* * * * *

- (7) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR shall be directed to the Department, **except as required in 10 CFR 20.2206 (relating to Radiation Exposure Information and Reporting System (REIRS))** [and, for NRC licenses, to the NRC until agreement state status is in effect].

* * * * *

Subchapter M. REPORTS

§ 219.229. Other medical reports.

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

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

- (1) **Notify the Department regarding the medical event within one business day.**
- (2) **Provide a written report, including the analysis of the medical event, by the Qualified Medical Physicist, as defined in § 221.2 (relating to definitions), to the Department within 15 business days.**
- (3) **Provide a clinical summary to the prescribing physician and patient within 15 business days.**
- (4) **Maintain a record of the medical event as part of the patient's permanent medical record.**

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

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

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

* * * * *

- (4) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR shall be directed to the Department[**and, for NRC licenses, to the NRC until agreement state status is in effect.**]

CHAPTER 221. X-RAYS IN THE HEALING ARTS GENERAL PROVISIONS

§ 221.1. Purpose and scope.

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

§ 221.2. Definitions.

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

* * * * *

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

Air kerma rate – Air kerma per unit time.

* * * * *

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

* * * * *

CBCT - Cone Beam Computed Tomography – A digital volume tomography method used in some imaging applications using two-dimensional digital detector arrays, and a cone-shaped X-ray beam (instead of fan-shaped) that rotates around to generate a high resolution, 3D image, with high geometric accuracy. Reconstruction algorithms can be used to generate images of any desired plane.

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

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

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

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

* * * * *

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

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

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

DRL - Diagnostic reference level—An investigational level, set as a standard by a recognized body (e.g., ACR, AAPM, NCRP, or similar), used to identify unusually high radiation doses for common diagnostic medical X-ray imaging procedures. DRLs are suggested action levels above which a facility should review its methods and determine if acceptable image quality can be achieved at lower doses. DRLs should not be applied to an individual patient.

* * * * *

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

DLP (mGy-cm) = CTDIvol (mGy) x scan length (cm)

* * * * *

Electronic brachytherapy – A modality of radiation therapy where an electrically generated source of ionizing radiation is placed in or near the tumor or target tissue to deliver therapeutic radiation dosage. X-ray devices specifically designed and solely used to treat skin cancer lesions are not considered electronic brachytherapy devices under this definition and shall meet the applicable parts of Title 25 pertaining to registration and use.

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

* * * * *

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

* * * * *

General supervision – The overall direction and control of a qualified practitioner.
The qualified practitioner is not required to be present during the performance of the procedure.

* * * * *

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

High-risk procedure – Any radiologic procedure that utilizes energies of less than 1 million electron volts (MeV) that could exceed skin doses of 200 rads (2 Gy).

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

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

* * * * *

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

* * * * *

Medical physics – An application of physics that addresses the needs of medicine or healthcare. Subfields of medical physics include the following:

- (i) Therapeutic medical physics.**
- (ii) Diagnostic medical physics or imaging.**
- (iii) Nuclear medical diagnostic or molecular imaging and therapy.**
- (iv) Medical health physics or radiation protection.**

* * * * *

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

* * * * *

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

Personal supervision – A qualified practitioner who exercises general supervision and is present in the room or adjacent control area during the performance of the procedure.

* * * * *

OMP - Qualified medical physicist – An individual who is competent to independently provide clinical professional services in one or more of the subfields of medical physics or health physics.

(i) A QMP meets the following credentials:

- (A) Is certified in the field of medical physics, radiological physics, medical health physics or health physics by an appropriate national certifying body recognized by the Department.**
- (B) Complies with the certifying body's requirements for continuing education and recertification.**
- (C) Provides clinical professional services and practices only in the subfields of medical physics or health physics, consistent with the individual's training and experience, and in accordance with his respective certifying body's code of ethics.**

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

- (A) Has earned a master's or doctoral degree, or both, in physics, medical physics, biophysics, radiological physics, health physics, or equivalent disciplines from an accredited college or university.**
- (B) Has 3 years of documented relevant clinical training and experience in each of the subfields noted in the medical physics definition, under the supervision of a QMP who is qualified to practice in the same subfield(s), for each of the areas in which the individual intends to practice.**
- (C) Completes the continuing education requirements of an applicable certifying body of the subfields of medical physics or health physics in which the individual practices.**

(iii) An individual who has been practicing as a QMP in one or more of the subfields of medical physics or health physics for at least 5 years prior to

(Editor's Note: The blank refers to the date of adoption of this proposal.) is exempt from the requirements of subparagraphs (i) and (ii). Documentation of at least 5 years of practicing as a QMP in one or more of the subfields of medical physics or health physics must be maintained for each of the subfields of medical physics or health physics in which the individual practices. As of (Editor's Note: The blank refers to the date of adoption of this proposal.), an individual who qualifies as a QMP under this subsection must meet the continuing education requirements in subparagraph (ii)(C).

* * * * *

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

* * * * *

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

* * * * *

ADMINISTRATIVE CONTROLS

§ 221.11. Registrant responsibilities.

* * * * *

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

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

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

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

* * * * *

(1) The registrant shall have a quality assurance program. This quality assurance program shall be documented and be in accordance with guidelines established by the Department or by another appropriate organization recognized by the Department. At a minimum, the quality assurance program shall address repeat rate; **diagnostic reference levels**; image recording, processing and viewing; **image quality and artifacts**; and maintenance and modifications to the quality assurance program. **For CT, each study shall be checked. If an artifact is present, the registrant shall take corrective action as appropriate.** Records shall be maintained by the registrant for inspection by the Department for [3]5 years. The Department's guidelines and a list of recognized organizations will be maintained and made available on the Department's website and on request.

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

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

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

§ 221.16 Training, competency and continuing education.

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

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

- (i) **Basic properties of radiation.**
- (ii) **Units of measurement.**
- (iii) **Sources of radiation exposure.**
- (iv) **Methods of radiation protection for patients and others.**

- (v) **Biological effects of radiation exposure.**
 - (vi) **Facility-specific and modality-specific X-ray equipment.**
 - (vii) **Facility-specific and modality-specific image recording and processing.**
 - (viii) **Patient exposure and positioning.**
 - (ix) **Facility-specific and modality-specific procedures.**
 - (x) **Facility-specific and modality-specific quality assurance.**
 - (xi) **Facility-specific and modality-specific dose reduction, monitoring, and recording procedures.**
 - (xii) **Units of measurement and dose, such as DAP (dose-area product) values, CTDI and air kerma.**
 - (xiii) **Factors affecting fluoroscopic outputs.**
 - (xiv) **High-level control options.**
 - (xv) **Dose management including dose reduction techniques, monitoring, and recording.**
 - (xvi) **Principles and operation of the specific fluoroscopic X-ray system(s) to be used.**
 - (xvii) **Fluoroscopic and fluorographic outputs of each mode of operation on the system(s) to be used clinically.**
 - (xviii) **Applicable State and Federal regulations.**
- (2) **An individual who operates X-ray equipment during potentially high-risk diagnostic or interventional procedures or supervises the operation of X-ray equipment during these procedures is registered or credentialed and privileged in the applicable specialty by a professional organization recognized by the Department.**
- (3) **Documentation demonstrating compliance with this section is maintained for inspection by the Department.**
- (b) **Continuing education.**
- (1) **The registrant shall ensure that all individuals who operate X-ray equipment during diagnostic or interventional procedures or supervise the operation of X-ray**

equipment during a procedure complete continuing education in biological effects of radiation, quality assurance and quality control, and radiation safety, including concepts for minimizing patient and occupational dose and emerging technologies.

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

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

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

DIAGNOSTIC INSTALLATIONS GENERAL REQUIREMENTS

§ 221.21. Diagnostic equipment requirements.

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

(b) Equipment registered after (Editor's Note: The blank refers to the date of adoption of this proposal.) must comply with 21 CFR § 1010.2 (relating to certification).

§ 221.25. Beam quality.

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

* * * * *

TABLE II

<i>[Design operating range (Kilovolts peak)]</i>	<i>Measured potential (Kilovolts peak)</i>	<i>Minimum half-value layer (millimeters of aluminum)</i>	
		<i>Specified dental systems*</i>	<i>All other X-ray systems</i>
Below 51	30	1.5	0.3

	40	1.5	0.4
	50	1.5	0.5
51 to 70	51	1.5	1.2
	60	1.5	1.3
	70	1.5	1.5
Above 70	71	2.1	2.1
	80	2.3	2.3
	90	2.5	2.5
	100	2.7	2.7
	110	3.0	3.0
	120	3.2	3.2
	130	3.5	3.5
	140	3.8	3.8
	150	4.1	4.1]

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

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

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

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

* * * * *

§ 221.35a. Fluoroscopic X-ray systems.

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

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

- (1) A licensed practitioner working within his scope of practice.**
- (2) A Department-recognized radiologist assistant (RA) working within his scope of practice and under the direct supervision of a licensed practitioner working within his scope of practice.**
- (3) An individual who passed the American Registry of Radiologic Technologists (ARRT) exam or equivalent, holds a valid certification and is under the personal supervision of a licensed practitioner working within his scope of practice.**
- (4) A medical resident, radiologist assistant or radiologic technology student in training who is under the personal supervision of a licensed practitioner working within his scope of practice.**

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

- (1) A measurement of entrance exposure rates over a representative range of attenuating materials, including those that are expected to drive the system to maximum output in all modes clinically used, including fluoroscopy, high-level control, acquisition, digital subtraction and cineradiography (CINE), when available. Measurements shall be performed with a calibrated dosimetry system per manufacturer recommendations not to exceed 2 years and records maintained**

for 5 years for inspection by the Department. These measurements shall be made as follows:

- (i) For systems without automatic exposure control, by utilizing an mA and kVp typical of the clinical use of the fluoroscopic system.
- (ii) For systems with automatic exposure control, by utilizing sufficient attenuating material in the useful beam to produce an mA and kVp typical of the clinical use of the fluoroscopic system.
- (2) A measurement and verification of compliance of maximum air kerma rate for fluoroscopy and high-level control, if available.
- (3) An evaluation of high-contrast resolution and low-contrast resolution in both fluoroscopic and spot-film modes.
- (4) An evaluation of the operation of the 5-minute timer, warning lights, interlocks and collision sensors.
- (5) An evaluation of the beam quality and collimation in the fluoroscopy and spot-film modes.
- (6) An evaluation of the availability and accuracy of technique indicators and integrated radiation dose displays.
- (7) An evaluation of any changes that may impact patient and personnel protection devices.

(d) Additional requirements for facilities performing FGI procedures.

- (1) The registrant utilizing FGI studies shall establish and implement written procedures, or procedures documented in an electronic reporting system, that include the following:
 - (i) Identification of individuals who are authorized to use fluoroscopic systems for interventional purposes.
 - (ii) A method to be used to monitor patient radiation dose during FGI procedures.
 - (iii) Dose notification levels, as appropriate, at which the physician is notified for actions that may be taken for patient safety.
 - (iv) SRDL values referencing or consistent with nationally recognized standards.

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

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

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

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

(i) Patient identification.

(ii) Type and date of examination.

(iii) Identification of the fluoroscopic system used.

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

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

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

(ii) Cumulative fluoroscopic exposure time.

(iii) Number of films or recorded exposures.

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

§ 221.57 Facilities using CR or DR.

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

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

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

- (1) Artifacts.**
- (2) Spatial resolution.**
- (3) Contrast/noise.**
- (4) Workstation monitors.**
- (5) Exposure indicator constancy.**

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

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

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

OTHER SYSTEMS

§ 221.61. Radiation therapy simulation systems.

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

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

§ 221.63. Therapy imaging guidance systems.

- (a) The QMP shall develop QC procedures and tolerances for therapy imaging guidance systems following nationally recognized standards or those recommended by the manufacturer.
- (b) If a system is a CBCT, it must conform to the requirements of § 221.64 (relating to CBCT).

§ 221.64. CBCT.

- (a) The following radiation measurements must be evaluated annually and as soon as practical after any component repair or change which, in the opinion of the QMP, may affect the performance of the CBCT unit:
 - (1) Beam alignment. The X-ray field in the plane of the image receptor shall not exceed beyond the edge of the image receptor by more than 2 percent of the SID, when the axis of the X-ray beam is perpendicular to the plane of the image receptor. In addition, the center of the X-ray field shall be aligned with the center of the image receptor to within 2 percent of the SID.
 - (2) A performance evaluation shall be performed by or under the direct supervision of a QMP. The evaluation shall follow nationally recognized standards and tolerances or those recommended by the manufacturer. The evaluation shall be performed within 30 days of initial installation, at intervals not to exceed 14 months, and within 30 days after any change or replacement of components which, in the opinion of the QMP, could cause a change in the radiation output or image quality.
 - (3) The registrant shall document and implement QC guidelines in accordance with nationally recognized guidelines.
 - (4) The registrant shall document and implement a policy addressing deviations from established protocols.
 - (5) In addition to the requirements of § 221.16 (relating to training, competency and continuing education), the CBCT X-ray system shall only be operated by an individual who has been specifically trained in its operation.
 - (6) The facility shall maintain documentation of the established standards and tolerances and testing results for 5 years for inspection by the Department.
- (b) The CBCT operator shall have instructions on performing routine QC, including the use of the CBCT phantom(s); a schedule of routine QC appropriate for the system; allowable variations set by the QMP, if required, for the indicated

parameters; and the results of at least the most recent routine QC completed on the system.

(c) CBCT systems capable of operating at no greater than 100 kV or 20 mA are exempt from an annual QMP performance evaluation.

§ 221.65. X-ray attenuation systems.

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

- (1) Section 221.202(a) (relating to equipment requirements) is exempted.
- (2) Instead of § 221.204(a) (relating to performance evaluations, routine QC and surveys), the registrant shall complete a performance evaluation on the CT system following the recommendations of a QMP, the system manufacturer, or a nationally recognized organization at intervals not to exceed 14 months.
- (3) Section 221.204(a)(4)(xi) is exempted.
- (4) Instead of § 221.204(b), checks shall be established and documented by the registrant following nationally recognized guidelines or those recommended by the manufacturer.

**THERAPEUTIC X-RAY SYSTEMS WITH ENERGIES
LESS THAN 1 MEV**

§ 221.71. Equipment requirements.

* * * * *

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

- (1) It must be possible to activate only one X-ray tube at one time.
- (2) There must be an indication at the control panel identifying which X-ray tube is energized.
- (3) There must be an indication at the tube housing assembly when that tube is energized.

- (l) There must be a means of determining the SSD to within 5 millimeters.
- (m) Unless it is possible to bring the X-ray output to the prescribed exposure parameters within 5 seconds, the entire useful beam shall be automatically attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly.
 - (1) After the unit is at operating parameters, the shutter shall be controlled electrically by the operator from the control panel.
 - (2) An indication of shutter position must appear at the control panel.

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

COMPUTED TOMOGRAPHY X-RAY SYSTEMS

§ 221.201. Definitions.

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

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

* * * * *

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

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

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

where:

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

μ_x = Linear attenuation coefficient of the material of interest.

μ_w = Linear attenuation coefficient of water.

CTDI—Computed tomography dose index—

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

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

where:

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

$D(z)$ = Dose at position z .

T = Nominal tomographic section thickness (cm).

N = Number of tomograms produced in a single scan.

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

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

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

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

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

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

I = table increment per axial scan (mm).

Thus,

$$\underline{\text{CTDI}_{\text{vol}} = (1 / \text{pitch}) \times \text{CTDI}_w}$$

CTDW_w - Weighted Computed Tomography Dose Index—The estimated average CTDI₁₀₀ across the field of view (FOV). The equation is:

$$\underline{\text{CTDI}_w = 1/3 \text{ CTDI}_{100.\text{center}} + 2/3 \text{ CTDI}_{100.\text{edge}}}$$

Where 1/3 and 2/3 approximate the relative areas represented by the center and edge values derived using the 16 or 32 cm acrylic phantom.
CTDI_w uses CTDI₁₀₀ and an f-factor for air (0.87 rad/R or 1.0 mGy/mGy).

* * * * *

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

* * * * *

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

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

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

Where

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

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

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

E = Exposure reading in milliroentgen (mR)

T = Nominal slice thickness in millimeters (mm) and

N = Number of slices per scan]

* * * * *

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

* * * * *

§ 221.202. Equipment requirements.

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

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

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

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

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

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

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

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

* * * * *

(4) The CT number for water for a region of interest, not exceeding 100 square millimeters, shall be $0 \pm [10.0]7.0$ CT number units. The facility's performance phantom shall be utilized, with the technique factors specified by the [qualified

expert]QMP, to confirm compliance. In instances when a CTN of 0 for water is inappropriate, as in 3D treatment planning, the [qualified expert]QMP may establish and maintain an equivalent value.

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

* * * * *

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

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

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

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

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

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

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

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

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

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

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

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

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

(v) Distance readout calibration.

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

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

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

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

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

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

(4) The performance evaluation shall include, but not be limited to, the following:

- (i) Geometric factors and alignment, including alignment light accuracy and table incrementation accuracy.**
- (ii) Slice localization from scanned projection radiograph (localization image).**
- (iii) Slice thickness.**
- (iv) Image quality including high-contrast (spatial) resolution, low-contrast resolution, image uniformity, noise, and artifact evaluation.**
- (v) CT number accuracy.**
- (vi) Image quality for acquisition workstation display devices (video and hard copy where applicable).**
- (vii) A review of the results of the routine QC required under subsection (b).**
- (viii) A safety evaluation of audible and visual signals and posting requirements.**
- (ix) A review of commonly used CT protocols along with the evaluation for appropriateness of dose and image quality, in comparison with the older protocols. The review should be by the QMP along with the radiologist and lead CT technologist.**
- (x) For dosimetry, a review of the protocols deemed appropriate by the QMP which could result in significant doses. This review shall include acquisition and reconstruction parameters, and radiation dose. At a minimum, the QMP shall review the following clinical protocols, if performed, at intervals not to exceed 14 months:**
 - (A) Pediatric head (1-year-old).**
 - (B) Pediatric abdomen (5-year-old; 40-50 lb. (about 20 kg)).**
 - (C) Adult head.**
 - (D) Adult abdomen (70 kg).**
 - (E) Brain perfusion.**
- (xi) Review DRL, notification values and alert values for the procedures reviewed under subparagraph (x) of this paragraph.**

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

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

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

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

(b) [Performance evaluations] Routine OC.

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

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

(i) Noise.

(ii) [Contrast scale.

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

(iv)] Mean CT number for water.

(vii) Artifact evaluation.

(vi) Acceptable tolerances.]

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

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

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

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

(c) *Radiation protection surveys.*

(1) All CT X-ray systems installed after (Editor's Note: The blank refers to the date of adoption of this proposal.) and those systems not previously surveyed shall have a survey performed by or under the direction of a QMP. In addition, such surveys shall be performed after any change in the facility or equipment which might cause a significant increase in radiation hazard.

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

(d) *Records.*

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

§ 221.205. Operating procedures.

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

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

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

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

(2) [A current]Current [technique chart] protocol information available at the control panel which specifies for each routine examination the CT conditions of operation **[and the number of scans per examination]**.

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

CHAPTER 223. VETERINARY MEDICINE

§ 223.1. Purpose and scope.

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

RADIOACTIVE MATERIAL

§ 223.22. Sealed and unsealed sources.

A veterinarian who uses sealed **or unsealed** sources for therapeutic treatment of animals shall comply with 10 CFR Part [35, Subparts F, G, H and K but is exempt from 10 CFR **35.632—35.645 and 35.2632—35.2645]30 (relating to rules of general applicability to domestic licensing of byproduct material) and 10 CFR Part 31 Section 31.11 (relating to general license for use of byproduct material for certain in vitro clinical or laboratory testing).**

ADMINISTRATIVE CONTROLS

§ 223.31. Registrant responsibilities.

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

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

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

(d) Only the staff, ancillary facility personnel or other persons required for the medical procedure or training may be in the room during the radiographic exposure. The following requirements apply to persons involved with the examination:

(1) No individual or extremity may be positioned in the useful beam unless required to conduct the procedure.

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

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

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

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

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

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

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

the QA program shall address radiation safety to personnel and modifications to the QA program.

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

(h) CT systems used solely for non-human imaging are exempt from §§ 221.202 – 221.205.

CHAPTER 225. RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

Subchapter A. GENERAL PROVISIONS

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

To reconcile differences between this chapter and the incorporated sections of 10 CFR Part 34, the following words and phrases shall be substituted for the language in 10 CFR Part 34 as follows:

* * * * *

(5) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR shall be directed to the Department [and, for NRC licenses, to the NRC until agreement state status is in effect].

§ 225.4a. Radiation safety program.

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

* * * * *

**Subchapter B. RADIATION-PRODUCING MACHINES
GENERAL TECHNICAL REQUIREMENTS**

§ 225.81. Permanent radiographic installations.

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

* * * *

(3) The radiographic exposure system may not be used if an entrance control device or alarm system is not operating properly. If an entrance control device or alarm system is not functioning properly, it shall be removed from service and repaired or replaced immediately. If no replacement is available, the facility may continue to be used provided that the registrant implements the continuous surveillance under 10 CFR 34.51 and 34.[52]53 (relating to surveillance; posting), § 225.83 (relating to records required at field radiography sites) and uses an alarming ratemeter. Before the entrance control device or alarm system is returned to service, the radiation safety officer or an individual designated by the radiation safety officer shall validate the repair.

- (b) Records of the tests performed under subsection (a) shall be maintained for inspection by the Department for [3]5 years.

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

ANALYTICAL X-RAY EQUIPMENT

§ 227.11a. Equipment requirements.

* * * *

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

CHAPTER 228. RADIATION SAFETY REQUIREMENTS FOR PARTICLE ACCELERATORS

ADMINISTRATIVE CONTROLS

§ 228.11a. Licensee responsibilities.

* * * * *

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

* * * * *

NOTIFICATION AND LICENSING PROCEDURES

§ 228.21a. Notification and license requirements.

- (a) A person who intends to purchase, construct or acquire an accelerator shall notify the Department of this intent by filing an application for a specific license within [30]90 days after the initial order is issued to obtain any or all parts of the accelerator.

* * * * *

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

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

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

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

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

GENERAL RADIATION SAFETY REQUIREMENTS

§ 228.35. Operating procedures.

* * * * *

(c) Each safety and warning device, [including]except interlocks, shall be checked at least every 3 months for proper functioning and shall be repaired as necessary. Interlocks shall be checked at least annually. Results of these checks and records of repairs shall be maintained for [4]5 years at the accelerator facility for inspection by the Department.

* * * * *

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

* * * * *

[(5)] (h) An individual who operates an accelerator system shall be instructed adequately in the safe operating procedures and be competent in the safe use of the equipment. The instructions shall include, but not be limited to, items included in Appendix A (relating to determination of competence) for medical accelerator operations, as well as basic radiation protection for non-medical accelerator operations. There shall be continuing education in radiation safety, biological effects of radiation, quality assurance and quality control.

§ 228.36. Radiation monitoring requirements.

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

RADIATION SAFETY REQUIREMENTS FOR ACCELERATORS USED IN THE HEALING ARTS

§ 228.61. Leakage radiation to the patient area.

(a) [New equipment] **Equipment** [shall] **must** meet the following requirements:

- (1) For operating conditions producing maximum leakage radiation, the dose due to leakage radiation, including X-rays, electrons and neutrons, at any point on a circle of 2 meters radius centered on and perpendicular to the central axis of the beam at the isocenter or normal treatment distance and outside the maximum useful beam size, may not exceed 0.1% of the maximum dose of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the plane surface. Measurements, excluding those for neutrons, shall be averaged over an area up to, but not exceeding, 100 square centimeters at the position specified. Measurements of the portion of the leakage radiation dose contributed by neutrons shall be averaged over an area up to, but not exceeding, 200 square centimeters.
- (2) For each system, the licensee shall determine or obtain from the manufacturer the leakage radiation existing at the positions specified in paragraph (1) for the specified operating conditions. The licensee shall maintain records for 5 years on leakage radiation measurements for inspection by the Department.

(b) [Existing Equipment] **Equipment manufactured or installed prior to July 17, 2004,** [shall] **must** meet the following requirements:

- (1) For operating conditions producing maximum leakage radiation, the absorbed dose due to leakage radiation, including neutrons, at any point on a circle of 2 meters radius centered on and perpendicular to the central axis of the beam 1 meter from the virtual source, may not exceed 0.1% of the maximum absorbed dose of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the surface of the circular plane. Measurements shall be averaged over an area up to but not exceeding 100 square centimeters at the positions specified.
- (2) For each system, the licensee shall have available the leakage radiation data existing at the positions specified in paragraph (1) for the specified operating conditions. The licensee shall maintain records on radiation leakage for 5 years for inspection by the Department.

§ 228.72. Selection of radiation type.

Equipment capable of [both] X-ray therapy [and] **or** electron therapy, **or both,** [shall] **must** meet the following additional requirements:

* * * * *

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

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

* * * * *

§ 228.75. Calibrations.

* * * * *

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

* * * * *

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

* * * * *

CHAPTER 230. PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

Subchapter B. GENERAL

§ 230.15. Packaging and transportation of unlicensed material.

Radioactive material not licensed by the Department or under the specific regulatory control of another state or federal agency that meets the definition of radioactive material in 49 CFR 173.403, must be packaged and transported in compliance with the standards and requirements of 49 CFR 173.107-173.477 (relating to class 7 (radioactive) materials).

CHAPTER 240. RADON CERTIFICATION

Subchap.	Sec.
A. GENERAL PROVISIONS.....	240.1
B. CERTIFICATION.....	240.101
C. CERTIFICATION REVIEW PROCEDURES AND STANDARDS	240.201
D. OPERATION REQUIREMENTS	240.301
E. ENFORCEMENT AND DECERTIFICATION	240.401
F. RESERVED [INTERIM CERTIFICATION]	240.501

Subchapter A. GENERAL PROVISIONS

GENERAL

Sec.

- 240.1. Description of regulatory structure.**
- 240.2. Scope.**
- 240.3. Definitions.**

GENERAL

§ 240.1. Description of regulatory structure.

* * * * *

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

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

§ 240.2. Scope.

- (a) This chapter applies to all persons except a person:
 - (1) Testing for or mitigating against radon contamination in a building that the person owns or [occupies] in which the person resides.
 - (2) Using measures designed to prevent radon contamination in newly constructed buildings. This exemption does not apply to radon testing or installation of radon mitigating devices in these buildings following occupancy.
 - (3) Performing testing or mitigation in the course of the person's normal duties as an employee or contractor of the Department or the Federal government.
 - (4) Performing **Department-approved** scientific research if the person discloses the information obtained to the Department under § 240.303 (relating to reporting of information) and the person informs the owner or occupant of the affected building of the following:
 - (i) That the person is not certified by the Department to test for or mitigate against radon contamination.
 - (ii) That the test results are not [certified] valid.

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

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

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

(ii) **Purveying does not include the activities of either placing or retrieving radon testing devices.**

(6) **Employed by a local government or a school who performs testing for that local government or school if the following criteria are met:**

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

⋮
≡

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

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

§ 240.3. Definitions.

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

AC – activated charcoal—A device used to measure radon by exposing activated charcoal to air in the area to be tested.

ALARA—As Low As Reasonably Achievable---Making every reasonable effort to maintain exposures as far below the dose limits as is practical, taking into account economic considerations and other societal concerns.

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

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

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

Alteration—A change to the original mitigation system design, including but not limited to fan size, number or placement of suction points or pipe diameter.

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

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

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

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

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

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

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

Control limit—A quality control value set at plus or minus three sigma.

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

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

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

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

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

Field blank—A quality control measurement made by analyzing unexposed (closed) detectors that have been maintained in a low-radon environment to assess radon

exposure to the detector from a source other than the concentration in the environment to be measured.

Firm—[A person, other than an individual] **A Department-certified entity that has one certified individual in responsible charge of the entity's testing, mitigation or laboratory radon activities.**

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

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

Laboratory—**A Department-certified individual or firm.**

Laboratory analysis—[The act of determining radon concentrations in air, water, soil or passive radon testing devices] **The act of analyzing a radon test device and calculating a radon concentration in air or water.**

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

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

MV—measured value—**The radon concentration reported by the analyst, in units of picocuries per liter or working levels.**

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

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

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

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

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

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

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

[Picocurie per liter—2.22 disintegrations per minute of radioactive material per liter of air.]

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

Primary tester—A tester who reads or analyzes, or both, [**the continuous monitors or electrets, or both,**] **a primary device** that the tester places or retrieves, or both.

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

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

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

$$\text{RPD} = \{(|\text{MV}_1 - \text{MV}_2|)/(\text{MV}_1 + \text{MV}_2)/2\} \times 100.$$

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

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

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

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

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

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

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

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

Test—The act of [examining] measuring for the presence of radon in a [building, soil,] building's air or water [for the presence of radon, including taking air, soil or water samples, or the act of diagnosing the cause of radon contamination in a building] supply.

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

WL—working level—[One working level is that amount of potential alpha-particle energy dissipated in air by the short-lived daughters in equilibrium with 100 pCi/l of Radon-222. One WL is equal to 130,000 Mev of potential alpha-particle energy deposited per liter of air.] Any combination of short-lived radon progeny (for radon-222: polonium-218, lead-214, bismuth-214, and polonium-214; and for radon-220: polonium-216, lead-212, bismuth-212, and polonium-212) in 1 liter of air that will result in the ultimate emission of 1.3×10^5 MeV of alpha particle energy.

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

WLM/yr—working level month per year—The cumulative exposure incurred over 1 year (2040 hours) from breathing in an atmosphere at a concentration of 1 WL for a working month of 170 hours.

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

Subchapter B. CERTIFICATION

CERTIFICATION FOR RADON TESTING

Sec.

- 240.101. [Requirement] **Requirements** for radon testing certification.
- 240.102. Prerequisites for radon testing certification.
- 240.103. Radon testing application contents.

240.104. Application filing deadline.

CERTIFICATION FOR RADON MITIGATION

- 240.111. **[Requirement] Requirements** for radon mitigation certification.
- 240.112. Prerequisites for radon mitigation certification.
- 240.113. Radon mitigation application contents.
- 240.114. Application filing deadline.

CERTIFICATION FOR RADON LABORATORY

- 240.121. **[Requirement] Requirements** for radon laboratory certification.
- 240.122. Prerequisites for radon laboratory certification.
- 240.123. Radon laboratory application contents.
- 240.124. Application filing deadline.

CERTIFICATION FOR PERSONS CERTIFIED IN ANOTHER STATE

- 240.131. States with reciprocal agreements with the Commonwealth.
- 240.132. Limited radon practice in this Commonwealth.
- 240.133. Certification application contents.

OTHER CERTIFICATION PROCEDURES

- 240.141. Withdrawal of applications or certifications.**
- 240.142. Testing and mitigation identification cards.**
- 240.143. Adding or removing devices from certification.**

CERTIFICATION FOR RADON TESTING

§ 240.101. **[Requirement] Requirements** for radon testing certification.

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

(b) For a firm to perform radon testing it shall employ [at least] one [person] individual certified to test, and the firm shall submit an application for certification and receive certification from the Department.

(c) [Not everyone within the firm is required to be certified to test. An individual performing testing and not working for a certified radon testing firm shall obtain radon testing certification prior to performing testing.] A certified primary tester does not also have to be certified in radon laboratory analysis to read or analyze continuous monitors or electret ion chambers that he or she places and retrieves.

(d) A person using [passive radon monitors] secondary radon testing devices, such as activated charcoal [canisters], from a certified radon laboratory does not also have to [become] be certified in radon laboratory analysis.

§ 240.102. Prerequisites for radon testing certification.

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

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

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

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

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

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

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

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

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

Within 5 days the firm shall notify the Department in writing when it loses its certified individual. Each testing firm employee, after the first initial testing firm employee, will be charged a fee as set forth in Appendix A (relating to radon certification fee schedule)].

- (2) The firm's certified individual may not also be a testing firm employee.**
 - (3) If a testing firm employee is no longer under the responsible charge of the firm's certified individual, the following apply:**
 - (i) The firm's certified individual shall notify the Department within 5 days of this change.**
 - (ii) The firm employee's Department listing becomes invalid.**
 - (4) A testing firm may list a maximum of five testing firm employees at one time.**
 - (5) Each testing firm employee shall conduct activities in accordance with the signed testing firm employee application.**
 - (6) Each testing firm employee applicant shall submit:**
 - (i) A nonrefundable fee as set forth in Appendix A (relating to radon certification fee schedule).**
 - (ii) A completed firm employee application as provided by the Department.**
 - (iii) Proof of passing a Department-approved radon measurement exam.**
 - (iv) The applicant's current photograph, in a format specified by the Department, to be used on the identification card as required in § 240.142 (relating to testing and mitigation identification cards).**
 - (7) The firm's certified individual must receive written approval from the Department before a testing firm employee may conduct radon testing activities.**
- (c) *Additional requirements.* If the applicant for testing certification is a firm, or an individual performing testing and not working for a certified radon testing firm, the applicant shall also have a quality assurance program[a health and safety program] and a continuing education program as required in [§§240.304-240.307] §§ 240.306 and 240.604 (relating to continuing education program; and QA requirements for testing using primary devices). In addition, the applicant shall be successfully enrolled in [the EPA] a Department-approved radon measurement proficiency program [or equivalent] as required in [§§ 240.304—] § 240.307 (relating to radon measurement proficiency program).

§ 240.103. Radon testing application contents.

- (a)** An application for radon testing certification, by [both]an individual [and]or a firm, shall be submitted to the Department in writing on forms provided by the Department and must contain:
- (1) Evidence that the applicant has the certification prerequisites in § 240.102 (relating to prerequisites for radon testing certification) [, including the services offered and experience in each. If the applicant is a firm, the]. The application must [also] include the duties assigned to the certified individual in responsible charge of the testing activities.
- (2) A nonrefundable fee as set forth in Appendix A (relating to radon certification fee schedule).
- (3) The applicant's name, address, [and] telephone number and, if the applicant is an individual, the applicant's date of birth. It must also indicate if the applicant is an individual, partnership, limited partnership, corporation or other entity. The application must include, when appropriate, the name and address of every officer, general and limited partner, director, principal shareholder, parent corporation and certified person within the applicant's organization.
- (4) Compliance information, including descriptions of notices of violation, administrative orders, civil penalty assessments and actions for violations of the act, this chapter or a term or condition of a certification.
- (5) Copies of reporting forms, information distributed to potential clients and recent or proposed advertisements.
- (6) The applicant's current photograph, in a format specified by the Department, to be used on the identification card as required in § 240.142 (relating to testing and mitigation identification cards).
- [(6)] (7) Other information the Department may require related to an applicant's qualifications or technical or administrative information related to radon testing.
- [(7)] (8) A verification by [a responsible official of] the applicant that the information contained in the application is correct to the best of the [official's] applicant's information and belief. This verification shall be subject to the penalties of 18 Pa.C.S. § 4904.
- (b)** Within 10 days of a change to the information submitted in the certified individual application or firm certification application, the certified individual shall submit to the Department a written and signed notification listing each change. The change may not take effect until the Department provides written approval of the change.

§ 240.104. Application filing deadline.

- (a)** A person who expects to conduct radon testing shall file a complete application for certification a minimum of 30 days prior to the anticipated starting date of testing activity. [and any]
- (b)** **A testing individual certification renewal** application postmarked after the **previous testing individual** certification expiration date will be charged a late application fee as set forth in Appendix A (relating to radon certification fee schedule).

CERTIFICATION FOR RADON MITIGATION

§ 240.111. [Requirement] Requirements for radon mitigation certification.

- (a)** A person may not mitigate radon contamination in a building or represent or advertise that he may so mitigate in a building **[or building lot]** in this Commonwealth[,] unless the person has first applied for and obtained certification **from the Department** to mitigate **or is a firm employee of a certified mitigation firm.**
- (b)** For a firm to perform radon mitigation it shall employ **[at least]** one **[person]** **individual** certified to mitigate, and the firm shall submit an application for certification **and receive certification from the Department prior to performing mitigation of radon contamination.** **[Not everyone within the firm is required to be certified to mitigate. An individual performing mitigation and not working for a certified radon mitigation firm shall obtain radon mitigation certification or prior to performing mitigation of radon contamination.]**

§ 240.112. Prerequisites for radon mitigation certification.

- (a) Individual certification for radon mitigation.** An individual will not be certified to mitigate unless **[he]the individual** has **[done the following]:**
- (1) [Taken] Completed** a Department-approved course on radon mitigation.
 - (2) [Taken and passed] Passed** a Department-approved written exam on radon mitigation **within 2 years before the postmark date of the individual's application submittal.** The applicant shall forward **[an official] a** copy of exam results to the Department.
 - (3) Had 1 year professional experience [or supervised experience]** in radon mitigation system installation or 3 years experience in architecture, engineering, electrical contracting, plumbing, carpentry, masonry or related trades.

- (4) Submitted a complete and accurate application to the Department including applicable fees.
- (b) *Firm certification for radon mitigation.* If the applicant for mitigation certification is a firm, it shall employ [**at least**] one individual who is certified to mitigate and who is in responsible charge of the firm's mitigation activities.
- (1) If the firm loses its certified mitigation individual, the **following apply:**
- (i) **The mitigation firm owner shall notify the Department in writing within 5 days of losing that individual.**
- (ii) **The firm's** certification automatically lapses and is void until the **Department approves in writing the mitigation firm owner's written and signed request for a certified individual to be in responsible charge of that firm's radon mitigation activities** [firm has notified the Department of employment of another certified individual. Within 5 days the firm shall notify the Department in writing when it loses its certified individual].
- (2) **The firm's certified individual may not also be a mitigation firm employee.**
- (3) **If the mitigation firm employee is no longer under the responsible charge of the firm's certified individual, the following apply:**
- (i) **The firm's certified individual shall notify the Department within 5 days of this change.**
- (ii) **The firm employee's Department listing becomes invalid.**
- (4) **The mitigation firm employee shall conduct activities in accordance with the signed mitigation firm employee application.**
- (5) **A mitigation firm may list a maximum of five mitigation firm employees at one time.**
- (6) **Each mitigation firm employee applicant shall submit:**
- (i) **A completed firm employee application as provided by the Department.**
- (ii) **The applicant's current photograph, in a format specified by the Department, to be used on the identification card as required in § 240.142 (relating to testing and mitigation identification cards).**
- (iii) **Proof of passing a Department-approved course on radon mitigation or passing a Department-approved mitigation exam.**

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

* * * *

§ 240.113. Radon mitigation application contents.

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

(1) Evidence that the applicant has the certification prerequisites contained in § 240.112 (relating to prerequisites for radon mitigation certification). [**, including the services offered and experience in each. If the applicant is a firm, the applicant**] **The application must** [shall also] include the duties assigned to the certified individual **in responsible charge of the mitigation activities.**

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

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

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

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

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

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

[**(6)**] **(8)** A verification by [a responsible official of] the applicant that the information contained in the application is correct to the best of the [official's] **applicant's** information and belief. **This verification shall be subject to the penalties of 18 Pa.**

C.S. § 4904.

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

§ 240.114. Application filing deadline.

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

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

CERTIFICATION FOR RADON LABORATORY

§ 240.121. [Requirement] Requirements for radon laboratory certification.

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

(b) For a firm to perform radon laboratory analysis it shall employ one individual certified to perform laboratory analysis, and the firm shall submit an application for certification and receive certification from the Department.

§ 240.122. Prerequisites for radon laboratory certification.

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

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

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

* * * * *

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

- (1) If the firm loses its certified individual, the **following apply:**
- (i) **The firm owner shall notify the Department in writing within 5 days of losing its certified individual.**
- (ii) **The firm's certification automatically lapses and is void until the Department approves in writing the firm owner's written and signed request for a certified individual to be in responsible charge of that firm's radon laboratory activities** [firm has notified the Department of employment of another certified individual. Within 5 days the firm shall notify the Department in writing when it loses its certified individual].
- (2) **The firm's certified individual may not also be a laboratory firm employee.**
- (3) **If a laboratory firm employee is no longer under the responsible charge of the firm's certified individual, the following apply:**
- (i) **The firm's certified individual shall notify the Department within 5 days of this change.**
- (ii) **The firm employee's Department listing becomes invalid.**
- (4) **Activities of the laboratory firm employee shall be conducted in accordance with the signed laboratory firm employee application.**
- (5) **Each laboratory firm employee applicant shall submit a completed and signed laboratory firm employee application as provided by the Department.**
- (6) **Each laboratory firm employee must receive written approval from the Department prior to conducting radon laboratory activities as a laboratory firm employee.**
- (c) *Additional requirements.* If the applicant for radon laboratory certification is a firm, or an individual performing laboratory analysis and not working for a certified laboratory, the applicant shall also have a quality assurance program and a continuing education program as required in [§§ 240.304—240.307] **§§ 240.306 and 240.604 (relating to continuing education program; and QA requirements for testing using primary devices).** In addition, the applicant shall be successfully enrolled in [the EPA] a **Department-approved** radon measurement proficiency program [or equivalent,] as required in [§§ 240.304—] § 240.307 **(relating to continuing education program).**

§ 240.123. Radon laboratory application contents.

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

(1) Evidence that the applicant has the certification prerequisites contained in § 240.122 (relating to prerequisites for radon laboratory certification). [, **including the services offered and experience in each. If the applicant is a firm, the] The [applicant] application** shall [also] include the duties assigned to the certified individual in responsible charge of the laboratory analysis activities.

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

* * * * *

(6) A verification by [a responsible official of] the applicant that the information contained in the application is correct to the best of the [official's] applicant's information and belief. This verification shall be subject to the penalties of 18 Pa. C.S. § 4904.

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

§ 240.124. Application filing deadline.

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

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

CERTIFICATION FOR PERSONS CERTIFIED IN ANOTHER STATE

§ 240.132. Limited radon practice in this Commonwealth.

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

- (1) [The person has obtained] **Obtains** certification to do so from a state with which the Department has entered into a reciprocal agreement.
- (2) [The person conducts] **Conducts** that activity in this Commonwealth [less] **fewer** than 90 days each calendar year.

§ 240.133. Certification application contents.

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

- (1) A copy of the [certificatin] **certification** from **the** foreign state.
- (2) A nonrefundable fee [of \$200.] **as set forth in Appendix A (relating to radon certification fee schedule).**
- (3) The applicant's name, address, [and] telephone number **and, if the applicant is an individual, date of birth**. It must also indicate if the applicant is an individual, partnership, limited partnership, corporation or other entity. The application must include, when appropriate, the name and address of every officer, general and limited partner, director, principal shareholder, parent corporation and certified person within the applicant's organization.

* * * * *

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

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

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

OTHER CERTIFICATION PROCEDURES

§ 240.141. Withdrawal of applications and certifications.

(a) *Withdrawal of applications.*

- (1) An application may be withdrawn before Department approval is granted.
- (2) Fees will not be refunded.
- (3) After an application for certification is withdrawn, a person who wishes to reapply for certification shall submit a new application along with the appropriate fee set forth in Appendix A (relating to radon certification fee schedule).
- (4) The withdrawal is complete when the following conditions have been met:
 - (i) The request for an application withdrawal has been submitted to the Department in writing and signed by the applicant.
 - (ii) The Department has confirmed the withdrawal in writing.

(b) *Withdrawal of certifications.*

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

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

- (1) The Department may withdraw a testing or laboratory individual certification when that individual no longer has Department-listed testing devices.
- (2) The Department will confirm the withdrawal in writing.

(d) *Re-instatement of withdrawn certifications.*

- (1) The previously certified individual may submit a written, signed request to reinstate the individual's testing, mitigation or laboratory individual certification or the

firm owner may request to re-instate the testing, mitigation or laboratory firm certification prior to the withdrawn certification's expiration date.

- (2) The Department will approve or disapprove this request in writing.
- (3) A person who wishes to reapply for certification after the expiration of the person's previous certification shall submit a new application along with appropriate fees as set forth in Appendix A (relating to radon certification fee schedule).

§ 240.142. Testing and mitigation identification cards.

- (a) The following persons shall obtain Department identification cards:
 - (1) Individuals for testing certification.
 - (2) Individuals for mitigation certification.
 - (3) Each testing firm employee.
 - (4) Each mitigation firm employee.
- (b) Each applicant referenced in subsection (a) shall submit the applicant's current photograph, in a format specified by the Department, to the Department with the application.
- (c) Each person listed in subsection (a) shall wear prominently the Department-issued identification card while performing radon-related activities and present the Department-issued identification card to a client upon request.

§ 240.143. Adding or removing devices from certification.

- (a) To add or remove a device from laboratory or testing certification, the certified individual shall submit a written and signed request to the Department.
- (b) The certified individual who analyzes each continuous monitor and electret reader shall provide in the request the specific serial number and proof of current calibration of each device to be added.
- (c) The certified individual who analyzes each continuous monitor and electret reader shall provide in the request the specific serial number of each device to be removed.
- (d) The device will be considered Department-listed or removed on the effective date stated in the Department's confirmation letter to the certified individual.
- (e) After the effective removal date of the device, the device may no longer be used to conduct radon testing activities or laboratory analysis.

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

Subchapter C. CERTIFICATION REVIEW PROCEDURES AND STANDARDS

Sec.

- 240.201. Criteria for [certification] issuance or denial of certifications or course provider applications.
240.202. Terms of certification.
240.203. Conditions of certification.
240.204. Certification renewal.
240.205. Certification modification.
240.206. Notice of certification.

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

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

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

* * * * *

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

§ 240.202. Terms of certification.

- (a) A certification will be valid for 2 years following issuance.
(b) Testing, mitigation or laboratory analysis [other radon-related activity] may not be conducted after the expiration of the term of certification.

§ 240.203. Conditions of certification.

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

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

* * * * *

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

(5) Certified individuals shall pass blind studies conducted by the Department. The individual measurement results of the blind study must achieve an individual relative percent error of less than or equal to +/- 25% of the reference value.

* * * * *

§ 240.204. Certification renewal.

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

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

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

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

(2) An individual certification application postmarked 1 year or more after expiration of certification is an initial application subject to the initial application

fee set forth in Appendix A (relating to radon certification fee schedule). This application is not subject to the late application fee set forth in Appendix A.

§ 240.205. Certification modification.

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

Subchapter D. OPERATION REQUIREMENTS

Sec.

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

§ 240.301. Advertising.

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

§ 240.302. [Notice to clients] Required client information.

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

NOTICE TO CLIENTS:

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

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

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

§ 240.303. Reporting of information.

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

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

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

(i) A primary tester performing analyses or a certified individual performing laboratory analyses shall report test results to the Department within 45 days of the analysis date. If no radon-related analysis is provided during a 45-day period, the certified individual shall inform the Department by the end of that 45-day period in a format approved by the Department. Radon tests used for diagnostic purposes shall be identified as “diagnostic” when submitted to the laboratory. [At a minimum, these results will be retained for 2 years.] The information must include:

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

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

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

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

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

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

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

(F) The date the analysis was performed.

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

(ii) The primary certified individual shall retain for 5 years the test result documentation identified in subparagraph (i).

(iii) The following test results should not be reported to the Department:

(A) An invalid test.

(B) A diagnostic test.

(C) A measurement performed only for quality assurance.

(2) Mitigation reporting.

(i) A mitigation certified individual shall report the mitigation activity results to the Department within 45 days of the mitigation system initial fan activation or the alteration to an existing mitigation system. If no mitigation activity is performed during a 45-day period, the certified individual shall inform the Department by the end of that 45-day period in a format approved by the Department. The reported information must include:

- (A) The name and certification number of the person providing the service.
- (B) The address of the building involved, including street and number, post office, full zip code and county.
- (C) The date of the initial fan activation or the alteration to an existing mitigation system.
- (D) The type of house or building.
- (E) The type of mitigation installation or alteration.
- (F) The cost to the client.
- (G) The postmitigation result.

(ii) The mitigation certified individual shall retain for 5 years the mitigation activity result documentation identified in subparagraph (i).

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

[c)] (4) Postmitigation testing and reporting. For a person performing mitigation, each building shall be tested for radon levels before and after the mitigation is performed. Each test must be at least 48 hours in duration and follow [EPA- or DEP-approved] Department-approved protocols, § 240.308(e) (relating to radon mitigation standards) after system installation, and § 240.309 (relating to testing protocols). The postmitigation test shall be conducted no sooner than 24 hours after completion of the mitigation. The results of [radon testing] the postmitigation test shall be reported in accordance with this section.

§ 240.304. [Quality assurance program.] [Reserved.]

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

- (1) **Organization and responsibilities.**
- (2) **Sampling procedures.**
- (3) **Detector custody.**
- (4) **Analytical procedures.**
- (5) **Data reduction, validation and reporting.**
- (6) **Corrective action.**
- (7) **Quality assurance reports to management.]**

§ 240.305. Health and safety program.

[A person conducting radon-related activities] **A certified individual** shall have a radon health and safety program to protect himself and **firm employees** [employees] from exposure to radon [during the course of their employment]. The program shall include records of each [individual's] **mitigator's** exposure to radon **during the course of his employment**. **The certified individual shall record the items on the form in Appendix C and retain the records for a period of 5 years.** [Persons conducting radon-related activities] **Testers and mitigators** shall maintain exposure to radon as low as reasonably achievable **(ALARA)**. **A tester or mitigator may not exceed 4 WLM/yr in radon exposure.**

§ 240.306. Continuing education program.

[A person conducting radon-related activities shall have a radon education program to assure that the applicant and all employees have a minimum of 4 hours initial training, and] **Upon certification renewal**, the certified [person] **individual** shall [participate in a continuing education program consisting of a minimum of 8 hours of Department-approved courses or seminars on radon testing or mitigation each year] **submit to the Department proof of having satisfactorily completed 16 credit hours of Department-approved continuing education courses or Department-approved equivalent**. **Continuing education credit hours may only be used for one certification period for each certification activity.**

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

[A person conducting radon testing or radon laboratory activities] An initial laboratory individual applicant, initial primary testing individual applicant, or an applicant applying to add a new primary testing or laboratory device shall provide written evidence of successful participation [in the most recent EPA Radon/Radon progeny Measurement Proficiency Program or an alternative program approved by the Department for each radon measurement utilized] in a Department-approved radon measurement proficiency program for each model type.

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

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

(1) The termination point must be vertical, upward, outside the structure, and discharging to the atmosphere. Rain caps or terminal bends may not be used.

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

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

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

(5) The termination point must be 10 feet or more from an operable window unit, door or other opening into conditioned spaces unless it is 2 feet above the top of such openings. The 10-foot distance may be measured directly between the opening and the exhaust point or with a flexible tape following the shortest path possible around intervening solid objects. A chimney is not considered an opening into conditioned spaces.

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

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

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

(1) Below grade or in the heated or cooled space of a building.

(2) In a basement, crawl space, or other interior location directly beneath the heated or cooled spaces of a building.

(c) Sealing.

(1) When accessible, the following are required to be adequately sealed with urethane caulk or equivalent material using methods and materials that are permanent and durable when installing a mitigation system:

- (i) Perimeter channel drains.
- (ii) Cracks that exist where the slab meets the foundation wall (floor wall joint).
- (iii) Openings or cracks in the foundation or at expansion or control joint.

(2) When the opening or channel is greater than 1/2 inch in width, a foam backer rod or other equivalent filler material shall be inserted into the channel before application of the sealant. Materials inserted into the channel must leave adequate space below the filler material to allow sub-surface drainage from the channel into the subslab material.

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

- (i) This technique may contribute to an increased heating and cooling penalty.
- (ii) This technique may decrease the efficiency of the radon mitigation system.
- (iii) This technique may increase the potential for backdrafting natural draft combustion appliances.

(d) Labeling.

(1) If the mitigation system is accessible and visible, then a system description label shall be prominently and permanently affixed to the mitigation system piping. If the mitigation system is concealed or not accessible, then the label shall be placed in another prominent location. The label shall be legible from a distance of at least three feet and include the following information:

- (i) "Radon Reduction System."
- (ii) The name and certification number of the mitigation certified individual.

- (iii) The contact telephone number of the mitigator.
 - (iv) The date of installation.
 - (v) "Building should be tested for radon at least every two years."
- (2) Each exposed and visible interior radon mitigation system vent pipe section shall be identified with at least one label on each floor level. The label shall read "Radon Reduction System."
- (e) Required client information. Upon completion of the mitigation project, the mitigator shall attach an information package to the mitigation system in a secure and permanent manner, visible location, and labeled "Radon Mitigation Information." The information package must include the following:
 - (1) A completed copy of the Radon Mitigation Project Record from "Pennsylvania Radon Mitigation Standards," 294-2309-002, October 1, 1997, Appendix A.
 - (2) A copy of contracts and warranties for the mitigation system.
 - (3) A description of the installed mitigation system and its basic operating principles.
 - (4) A description of the proper operating procedures of installed mechanical or electrical systems, including the manufacturer's operation and maintenance instructions, drain-filling instructions and warning device interpretations.
 - (5) A list of appropriate actions for the client to take if the system failure warning device indicates system degradation or failure.
 - (6) A recommendation to retest at least every two years.
 - (7) A recommendation to have an electrical inspection performed on the applicable components of the installed system.
- (f) Compliance. A person conducting radon [testing or] mitigation [for radon contamination] activities shall conduct the [testing and] mitigation in accordance with [EPA- or DEP-approved protocols] Department-approved mitigation standards and shall comply with applicable statutes, regulations, ordinances and building codes.

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

§ 240.309. Testing protocols.

(a) *Radon testing protocols.* The certified individual shall ensure that the requirements in this section are completed. For testing that is required to be reported to the Department under § 240.303(a) (relating to reporting of information), radon testing shall be performed in accordance with the following testing protocols:

- (1) *Placement of testing devices.* Testing devices shall be placed as follows:
 - (i) At least 3 feet from exterior doors, windows or ventilation ducts.
 - (ii) Out of the direct flow of air.
 - (iii) At least 1 foot from ceilings and exterior walls.
 - (iv) At least 20 inches but not more than 6 feet from the floor.
 - (v) At least 4 inches from other objects horizontally or vertically above the detector.
 - (vi) At least 4 feet from heat sources including fireplaces, furnaces and direct sunlight.
 - (vii) At least 7 feet from sump pits.
 - (viii) Where the device will remain undisturbed during the test period.
- (2) *Improper placement of testing devices.* Testing devices may not be placed in the following locations:
 - (i) Bathrooms.
 - (ii) Kitchens.
 - (iii) Within 10 feet of washer/dryer unit.
 - (iv) Spa rooms or other areas of high humidity.
 - (v) Closets.
 - (vi) Cupboards.
 - (vii) Sump pits.
 - (viii) Crawlspaces or nooks within the foundation.

(3) *Short-term tests.* Short-term tests shall be taken in the lowest livable level of each structural zone that contacts the soil.

(4) *Conditions of testing.* Testing shall be conducted under the following conditions:

(i) Testing devices must remain undisturbed during the testing period.

(ii) A short-term test must range in duration from 48 hours to 90 days.

(iii) Short-term tests must be conducted under closed-building conditions.

(iv) Closed-building conditions must begin at least 12 hours prior to the beginning of the test period for tests lasting less than 96 hours.

(v) Closed-building conditions consist of the following criteria:

(A) All windows must be closed.

(B) All external doors must be closed except for normal entry and exit. Structural openings due to disrepair or structural defects shall be repaired to correct their condition prior to initiation of testing.

(C) Normal operation of permanently installed HVAC systems must continue during closed-building conditions.

(D) Fireplaces, wood stoves and coal stoves may not be operated unless they are normal sources of heat for the building.

(E) Air-conditioning systems that recycle interior air may be operated during closed-building conditions.

(F) Whole-house fans may not be operated during the test period. Portable window fans shall be removed from windows or sealed in place. Window air conditioning units may only be operated in a recirculation mode. If the building contains an air handling system, the air handling system may not be set for continuous operation unless the air handling equipment is specifically used for radon control and is labeled accordingly.

(G) In buildings with permanently installed radon mitigation systems, the mitigation system must be functioning during the test period.

(H) Operation of fans, portable dehumidifiers, portable humidifiers, portable air filters and window air conditioners may not create a direct flow of air on the radon testing device.

(vi) All closed-building conditions shall be inspected and documented at the time of placement and retrieval of the detectors.

(vii) Short-term tests of fewer than 96 hours may not be conducted during severe storms or periods of sustained high winds of 30 miles per hour or greater. Local weather forecasts shall be checked and documented prior to placing short-term test devices when the test period is less than 96 hours.

(viii) Instructions describing closed-building conditions required in this section shall be provided to the persons who control the building and shall be documented.

(ix) Only co-located duplicate tests may be averaged.

(5) *Minimum requirements for short-term testing.*

(i) *Simultaneous testing using short-term passive devices.*

(A) Simultaneous testing must comprise at least 2 short-term indoor radon tests conducted simultaneously with identical test devices.

(B) Simultaneous testing devices shall be:

(I) Co-located and the near edges spaced 4 to 5 inches apart.

(II) Exposed for the same test period.

(C) Both tests and the average of the simultaneous tests shall be reported to the client, except as indicated in subclause (II):

(I) If the RPD is greater than 67% for simultaneous test results that are both between 2.0 and 3.9 pCi/L, the tests shall be reported to the client and the cause investigated, documented and corrected.

(II) If the RPD is greater than 36% for simultaneous test results that are both equal to or greater than 4.0 pCi/L, the tests may not be reported to the client, and the cause must be investigated, documented and corrected.

(D) If one test is equal to or greater than 4.0 pCi/L and one test is less than 4.0 pCi/L, and the higher test is more than twice the amount of the lower test, the tests may not be reported to the client.

(ii) *Continuous radon monitor (CRM) testing.*

(A) A CRM must have the capability to integrate and record a new result at least hourly.

- (B) The minimum test period is 48 hours, with 44 contiguous hours of usable data to produce a valid average. The first 4 hours of data from a CRM may be discarded.
 - (C) The contiguous results shall be averaged to produce a result that is reported to the client.
 - (D) A copy of the hourly printout shall be provided to the client as part of the test results.
- (6) *Real estate testing.* Real estate testing shall be conducted using the following anti-tampering procedures:
- (i) Testing devices shall be secured against movement by employing anti-tampering methods.
 - (ii) The buyer, seller, occupant, real estate professional or other individual in control of the property shall sign a Conditions for Short-Term Radon Testing Agreement, which must contain the information in Appendix B (relating to non-interference agreement for real estate radon testing).
 - (iii) If the Conditions for Short-Term Radon Testing Agreement cannot be signed by the buyer, seller, occupant, real estate professional or other individual in control of the property, the reason shall be documented on the completed agreement.
 - (iv) A Radon Testing in Progress Notice shall be posted at every building entry and in a conspicuous indoor location. The notice shall be posted upon initiation of a radon test and include the following statements:
- (A) “Radon Testing in Progress.”
 - (B) “Keep all windows closed.”
 - (C) “Keep all exterior doors closed, except for normal entry and exit.”
 - (D) “Do not move or touch the radon testing device.”
- (7) *Multifamily building tests.* Multifamily building tests shall be performed in accordance with ANSI/AARST MSMF-2010 *Protocol for Conducting Radon and Radon Decay Product Measurements in Multifamily Buildings* or its equivalent as determined by the Department.
- (8) *School and commercial building tests.* School and commercial building tests shall be performed in accordance with *Radon Measurement in Schools* (EPA 402-R-92-014) or its equivalent as determined by the Department.

(9) *New construction and buildings under renovation.* This paragraph provides the testing requirements for new construction and buildings under renovation. A newly constructed building or existing building under renovation may not be tested for radon or radon progeny unless the following items have been installed:

- (i) Insulation.
- (ii) Exterior doors with associated hardware.
- (iii) Windows.
- (iv) Fireplaces and fireplace dampers, if they are or will be installed.
- (v) Heating, air conditioning and plumbing appliances.
- (vi) Ceilings.
- (vii) Interior trim and coverings for the exterior walls.
- (viii) Exterior siding, weatherproofing and caulking.
- (ix) Interior and exterior structural components.
- (x) Interior or exterior work that may adversely affect the test validity.

(10) *Postmitigation testing.*

- (i) Testing conducted while temporary radon reduction systems are in use may not be used as the postmitigation test.
- (ii) The mitigation system must be operated continuously during the entire test period.
- (iii) The postmitigation test may not be performed sooner than 24 hours or later than 30 days following the completion and activation of the mitigation system or an alteration to an existing system.
- (iv) Postmitigation testing shall be conducted in accordance with this subsection.

(b) *Result Report Form.*

(1) A tester shall have a Department-approved Result Report Form. Testers shall provide the client with a completed Result Report Form within 10 working days from the completion of the test or the receipt of the test results from the laboratory. The Result Report Form must contain:

- (i) Each test result in pCi/L and rounded to one decimal place. Standard mathematical rules for rounding shall be followed.
- (ii) Notification of an invalid radon test with an explanation and without a test result given.
- (iii) The average of co-located test device results as well as the individual results.
- (iv) The exact start and stop dates and times of the test period.
- (v) The complete street address of the test location, including, when applicable, the apartment, suite or building number.
- (vi) The test device used and its manufacturer, model and serial number.
- (vii) The complete name, street address and telephone number of the tester.
- (viii) The name and Department certification number of each tester placing and retrieving each testing device.
- (ix) The name and certification number of the laboratory analyzing the testing device, if applicable.
- (x) A statement whether a mitigation system was observed in the building during placement or retrieval of the testing device, including whether the mitigation system was operating.
- (xi) A statement describing if tampering, interference or deviations from the required test conditions was observed.
- (xii) A description of the condition (open, closed or N/A) of permanent vents that allow outdoor air into the building, such as crawlspace vents or combustion air supply to combustive appliances.
- (xiii) A description of severe weather conditions during the test period.
- (xiv) The location within the building of each testing device.
- (xv) The Pennsylvania “Notice to Clients” statement as indicated in § 240.302 (relating to required client information).
- (xvi) If using a continuous radon monitor, a copy of the device printout.
- (xvii) If using a continuous radon monitor or electret reader, the calibration expiration date.

(xviii) If using a continuous radon monitor or electret reader, the device serial number.

(xix) The following radon health risk information:

“Radon is the second leading cause of lung cancer, after smoking. The U.S. Environmental Protection Agency (EPA) and the Surgeon General strongly recommend taking further action when the home’s radon test results are 4.0 pCi/L or greater. The national average indoor radon level is about 1.3 pCi/L. The higher the home’s radon level the greater the health risk to you and your family. Reducing your radon levels can be done easily, effectively and fairly inexpensively. Even homes with very high radon levels can be reduced below 4.0 pCi/L. For further information about reducing elevated radon levels, please refer to the ‘Pennsylvania Citizen’s Guide to Radon.’”

(2) A laboratory shall use a Department-approved Result Report Form. Laboratories shall provide the client with a completed Result Report Form within 10 working days after completion of test analysis. The Result Report Form must contain:

- (i) Each test result in pCi/L and rounded to one decimal place. Standard mathematical rules for rounding shall be followed.
- (ii) Notification of invalid radon tests with an explanation and without a test result given.
- (iii) The average of co-located testing devices as well as the individual results.
- (iv) The exact start and stop dates and times of the test period.
- (v) The complete street address of the test location, including, when applicable, the apartment, suite or building number.
- (vi) The test device used and its manufacturer, model and serial numbers.
- (vii) The name and certification number of the laboratory analyzing the testing device.
- (viii) The location within the building of each test device.
- (ix) The Pennsylvania “Notice to Clients” statement as indicated in § 240.302.
- (x) If using a continuous radon monitor, a copy of the device printout.
- (xi) The calibration expiration date of the electret reader or continuous monitor.
- (xii) The following radon health risk information:

Radon is the second leading cause of lung cancer, after smoking. The U.S. Environmental Protection Agency (EPA) and the Surgeon General strongly recommend taking further action when the home's radon test results are 4.0 pCi/L or greater. The national average indoor radon level is about 1.3 pCi/L. The higher the home's radon level the greater the health risk to you and your family. Reducing your radon levels can be done easily, effectively and fairly inexpensively. Even homes with very high radon levels can be reduced below 4.0 pCi/L. For further information about reducing elevated radon levels, please refer to the "Pennsylvania Citizen's Guide to Radon."

Subchapter E. ENFORCEMENT AND DECERTIFICATION

Sec.

- 240.401. Inspection.
- 240.402. Civil penalties.
- 240.403. Decertification.

§ 240.401. Inspection.

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

* * * * *

- (b) The Department, its agents and [employees] **employees** may conduct inspections of a building, property, premises or place of business of a person who conducts radon-related activities if a person presents information to the Department or the Department has access to information which gives it reason to believe that one of the following exists:

* * * * *

- (c) An agent or [employe] **employee** of the Department may not enter a private residence for the purpose of conducting an inspection under this section without a search warrant or without the consent of the occupant.

* * * * *

[Subchapter F. INTERIM CERTIFICATION]

[Sec.]

- [240.501. Scope.]

- [240.502. Reapplication when this chapter is adopted as final.]

[§ 240.501. Scope.] [Reserved.]

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

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

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

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

Subchapter G. QUALITY ASSURANCE (QA) REQUIREMENTS

Sec.

- 240.601. Scope
- 240.602. General requirements.
- 240.603. QA program.
- 240.604. QA requirements for testing using primary devices.
- 240.605. QA requirements for testing using secondary devices.
- 240.606. QA requirements for laboratories.

§ 240.601. Scope.

- (a) This subchapter applies to QA requirements for:
 - (1) Persons conducting radon testing and radon laboratory analysis activities.
 - (2) Testing devices listed with the Department on the individual's certification.
- (b) The subchapter does not apply to tests performed for the sole purpose of diagnostic testing.

§ 240.602. General requirements.

- (a) The certified individual is responsible for all requirements in this subchapter, including when QA activity is performed by others.
- (b) QA requirements and corrective actions in this section shall be documented and the records retained for a minimum of 5 years.

§ 240.603. QA program.

A person conducting radon testing or radon laboratory analysis activities shall have a QA program to ensure the measurements are accurate and errors are controlled. The program shall ensure that testing devices are routinely and properly calibrated. The program shall provide the information related to the following activities:

- (1) Organization and responsibilities.
- (2) Sampling procedures.
- (3) Detector custody.
- (4) Analytical procedures.
- (5) Data reduction, validation and reporting.
- (6) Corrective action.
- (7) QA reports to management.

§ 240.604. QA requirements for testing using primary devices.

(a) CRMs for primary testers.

- (1) *Calibration.* Each Department-listed CRM must have a current calibration. To have a current calibration, the CRM shall be calibrated in a Department-approved calibration facility within 1 year from the date of the previous calibration and when alterations or repairs are made to the CRM.
- (2) *Background measurements.* Background measurements shall be performed and documented after every 1,000 hours of operation of scintillation cell-type CRM. These background measurements shall be checked by purging the unit with clean, aged air or nitrogen in accordance with the manufacturer's instructions. For all CRMs, the background shall be monitored in accordance with the manufacturer's instructions.
- (3) *Check source counting.* For a CRM with a check source, check source counting shall be documented and completed with that check source prior to each test.

(4) *Routine instrument checks.* Before and after each measurement, the CRM shall be checked according to the manufacturer's instructions. For each check, the following shall be verified:

- (i) The correct input parameters and the unit's clock or timer are set properly.
- (ii) The pump's flow rates are within the range of the manufacturer's specifications.

(5) *Data collection log.*

- (i) CRM data shall be tracked on a form that contains the following:
 - (A) The CRM serial number.
 - (B) The exposure dates and times.
 - (C) The test result.
 - (D) The address of the building tested.
 - (E) The test location in the building.
 - (F) The name of the tester who placed the CRM.
 - (G) The name of the tester who retrieved the CRM.
 - (H) The calibration, repair and Department listing dates.
- (ii) For a CRM without a radioactive check source, the data collection log shall also contain the following intercomparison measurement information:
 - (A) The intercomparison devices' serial numbers.
 - (B) The RPD value.
 - (C) The intercomparison measurements results.

(6) *Intercomparison measurements.* An intercomparison measurement shall be performed for each CRM without a radioactive check source.

- (i) Intercomparison measurements shall be made at least every 10th test with another Department-listed passive device that is analyzed by a Department-certified laboratory or with another CRM with a hard copy printout. The intercomparison measurements shall be distributed systematically throughout the entire population of test locations. Original printouts or Department-certified laboratory results, or both,

shall be kept for each intercomparison. Each intercomparison measurement must be performed with the devices side by side for the measurement for at least 48 hours.

- (ii) For intercomparison measurements, the RPD shall be used to track performance. The RPD value shall be tracked using control charts from “Protocols for Radon and Radon Decay Product Measurements in Homes,” EPA 402-R-92-003, May 1993, Appendix B, Exhibit B-2 and Exhibit B-3.
- (iii) If the RPD value exceeds the control limit, the CRM may not be used for radon measurements until the problem is identified and corrected. If the RPD value exceeds the warning level, the criteria in “Protocols for Radon and Radon Decay Product Measurements in Homes,” EPA 402-R-92-003, May 1993, Appendix B, Exhibit B-5, shall be followed.
- (iv) In addition to the control charts, all intercomparison measurements shall be documented on the CRM data collection log.

(b) *CWLMs for primary testers.*

- (1) *Calibration.* Each Department-listed CWLM must have a current calibration. To have a current calibration, the CWLM shall be calibrated in a Department-approved calibration facility within 1 year from the date of the previous calibration and when alterations or repairs are made to the CWLM.
- (2) *Background measurements.* CWLM background measurements shall be performed and documented at least every 168 hours of operation and when the unit is calibrated.
- (3) *Routine instrument checks.* Routine instrument checks for each CWLM shall be documented and performed before and after each test by using an Am-241 or similar energy check source. Pumps and flow meters shall be checked in accordance with the manufacturer's instructions and documented. The pump and flow meter check shall be performed with a dry-gas meter or other flow measurement device of traceable accuracy.

(4) *Data collection log.*

- (i) CWLM data shall be tracked on a form that contains the following:
 - (A) The CWLM serial number.
 - (B) The exposure dates and times.
 - (C) The test result.
 - (D) The address of the building tested.

- (E) The test location in the building.
 - (F) The name of the tester who placed the CWLM.
 - (G) The name of the tester who retrieved the CWLM.
 - (H) The calibration, repair and Department listing dates.
- (ii) For CWLMs without a radioactive check source, the data collection log shall also contain the following intercomparison measurement information:
- (A) The intercomparison devices' serial numbers.
 - (B) The RPE value or RPD value.
 - (C) The intercomparison measurement results.
- (5) *Intercomparison measurements.* An intercomparison measurement shall be performed for each CWLM monitor without a radioactive check source.
- (i) A CWLM without radioactive check source capability must have an informal intercomparison measurement made with another CWLM with a hard copy printout at least every 10th test. This printout shall be retained for each intercomparison. The intercomparison measurements shall be distributed systematically throughout the entire population of test locations. Each intercomparison measurement must be performed with the devices side by side for the measurement for at least 48 hours.
 - (ii) Each intercomparison shall be documented on the data collection log.
 - (iii) For intercomparison measurements the RPD shall be used to track performance. The RPD value shall be tracked using control charts from "Protocols for Radon and Radon Decay Product Measurements in Homes," EPA 402-R-92-003, May 1993, Appendix B, Exhibit B-2 and Exhibit B-3.
 - (iv) If the RPD value exceeds the control limit, the CRM may not be used for radon measurements until the problem is identified and corrected. If the RPD value exceeds the warning level, the criteria in "Protocols for Radon and Radon Decay Product Measurements in Homes," EPA 402-R-92-003, May 1993, Appendix B, Exhibit B-5, shall be followed.
- (c) *Electret ion chambers for primary testers.*
- (1) *Calibration.* Each Department-listed electret reader must have a current calibration. To have a current calibration, the electret reader shall be calibrated in a Department-approved calibration facility within 1 year from the date of the previous calibration and when alterations or repairs are made to the electret reader. Each electret

reader shall be calibrated simultaneously with its corresponding reference electret's recertification.

(2) *Data collection log.* Electret custody shall be tracked on a form that contains the following:

- (i) The electret serial number.
- (ii) The electret chamber serial number.
- (iii) The initial voltage reading.
- (iv) The final voltage reading.
- (v) The exposure dates and times.
- (vi) The test result.
- (vii) The serial number of duplicate electret.
- (viii) The RPD value.
- (ix) The address of the building tested.
- (x) The test location in the building.
- (xi) The name of the tester who placed the electret.
- (xii) The name of the tester who retrieved the electret.

(3) *Known exposure measurements (spikes).*

- (i) Spikes shall be conducted at a rate of 3 for each 100 test devices deployed, with a minimum of 3 spikes for each certification year when tests were conducted in the certification year, and with a maximum of 6 spikes each month.
- (ii) Spikes shall be analyzed in the same manner as all other testing.
- (iii) Spikes shall be monitored using a means control chart. The means control chart must be established as follows:
 - (A) Using an RPE value of plus and minus 10%, which corresponds to the 1 sigma level.
 - (B) A warning level of the RPE of plus and minus 20%, which corresponds to the 2 sigma warning level.

(C) Control limits of the RPE of plus and minus 30%, which corresponds to the 3 sigma control level.

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

(v) Each RPE value shall be plotted on the means control chart within 1 week of return of the device from the chamber. If the RPE value is outside the 3 sigma control level, all measurements shall cease until the problem is evaluated and corrected. All evaluations shall be documented.

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

- (A) The radon chamber name.
- (B) The electret serial numbers.
- (C) The electret chamber serial numbers.
- (D) The reference value from radon chamber.
- (E) The measured spike value or values.
- (F) The individual RPE results.
- (G) The certification year beginning date and end date.
- (H) The exposure dates.

(4) *Duplicate measurements.*

(i) Duplicates shall be made in at least 10% of the total number of test devices deployed each month, or 50 each month, whichever is smaller.

(ii) The RPD shall be calculated for all duplicate results with an average of greater than or equal to 2.0 pCi/L. Two control charts must be constructed to monitor duplicate precision:

- (A) One for duplicates when the average is greater than or equal to 4.0 pCi/L.
- (B) One for duplicates when the average is greater than or equal to 2.0 pCi/L and less than 4.0 pCi/L.

- (iii) Each RPD value shall be plotted on the control chart within 1 week of performing the duplicate measurement.
 - (iv) The RPD shall be tracked using control charts from “Protocols for Radon and Radon Decay Product Measurements in Homes,” EPA 402-R-92-003, May 1993, Appendix B, Exhibit B-2 and Exhibit B-3.
 - (v) For duplicates when the average is greater than or equal to 4.0 pCi/L, the following apply:
 - (A) The control level shall be set at an RPD of 14%.
 - (B) The warning level shall be set at an RPD of 28%.
 - (C) The control limit shall be set at an RPD of 36%.
 - (vi) For duplicates when the average is greater than or equal to 2.0 pCi/L and less than 4.0 pCi/L, the following apply:
 - (A) The control level shall be set at an RPD of 25%.
 - (B) The warning level shall be set at an RPD of 50%.
 - (C) The control limit shall be set at an RPD of 67%.
 - (vii) If the plotted RPD result falls outside of the control limit, the measurements shall cease until the problem is identified and corrected.
 - (viii) If the plotted RPD result falls outside of the warning level, “Protocols for Radon and Radon Decay Product Measurements in Homes”,” EPA 402-R-92-003, May 1993, Appendix B, Exhibit B-5 shall be used to determine the action to be taken.
 - (ix) Documentation of duplicates must include the following:
 - (A) The device serial numbers.
 - (B) The exposure dates.
 - (C) Each duplicate measurement result.
 - (D) The RPD results.
- (5) *Electret voltage drift.* The tester shall maintain documentation that electret voltage drift testing has been performed as follows:

- (i) For each new shipment of 20 electrets or fewer, a minimum of 1 electret shall be set aside from each new shipment and evaluated for voltage drift.
- (ii) For each new shipment of more than 20 electrets, a minimum of 5% of the electrets or 10 electrets, whichever number is smaller, shall be evaluated for voltage drift.
- (iii) Electrets shall be covered with protective caps in a low-radon environment.
- (iv) For short-term and long-term electrets, an initial and a final voltage reading shall be made.
 - (A) For short-term electrets the final voltage reading shall be made at 4 weeks.
 - (B) For long-term electrets the final voltage reading shall be made at 3 months.
- (v) If the short-term voltage loss is greater than 6 volts per month or if the long-term voltage loss is greater than 12 volts over a 3-month period, testing with this shipment may not occur until the voltage loss is corrected.
- (vi) Documentation of electret voltage drift must include the following:
 - (A) Whether it is a short- or long-term electret.
 - (B) The date of receipt of the new shipment.
 - (C) The electret serial number.
 - (D) Initial voltages and dates.
 - (E) Final voltages and dates.
 - (F) The reader serial number.
 - (G) Corrective actions performed.

(6) *Voltmeter routine instrument checks.*

- (i) Proper operation of the surface voltmeter shall be monitored following the manufacturer's procedures for analyzing the reference electrets and zeroing the voltmeter.
- (ii) A voltage reading of a reference electret difference of more than 2 volts from the reference electret specified value shall be considered a wrong reading. The second reference electret in the set must be read to determine whether the wrong reading is in

the first reference electret or in the reader. Corrective action shall be taken in consultation with the manufacturer.

- (iii) When zeroing the reader, if the voltmeter displays more than (+/-) 3 volts, corrective action shall be taken in consultation with the manufacturer.
- (iv) Voltmeter checks shall be conducted at least once each week while the voltmeter is in use and shall be documented. Documentation of routine instrument checks must include the following:

- (A) The reader serial number.
- (B) The date of analysis.
- (C) Zero value.
- (D) The reference electret values.
- (E) Corrective actions performed.

§ 240.605. QA requirements for testing using secondary devices.

(a) *CRMs for secondary testers.*

- (1) *Calibration.* Each Department-listed CRM must have a current calibration. To have a current calibration, the CRM shall be calibrated in a Department-approved calibration facility within 1 year from the date of the previous calibration and when alterations or repairs are made to the CRM. A current calibration certificate shall be retained for each monitor.
- (2) *Check source counting.* For a CRM with a check source, check source counting shall be documented and completed with that check source prior to each test.
- (3) *Routine instrument checks.* Before and after each measurement, the CRM shall be checked according to the manufacturer's instructions. For each check, the following shall be verified:
 - (i) The correct input parameters and the unit's clock or timer are set properly.
 - (ii) The pump's flow rates are within the range of the manufacturer's specifications.
- (4) *Data collection log.*
 - (i) CRM data shall be tracked on a form that contains the following:
 - (A) The CRM serial number.

- (B) The exposure dates and times.
 - (C) The test result.
 - (D) The address of the building tested.
 - (E) The test location in the building.
 - (F) The name of the tester who placed the CRM.
 - (G) The name of the tester who retrieved the CRM.
 - (H) The calibration, repair and Department listing dates.
- (ii) For a CRM without a radioactive check source, the data collection log shall also contain the following intercomparison measurement information:
- (A) The intercomparison device serial number.
 - (B) The RPE value or RPD value.
 - (C) The intercomparison measurement result.
- (5) *Intercomparison measurements.* An intercomparison measurement shall be performed for each CRM without a radioactive check source.
- (i) Intercomparison measurements shall be made at least every 10th test with another Department-listed passive device that is analyzed by a Department-certified laboratory or with another CRM with a hard copy printout. The intercomparison measurements shall be distributed systematically throughout the entire population of test locations. Original printouts or Department- certified laboratory results, or both, shall be kept for each intercomparison. Each intercomparison measurement must be performed with the devices side by side for the measurement for at least 48 hours.
 - (ii) When performing intercomparison measurements, the RPD shall be used to track performance. The RPD value shall be tracked using control charts from "Protocols for Radon and Radon Decay Product Measurements in Homes," EPA 402-R-92-003, May 1993, Appendix B, Exhibit B-2 and Exhibit B-3.
 - (iii) If the RPD value exceeds the control limit, the CRM may not be used for radon measurements until the problem is identified and corrected. If the RPD value exceeds the warning level, the criteria in the "Protocols for Radon and Radon Decay Product Measurements in Homes," EPA 402-R-92-003, May 1993, Appendix B, Exhibit B-5, shall be followed.

(iv) In addition to the control charts, all intercomparison measurements shall be documented on the CRM data collection log.

(b) *CWLM for secondary testers.*

(1) *Calibration.* Each Department-listed CWLM must have a current calibration. To have a current calibration, the CWLM shall be calibrated in a Department-approved calibration facility within 1 year from the date of the previous calibration and when alterations or repairs are made to the CWLM. A current calibration certificate shall be retained for each monitor.

(2) *Data collection log.*

(i) CWLM data shall be tracked on a form that contains the following:

- (A) The CWLM serial number.
- (B) The exposure dates and times.
- (C) The test result.
- (D) The address of the building tested.
- (E) The test location in the building.
- (F) The name of the tester who placed the CWLM.
- (G) The name of the tester who retrieved the CWLM.
- (H) The calibration, repair and Department listing dates.

(ii) For CWLMs without a radioactive check source, the data collection log shall also contain the following intercomparison measurement information:

- (A) The intercomparison device serial number.
- (B) The RPD value.
- (C) The intercomparison measurement result.

(3) *Intercomparison measurements.* An intercomparison measurement shall be performed for all CWLM monitors without a radioactive check source.

(i) A CWLM without radioactive check source capability shall have an informal intercomparison measurement made with another CWLM with a hard copy printout at least every 10th test. This printout must be retained for each intercomparison. The

intercomparison measurements shall be distributed systematically throughout the entire population of test locations. Each intercomparison measurement must be performed with the devices side by side for the measurement for at least 48 hours.

- (ii) Each intercomparison shall be documented on the data collection log.
- (iii) When performing intercomparison measurements, the RPD shall be used to track performance. The RPD value shall be tracked using control charts from "Protocols for Radon and Radon Decay product measurements in Homes," EPA 402-R-92-003, May 1993, Appendix B, Exhibit B-2 and Exhibit B-3.
- (iv) If the RPD value exceeds the control limit, the CRM may not be used for radon measurements until the problem is identified and corrected. If the RPD value exceeds the warning level, the criteria in the "Protocols for Radon and Radon Decay Product Measurements in Homes," EPA 402-R-92-003, May 1993, Appendix B, Exhibit B-5, shall be followed.

(c) *Electret ion chambers for secondary testers.*

- (1) *Data collection log.* Electret data shall be tracked on a form that contains the following:
 - (i) The electret serial number.
 - (ii) The electret chamber serial number.
 - (iii) The initial voltage reading.
 - (iv) The final voltage reading.
 - (v) The exposure dates and times.
 - (vi) The test results.
 - (vii) The serial number of duplicate electret.
 - (viii) The RPD value.
 - (ix) The address of the building tested.
 - (x) The test location in the building.
 - (xi) The name of the tester who placed the electret.
 - (xii) The name of the tester who retrieved the electret.

- (2) *Known exposure measurements (spikes).*
- (i) Spikes shall be conducted at a rate of 3 for each 100 test devices deployed, with a minimum of 3 spikes for each certification year when tests were conducted in the certification year, and with a maximum of 6 spikes each month.
 - (ii) Spikes shall be submitted to a Department-certified laboratory labeled as QA. The reference value of the spiked device may not be revealed to the laboratory prior to analysis.
 - (iii) Spikes shall be monitored using a means control chart. The means control chart must be established as follows:
 - (A) Using an RPE value of plus and minus 10%, which corresponds to the 1 sigma level.
 - (B) A warning level of the RPE of plus and minus 20%, which corresponds to the 2 sigma warning level.
 - (C) Control limits of the RPE of plus and minus 30%, which correspond to the 3 sigma control level.
 - (iv) The control and warning levels identified in subparagraph (iii) shall be adjusted when the RPE of at least 20 spike results have been calculated. The standard deviation of the 20 or more RPE values shall also be calculated and the warning and control limits shall be re-established on new control charts.
 - (v) Each RPE value shall be plotted on the means control chart within 1 week of return of the device from the chamber. If the RPE value is outside the 3 sigma control level, all measurements shall cease until the problem is evaluated and corrected. All evaluations shall be documented.
 - (vi) In addition to the means control chart, all spikes shall be documented on a form that contains the following:
 - (A) The radon chamber name.
 - (B) The electret serial numbers.
 - (C) The electret chamber serial numbers.
 - (D) The reference value from radon chamber.
 - (E) The measured spike value or values.
 - (F) The individual RPE results.

- (G) The certification year beginning date and end date.
 - (H) The exposure dates.
- (3) *Duplicate measurements.*
- (i) Duplicates shall be made in at least 10% of the total number of test devices deployed each month, or 50 each month, whichever is smaller.
 - (ii) The RPD shall be calculated for all duplicate results with an average of greater than or equal to 2.0 pCi/L. Two control charts must be constructed to monitor duplicate precision:
 - (A) One for duplicates when the average is greater than or equal to 4.0 pCi/L.
 - (B) One for duplicates when the average is greater than or equal to 2.0 pCi/L and less than 4.0 pCi/L.
 - (iii) Each RPD value shall be plotted on the control chart within 1 week of performing the duplicate measurement.
 - (iv) The RPD shall be tracked using control charts from "Protocols for Radon and Radon Decay Product Measurements in Homes," EPA 402-R-92-003, May 1993, Appendix B, Exhibit B-2 and Exhibit B-3.
 - (v) For duplicates when the average is greater than or equal to 4.0 pCi/L, the following apply:
 - (A) The control level shall be set at an RPD of 14%.
 - (B) The warning level shall be set at an RPD of 28%.
 - (C) The control limit shall be set at an RPD of 36%.
 - (vi) For duplicates when the average is greater than or equal to 2.0 pCi/L and less than 4.0 pCi/L, the following apply:
 - (A) The control level shall be set at an RPD of 25%.
 - (B) The warning level shall be set at an RPD of 50%.
 - (C) The control limit shall be set at an RPD of 67%.
 - (vii) If the plotted RPD result falls outside of the control limit, the measurements shall cease until the problem is identified and corrected.

(viii) If the plotted RPD result falls outside of the warning level, "Protocols for Radon and Radon Decay Product Measurements in Homes," EPA 402-R-92-003, May 1993, Appendix B, Exhibit B-5 shall be used to determine the action to be taken.

(ix) Documentation of duplicates must include the following:

- (A) The device serial numbers.
- (B) The exposure dates.
- (C) Each duplicate measurement result.
- (D) The RPD results.

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

(1) *Data collection log.* Detector data shall be tracked on a form that contains the following:

- (i) The device serial number.
- (ii) The serial number of duplicate devices.
- (iii) The serial number of spiked devices.
- (iv) The exposure dates and times.
- (v) The test results.
- (vi) The RPE value or RPD value.
- (vii) The address of the building tested.
- (viii) The test location in the building.
- (ix) The name of the tester who placed the device.
- (x) The name of the tester who retrieved the device.
- (xi) The name of the laboratory to which device was sent.

(2) *Known exposure measurements (spikes).*

- (i) Spikes shall be conducted at a rate of 3 for each 100 test devices deployed, with a minimum of 3 spikes for each certification year when tests were conducted in the certification year, and with a maximum of 6 spikes each month.
- (ii) Spikes shall be submitted to a Department-certified laboratory labeled as QA. The reference value of the spiked device may not be revealed to the laboratory prior to analysis.
- (iii) Spikes shall be monitored using a means control chart. The means control chart must be established as follows:
 - (A) Using an RPE value of plus and minus 10%, which corresponds to the 1 sigma level.
 - (B) A warning level of the RPE of plus and minus 20%, which corresponds to the 2 sigma warning level.
 - (C) Control limits of the RPE of plus and minus 30%, which correspond to the 3 sigma control level.
- (iv) The control and warning levels identified in subparagraph (iii) shall be adjusted when the RPE of at least 20 spike results has been calculated. The standard deviation of the 20 or more RPE values shall also be calculated and the warning and control limits shall be re-established on new control charts.
- (v) Each RPE value shall be plotted on the means control chart within 1 week of receiving the result from the laboratory. If the RPE value is outside the 3 sigma control level, all measurements shall cease until the problem is evaluated and corrected. All evaluations shall be documented.
- (vi) In addition to the means control chart, all spikes shall be documented on a form that contains the following:
 - (A) The radon chamber name.
 - (B) The device serial numbers.
 - (C) The reference value from radon chamber.
 - (D) The measured spike value or values.
 - (E) The individual RPE results.
 - (F) The certification year beginning date and end date.
 - (G) The exposure dates.

(3) *Duplicate measurements.*

- (i) Duplicates shall be made in at least 10% of the total number of test devices deployed each month, or 50 each month, whichever is smaller.
- (ii) The RPD shall be calculated for all duplicate results with an average of greater than or equal to 2.0 pCi/L. Two control charts must be constructed to monitor duplicate precision:
 - (A) One for duplicates when the average is greater than or equal to 4.0 pCi/L.
 - (B) One for duplicates when the average is greater than or equal to 2.0 pCi/L and less than 4.0 pCi/L.
- (iii) Each RPD value shall be plotted on the control chart within 1 week of performing the duplicate measurement.
- (iv) The RPD shall be tracked using control charts from “Protocols for Radon and Radon Decay Product Measurements in Homes,” EPA 402-R-92-003, May 1993, Appendix B, Exhibit B-2 and Exhibit B-3.
- (v) For duplicates when the average is greater than or equal to 4.0 pCi/L, the following apply:
 - (A) The control level shall be set at an RPD of 14%.
 - (B) The warning level shall be set at an RPD of 28%.
 - (C) The control limit shall be set at an RPD of 36%.
- (vi) For duplicates when the average is greater than or equal to 2.0 pCi/L and less than 4.0 pCi/L, the following apply:
 - (A) The control level shall be set at an RPD of 25%.
 - (B) The warning level shall be set at an RPD of 50%.
 - (C) The control limit shall be set at an RPD of 67%.
- (vii) If the plotted RPD result falls outside of the control limit, the measurements shall cease until the problem is identified and corrected.
- (viii) If the plotted RPD result falls outside of the warning level, “Protocols for Radon and Radon Decay Product Measurements in Homes,” EPA 402-R-92-003, May 1993, Appendix B shall be used to determine the action to be taken.

(ix) Documentation of duplicates must include the following:

- (A) The device serial numbers.
- (B) The exposure dates.
- (C) Each duplicate measurement result.
- (D) The RPD results.

(4) *Field blanks.*

(i) Field blank results shall be monitored and recorded. Field blanks shall be performed at a rate of 5% of the devices that are deployed each month, or 25 each month, whichever is smaller, or a minimum of 1 per certification year, unless tests are not performed. These devices shall be set aside, kept in a low-radon environment and labeled as QA when submitted to the laboratory.

(ii) If a field blank has a concentration greater than the lowest level of detection (LLD) as established by the laboratory, the following shall occur:

- (A) The occurrence shall be documented and reported to the laboratory.
- (B) The cause shall be investigated in conjunction with the laboratory and documented.

(iii) Documentation of field blanks must include the following:

- (A) The device serial numbers.
- (B) The date submitted to laboratory.
- (C) The measurement results.
- (D) The laboratory's reported LLD.

§ 240.606. QA requirements for laboratories.

(a) *CRMs for laboratories.*

(1) *Calibration.* Each Department-listed CRM must have a current calibration. To have a current calibration, the CRM shall be calibrated in a Department-approved calibration facility within 1 year from the date of the previous calibration and when alterations or repairs are made to the CRM. A current calibration certificate shall be

retained for each monitor. Analysis may not be performed on a monitor that was not calibrated during any portion of the testing period.

(2) *Data collection log.* CRM data shall be tracked on a form that contains the following:

- (i) The CRM serial number.
- (ii) The exposure dates and times.
- (iii) The test result.
- (iv) The address of the building tested.
- (v) The test location in the building.
- (vi) The name of the tester who placed the CRM.
- (vii) The name of the tester who retrieved the CRM.
- (viii) The calibration, repair and Department listing dates.

(b) *CWLM for laboratories.*

(1) *Calibration.* Each Department-listed CWLM must have a current calibration. To have a current calibration, the CWLM shall be calibrated in a Department-approved calibration facility within 1 year from the date of the previous calibration and when alterations or repairs are made to the CWLM. A current calibration certificate shall be retained for each monitor. Analysis may not be performed on a monitor that was not calibrated during any portion of the testing period.

(2) *Data collection log.* CWLM data shall be tracked on a form that contains the following:

- (i) The CWLM serial number.
- (ii) The exposure dates and times.
- (iii) The test result.
- (iv) The address of the building tested.
- (v) The test location in the building.
- (vi) The name of the tester who placed the CWLM.

- (vii) The name of the tester who retrieved the CWLM.
- (viii) The calibration, repair and Department listing dates.

(c) *Electret ion chamber for laboratory analysis.*

(1) *Calibration.* Each Department-listed electret reader shall have a current calibration. To have a current calibration, the electret reader shall be calibrated in a Department-approved calibration facility within 1 year from the date of the previous calibration and when alterations or repairs are made to the electret reader. Each electret reader shall be calibrated simultaneously with its corresponding reference electret's recertification.

(2) *Voltmeter routine instrument checks.*

- (i) Proper operation of the surface voltmeter shall be monitored following the manufacturer's procedures for zeroing the voltmeter and analyzing the reference electrets.
- (ii) A voltage reading of a reference electret difference of more than 2 volts from its specified value shall be considered a wrong reading and corrective action shall be taken.
- (iii) If the voltmeter displays more than (+/-) 3 volts, corrective action shall be taken.
- (iv) Voltmeter checks shall be conducted at least once each week while the voltmeter is in use and shall be documented. Documentation of routine instrument checks must include the following:
 - (A) The reader serial number.
 - (B) The date of analysis.
 - (C) Zero value.
 - (D) The reference electret values.
 - (E) Corrective actions performed.

(3) *Known exposure measurements (spikes).*

- (i) Spikes shall be conducted at a rate of 3 for each 100 test devices deployed, with a minimum of 3 spikes for each certification year when tests were conducted in the certification year, and with a maximum of 6 spikes each month.
- (ii) Spikes shall be analyzed in the same manner as all other testing.

(iii) Spikes shall be monitored using a means control chart. The means control chart must be established as follows:

(A) Using an RPE value of plus and minus 10%, which corresponds to the 1 sigma level.

(B) A warning level of the RPE of plus and minus 20%, which corresponds to the 2 sigma warning level.

(C) Control limits of the RPE of plus and minus 30%, which correspond to the 3 sigma control level.

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

(v) Each RPE value shall be plotted on the means control chart within 1 week of return of the device from the radon chamber. If the RPE value is outside the 3 sigma control level, all measurements shall cease until the problem is evaluated and corrected. All evaluations shall be documented.

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

(A) The radon chamber name.

(B) The electret serial numbers.

(C) The reference value from the radon chamber.

(D) The measured spike value or values.

(E) The individual RPE results.

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

(G) The exposure dates.

(4) *Duplicate measurements.*

(i) Duplicates shall be made in at least 10% of the total number of test devices deployed each month, or 50 each month, whichever is smaller.

(ii) The RPD shall be calculated for all duplicate results with an average of greater than or equal to 2.0 pCi/L. Two control charts must be constructed to monitor duplicate precision:

- (A) One for duplicates when the average is greater than or equal to 4.0 pCi/L.
- (B) One for duplicates when the average is greater than or equal to 2.0 pCi/L and less than 4.0 pCi/L.

(iii) Each RPD value shall be plotted on the control chart within 1 week of performing the duplicate measurement.

(iv) The RPD shall be tracked using control charts from “Protocols for Radon and Radon Decay Product Measurements in Homes,” EPA 402-R-92-003, May 1993, Appendix B, Exhibit B-2 and Exhibit B-3.

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

- (A) The control level shall be set at an RPD of 14%.
- (B) The warning level shall be set at an RPD of 28%.
- (C) The control limit shall be set at an RPD of 36%.

(vi) For duplicates when the average is greater than or equal to 2.0 pCi/L and less than 4.0 pCi/L, the following apply:

- (A) The control level shall be set at an RPD of 25%.
- (B) The warning level shall be set at an RPD of 50%.
- (C) The control limit shall be set at an RPD of 67%.

(vii) If the plotted RPD result falls outside of the control limit, the measurements shall cease until the problem is identified and corrected.

(viii) If the plotted RPD result falls outside of the warning level, “Protocols for Radon and Radon Decay Product Measurements in Homes,” EPA 402-R-92-003, May 1993, Appendix B, Exhibit B-5 shall be used to determine the action to be taken.

(ix) Documentation of duplicates must include the following:

- (A) The device serial numbers.
- (B) The exposure dates.

- (C) Each duplicate measurement result.
 - (D) The RPD results.
- (5) *Electret voltage drift.*
- (i) For shipments of 20 electrets or fewer, a minimum of 1 electret shall be set aside from each new shipment and evaluated for voltage drift.
 - (ii) For shipments of more than 20 electrets, a minimum of 5% of the electrets or 10 electrets, whichever number is smaller, shall be evaluated for voltage drift.
 - (iii) Electrets shall be covered with protective caps in a low-radon environment.
 - (iv) For short-term and long-term electrets, an initial and a final voltage reading shall be made.
 - (A) For short-term electrets the final voltage reading shall be made at 4 weeks.
 - (B) For long-term electrets the final voltage reading shall be made at 3 months.
 - (v) If the short-term voltage loss is greater than 6 volts per month or if the long-term voltage loss is greater than 12 volts over a 3-month period, testing with this shipment may not occur until the voltage loss is corrected.
 - (vi) Documentation of electret voltage drift must include the following:
 - (A) Whether it is a short- or long-term electret.
 - (B) The date of receipt of the new shipment.
 - (C) The electret serial number.
 - (D) Initial voltages and dates.
 - (E) Final voltages and dates.
 - (F) The reader serial number.
 - (G) Corrective actions performed.
- (d) *AC and LS.*
- (1) *Calibration.* All AC or LS laboratory systems shall be calibrated at least once every 12 months, when alterations or repairs are made to the system, or when a new

batch of charcoal is received. This requires a determination of calibration factors for AC and LS devices by the exposure of these devices to a known concentration of radon in a DEP-approved radon chamber. Calibration factors shall be determined for a range of exposure times and humidity levels.

- (2) *Laboratory control devices.* The laboratory background level for each batch of AC/LS devices shall be established by each laboratory. Laboratories shall measure the background of at least 5% of unexposed AC and LS devices that have been processed according to their standard operating procedures (laboratory blanks).
- (3) *Routine counting system checks.* Daily counting of a reference source shall be performed and documented. The characteristics of the check source (geometry, type of radiation emitted, and the like) must be similar to the samples to be analyzed. The count rate of the check sources must be high enough to yield reliable counting statistics in a short period of time, such as 1,000 to 10,000 counts per minute, to provide a maximum random uncertainty of 5%.
- (4) *Known exposure measurements (spikes).*
 - (i) Spikes shall be conducted at a rate of 3 for each 100 test devices deployed, with a minimum of 3 spikes for each certification year when tests were conducted in the certification year, and with a maximum of 6 spikes each month.
 - (ii) Spikes shall be analyzed in the same manner as all other testing.
 - (iii) Spikes shall be monitored using a means control chart. The means control chart must be established as follows:
 - (A) Using an RPE value of plus and minus 10%, which corresponds to the 1 sigma level.
 - (B) A warning level of the RPE of plus and minus 20%, which corresponds to the 2 sigma warning level.
 - (C) Control limits of the RPE of plus and minus 30%, which correspond to the 3 sigma control level.
 - (iv) The control and warning levels identified in subparagraph (iii) shall be adjusted when the RPE of at least 20 spike results has been calculated. The standard deviation of the 20 or more RPE values shall also be calculated and the warning and control limits shall be re-established on new control charts.
 - (v) Each RPE value shall be plotted on the means control chart within 1 week of receiving the result from the laboratory. If the RPE value is outside the 3 sigma control level, all measurements shall cease until the problem is evaluated and corrected. All evaluations shall be documented.

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

- (A) The radon chamber name.
- (B) The device serial numbers.
- (C) The reference value from the radon chamber.
- (D) The measured spike value or values.
- (E) The individual RPE results.
- (F) The certification year beginning date and end date.
- (G) The exposure dates.

(5) *Duplicate measurements.*

- (i) Duplicates shall be made in at least 10% of the total number of test devices deployed each month, or 50 each month, whichever is smaller.
- (ii) The RPD shall be calculated for all duplicate results with an average of greater than or equal to 2.0 pCi/L. Two control charts must be constructed to monitor duplicate precision:
 - (A) One for duplicates when the average is greater than or equal to 4.0 pCi/L.
 - (B) One for duplicates when the average is greater than or equal to 2.0 pCi/L and less than 4.0 pCi/L.
- (iii) Each RPD value shall be plotted on the control chart within 1 week of performing the duplicate measurement.
- (iv) The RPD shall be tracked using control charts from "Protocols for Radon and Radon Decay Product Measurements in Homes," EPA 402-R-92-003, May 1993, Appendix B, Exhibit B-2 and Exhibit B-3.
- (v) For duplicates when the average is greater than or equal to 4.0 pCi/L, the following apply:
 - (A) The control level shall be set at an RPD of 14%.
 - (B) The warning level shall be set at an RPD of 28%.

(C) The control limit shall be set at an RPD of 36%.

(vi) For duplicates when the average is greater than or equal to 2.0 pCi/L and less than 4.0 pCi/L, the following apply:

(A) The control level shall be set at an RPD of 25%.

(B) The warning level shall be set at an RPD of 50%.

(C) The control limit shall be set at an RPD of 67%.

(vii) If the plotted RPD result falls outside of the control limit, the measurements shall cease until the problem is identified and corrected.

(viii) If the plotted RPD result falls outside of the warning level, "Protocols for Radon and Radon Decay Product Measurements in Homes," EPA 402-R-92-003, May 1993, Appendix B shall be used to determine the action to be taken.

(ix) Documentation of duplicates must include the following:

(A) The device serial numbers.

(B) The exposure dates.

(C) Each duplicate measurement result.

(D) The RPD results.

(e) *Alpha tracks.*

(1) *Calibration.* All AT laboratory systems shall be calibrated at least once every 12 months, when alterations or repairs are made to the system, or when each new batch or sheet of detector material is received. This requires a determination of calibration factors for AT devices by the exposure of these devices to different concentrations of radon in a DEP-approved radon chamber.

(2) *Laboratory control detectors.* Laboratory control detectors for each batch of ATs shall be established and documented. Each laboratory shall measure the background of a statistically significant number of unexposed ATs. The laboratory control background value shall be subtracted from the field readings to produce a final result.

(3) *Known exposure measurements (spikes).*

(i) Spikes shall be conducted at a rate of 3 for each 100 test devices deployed, with a minimum of 3 spikes for each certification year when tests were conducted in the certification year, and with a maximum of 6 spikes each month.

(ii) Spikes shall be analyzed in the same manner as all other testing. The reference value of a spike may not be revealed to the laboratory prior to analysis.

(iii) Spikes shall be monitored using a means control chart. The means control chart must be established as follows:

(A) Using an RPE value of plus and minus 10%, which corresponds to the 1 sigma level.

(B) A warning level of the RPE of plus and minus 20%, which corresponds to the 2 sigma warning level.

(C) Control limits of the RPE of plus and minus 30%, which correspond to the 3 sigma control level.

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

(v) Each RPE value shall be plotted on the means control chart within 1 week of receiving the result from the laboratory. If the RPE value is outside the 3 sigma control level, all measurements shall cease until the problem is evaluated and corrected. All evaluations shall be documented.

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

(A) The radon chamber name.

(B) The device serial numbers.

(C) The reference value from radon chamber.

(D) The measured spike value or values.

(E) The individual RPE results.

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

(G) The exposure dates.

(4) *Duplicate measurements.*

- (i) Duplicates shall be made in at least 10% of the total number of test devices deployed each month, or 50 each month, whichever is smaller.
- (ii) The RPD shall be calculated for all duplicate results with an average of greater than or equal to 2.0 pCi/L. Two control charts must be constructed to monitor duplicate precision:
 - (A) One for duplicates when the average is greater than or equal to 4.0 pCi/L.
 - (B) One for duplicates when the average is greater than or equal to 2.0 pCi/L and less than 4.0 pCi/L.
- (iii) Each RPD value shall be plotted on the control chart within 1 week of performing the duplicate measurement.
- (iv) The RPD shall be tracked using control charts from “Protocols for Radon and Radon Decay Product Measurements in Homes,” EPA 402-R-92-003, May 1993, Appendix B, Exhibit B-2 and Exhibit B-3.
- (v) For duplicates when the average is greater than or equal to 4.0 pCi/L, the following apply:
 - (A) The control level shall be set at an RPD of 14%.
 - (B) The warning level shall be set at an RPD of 28%.
 - (C) The control limit shall be set at an RPD of 36%.
- (vi) For duplicates when the average is greater than or equal to 2.0 pCi/L and less than 4.0 pCi/L, the following apply:
 - (A) The control level shall be set at an RPD of 25%.
 - (B) The warning level shall be set at an RPD of 50%.
 - (C) The control limit shall be set at an RPD of 67%.
- (vii) If the plotted RPD result falls outside of the control limit, the measurements shall cease until the problem is identified and corrected.
- (viii) If the plotted RPD result falls outside of the warning level, “Protocols for Radon and Radon Decay Product Measurements in Homes,” EPA 402-R-92-003, May 1993, Appendix B, Exhibit B-5 shall be used to determine the action to be taken.
- (ix) Documentation of duplicates shall include the following:

- (A) The device serial numbers.
- (B) The exposure dates.
- (C) Each duplicate measurement result.
- (D) The RPD results.

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

Appendix B

Non-interference Agreement for Real Estate Radon Testing

Property name:

Property address:

Property city, state, zip:

Dates of test:

I hereby agree to abide by the following conditions to ensure a valid radon test result:

- 1) I will maintain closed-house conditions during the entire test period, and for 12 hours prior to any test of less than 96 hours, by doing the following:
 - Continuing normal operation of permanently installed HVAC systems.
 - Minimizing operation of dryers, range hoods, bathroom fans and other mechanical systems, understanding that drawing air out of the building may adversely affect the test results.
 - In buildings having permanently installed radon mitigation systems, keeping the mitigation system functioning during the testing interval.
 - Operating window air conditioning systems if set to recycle interior air.
 - Keeping all windows closed.
 - Keeping all external doors closed except for normal entry and exit.
 - Not operating whole-house fans. Removing portable window fans from the window or covering and sealing the window fan.
 - Not operating fireplaces, wood/coal stoves or combustion appliances, except water heaters and cooking appliances, unless they are the primary sources of heat for the building.
 - Not operating ceiling fans, portable dehumidifiers, portable humidifiers, portable air filters and window air conditioners within 20 feet of the detector.
- 2) I will not interfere with or move the radon test device.

If the certified tester determines that these conditions were not maintained, this test will be deemed invalid.

Signature of Person
in Control of Property

Printed Name of Person
in Control of Property

Date

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

Appendix C

Radon Exposure Tracking Record

Name _____ Month(s) _____

Company Name _____

Employee ID Number _____ Year _____

1. Based upon an annual recommended health and safety limit of 4 working level months (4 WLM)
 2. Highest Premitigation Level (a) or On-site Measurement (b)

WL = (pCi/L)/200 (assuming 50% ER)