Regulatory Analysis Form

(Completed by Promulgating Agency)

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

INDEPENDENT REGULATORY REVIEW COMMISSION

(1) Agency

Department of Environmental Protection

(2) Agency Number:

Identification Number: 7-499

IRRC Number:

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

(4) Short Title: Radiological Health Revisions

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

Primary Contact: Laura Edinger, 783-8727, ledinger@pa.gov
Secondary Contact: Jessica Shirley, 783-8727, jesshirley@pa.gov

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

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

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

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

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

The proposed amendments are based on standards set by the current recognized accrediting bodies and national organizations such as the National Council on Radiation Protection and Measurements (NCRP) and the Conference of Radiation Control Program Directors (CRCPD).

The radon certification regulations were first promulgated in 1991 and, other than minor amendments in 2004, 2008, and 2009, have not been significantly revised since that time. The proposed rulemaking would revise the radon certification application requirements and the reporting requirements for certified radon service providers to add clarity to both processes. The amendments to the testing and mitigation protocol requirements and the quality assurance and quality control requirements would provide greater detail regarding how these programs should be designed and what goals they should accomplish.

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

The proposed amendments to Chapters 215-221, 223, 225, 227, 228, and 230 are authorized under the following:

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

The proposed amendments to Chapter 240 are authorized under the following:

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

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

This regulation is not mandated by any federal or state law or court order, or federal regulation, and there are no relevant state or federal court decisions.

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

See response to #7 above. The proposed rulemaking provides an opportunity to further clarify and fortify requirements in the regulations, most notably requirements for computed tomography, fluoroscopy and emerging technology systems, as well as radon certification.

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

The regulated community and all citizens of the Commonwealth will benefit from these proposed regulations. For example, the approximate 5,500 dentists, 230 hospitals, 860 clinics, 750 chiropractors, 490 podiatrists, registered with the Department performing, at a minimum, 10 scans per day results in millions of scans being done annually.

The proposed amendments to the radon certification regulations add clarity to the application and reporting requirements, making it easier for the regulated community to understand what is required during each process. The amendments to the testing and mitigation protocols and quality assurance and quality control requirements ensure that the radon services provided to the public will protect the public's health and welfare from the dangers of radon. The quality assurance and quality control requirements being proposed also benefit the regulated community by eliminating certain equipment check requirements when the equipment is not used. It also removes cross checks and duplicate tests for

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

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

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

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

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

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

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

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

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

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

Section 306. Conflicting laws.

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

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

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

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

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

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

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

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

A small number of registrants will be affected by being required to use a qualified medical physicist, as newly defined in the regulatory amendments. The majority of registrants already employ the services of a qualified medical physicist. All registrants and licensees will be affected by the requirement to have a

written directive (prescription) by a licensed physician before the administration of any radiation source. Many of the requirements in the proposed rulemaking reflect current industry practices, as discovered through Department inspections and through conversation with the RPAC members, and therefore are not expected to impose additional requirements on the regulated community.

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

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

Currently, there exist approximately 11,000 X-ray machine registrants, 825 radioactive material licensees, 150 accelerator licensees, 325 X-ray service providers and about 600 entities performing certified radon activities that would be required to comply with the proposed regulations. All future registrants, licensees, and certified radon service providers will also be required to comply.

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

Benefits

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

The benefits of the proposed radon certification amendments include adding clarity to the application and reporting requirements, making it easier for the regulated community to understand what is required during each process. The benefits of the amendments to the testing and mitigation protocols and quality assurance and quality control requirements include ensuring that radon services provided to the public will protect the public's health and welfare from the dangers of radon. The U.S. EPA as well as other national and international health and radiation safety organizations have declared radon to be the second leading cause of lung cancer after smoking, and the leading cause of lung cancer in non-smokers. Pennsylvania residents are at particular risk since the radon levels in this state are much more significant than most other parts of the country. The quality assurance and quality control requirements being proposed also benefit the regulated community by eliminating certain equipment check requirements when the equipment is not used and by removing cross checks and duplicate tests for testers who use continuous monitors and continuous working level monitors. The proposed amendment to eliminate the requirement to have one year of radon testing experience prior to certification would benefit the regulated community by simplifying and shortening the process for an individual to become certified to

test for radon. All PA residents who have tested their homes for radon and subsequently taken action to reduce those high levels via a certified radon mitigation contractor will benefit from continued strong regulatory oversight of the radon industry, by assuring that testing is done properly and that mitigation systems are installed according to Department standards. The consumer of these services benefits by having improved indoor air quality, with reduced exposure to this radioactive gas.

Financial, Economic, and Social Impacts

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

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

Radon Certification

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

The proposed amendments, which would require certified firms to employ one certified individual per five firm employees, may increase costs for the regulated community. This amendment would benefit the public by protecting public health and welfare from the dangers of radon, because it would ensure that uncertified firm employees are being adequately supervised by the firm's certified individuals. This amendment may cost a certified firm an additional $300 (for mitigation individuals) or $350 (for testing

individuals) every two years for each additional certified individual they are required to employ. *See* 25 Pa. Code Chapter 240 Appendix A (relating to Radon Certification Fee Schedule).

There are no social impacts associated with the proposed rulemaking.

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

There are no adverse effects associated with the proposed rulemaking.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

	Current FY 2015/16	FY +1 2016/17	FY +2 2017/18	FY +3 2018/19	FY +4 2019/20	FY +5 2020/21
SAVINGS:	**$**	**$**	**$**	**$**	**$**	**$**
Regulated Community	0	0	0	0	0	0
Local Government	0	0	0	0	0	0
State Government	0	0	0	0	0	0
Total Savings	0	0	0	0	0	0
COSTS:						
Regulated Community	$40,500	$33,300	$40,500	$33,300	$40,500	$33,300
Local Government	0	0	$0	0	$0	0
State Government	0	0	0	0	0	0
Total Costs	$40,500	$33,300	$40,500	$33,300	$40,500	$33,300
REVENUE LOSSES:						
Regulated Community	0	0	0	0	0	0
Local Government	0	0	0	0	0	0
State Government	0	0	0	0	0	0
Total Revenue Losses	0	0	0	0	0	0

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

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

Program	FY -3 2013/2014	FY -2 2014/2015	FY -1 2015/2016	Current FY 2016/2017
Radiation Protection Fund	$11,113,000	$11,018,000	$13,044,000	$14,953,000

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

- **(a) An identification and estimate of the number of small businesses subject to the regulation.**
- **(b) The projected reporting, recordkeeping and other administrative costs required for compliance with the proposed regulation, including the type of professional skills necessary for preparation of the report or record.**
- **(c) A statement of probable effect on impacted small businesses.**
- **(d) A description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation.**

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

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

> For example, the costs for a hypothetical firm with one certified individual and five employees would be $1,150 for the firm plus $400 for the employees, or $1,540. The cost for the same scenario above, but each individually certified, would be $350 per individual multiplied by six individuals, or $2,100. These cost analyses do not include course work and exams which would be more costly for all employees being individually certified.

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

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

No special provisions needed to be developed.

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

No alternative regulatory provisions have been considered or rejected for the radiological health amendments since the majority of the amendments are current industry radiation protection practices and are based on suggested state regulations (SSRs).

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

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

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

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

Performance standards for small businesses were not considered to replace design or operation standards required by the proposed rulemaking because the risk level remains the same for small businesses who operate radiation-producing machines or small businesses who perform radon services. The exemption of small businesses from all or any part of the requirements contained in the proposed rulemaking was also not considered for this same reason.

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

The primary intention of the radon certification regulations is stated in the Act (Act 1987-43), "… to protect property owners from unqualified or unscrupulous consultants and firms by requiring the Department of Environmental Resources to establish and carry out a program of certification of persons who perform radon progeny testing or carry out remedial radon measures". All data is subsequent to this primary intent. Radon testing and mitigation data is generated by the radon industry and that data is reported to the Department and stored in a DEP Oracle database that is only accessible to authorized persons. Radon test records are confidential per the Radon Certification Act (Act 43), Section 9 (Confidentiality of Data). These amendments are also based on DEP's expertise and experience.

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

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

Pennsylvania also has about 6,000 test results greater than 100 pCi/L, which is 25 times greater than the U.S. EPA guideline of 4 pCi/L.
This radon test data supports the continued need for a strong regulatory arm to assure that testing and mitigation are being performed accurately and appropriately.

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

A. The date by which the agency must receive public comments: Quarter 1, 2017

B. The date or dates on which public meetings or hearings will be held: N/A

C. The expected date of promulgation of the proposed regulation as a final-form regulation: Quarter 4, 2017

D. The expected effective date of the final-form regulation: Quarter 4, 2017

E. The date by which compliance with the final-form regulation will be required: Quarter 4, 2017

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

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

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