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):**

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

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

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

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

The Environmental Quality Board (Board) last updated its radiological health regulations in 2009. Significant technological advances in the use of radiation sources prompted the need to amend the regulations to establish and maintain adequate radiation protection standards and oversight.

This final-form rulemaking clarifies the radon certification application and reporting requirements for certified radon service providers. The amendments to the testing and mitigation protocol requirements and the quality assurance and quality control requirements will provide greater detail regarding the goals and designs these programs.

(8) **State the statutory authority for the regulation. Include <u>specific</u> statutory citation.**

The amendments to Chapters 215-221, 223-228, 230 and 232 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 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. These regulations are necessitated by technologic advances and practical needs to protect public health and safety. 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.

Radiological Health

This final-form rulemaking clarifies and strengthens requirements, most notably for computed tomography, fluoroscopy and emerging technology systems. Requirements for a new technology, electronic brachytherapy, were added to the regulations. Electronic brachytherapy requires licensure rather than registration due to the higher energies produced. Existing practices required by other sources and contained in long-standing guidance documents are now included.

In general, this rulemaking embodies the theory that regulatory clarity and codification of best practices can improve the quality of services to the public. The industry had moved ahead of the Commonwealth regulations in technology and safety. The Department engaged with the business community, learned about practices that had already become standard, and is codifying them in this final-form rulemaking. This process ensures that the requirements are made known to the industry. Some requirements are already required of operators by insurance companies (including Medicare and Medicaid), and most others are standards from national organizations, such as the Joint Commission, or are contained in existing technical guidance documents.

These standards include equipment checks, quality control, continuing education, and the requirement that businesses utilize a qualified medical physicist. As explained above, these requirements are already commonplace. Continuing education can be performed by the firm's own employees and is in many cases available for free. Businesses who would need a qualified medical physicist already employ at least one individual with the necessary qualifications due to existing requirements from the entities listed above.

As set forth in this final-form rulemaking, users of radiation sources will be required to comply with radiation protection standards that will protect and benefit employees and the public. This final-form rulemaking will ensure that trained professionals are operating 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 this final-form rulemaking. For example, the approximately 5,500 dentists, 230 hospitals, 860 clinics, 750 chiropractors, 490 podiatrists, registered with the Department that perform, at a minimum, 10 scans per day resulting in millions of scans annually, will be required to establish and maintain appropriate radiation protection standards and oversight.

Radon

The 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 public health and welfare from the dangers of radon. The quality assurance and quality control requirement amendments benefit the regulated community by eliminating certain equipment check requirements when the equipment is not used. These amendments also remove cross-checks and duplicate tests for testers who use continuous monitors and continuous working level monitors. This final-form rulemaking will eliminate the requirement to have one year of radon testing experience prior to certification as a radon tester. This amendment will benefit the regulated community by simplifying and shortening the process for an individual to become certified to test for radon.

The U.S. Environmental Protection Agency (EPA) and 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 because the radon levels in Pennsylvania are much more significant than in most other parts of the country.

All Pennsylvania residents, including those who have tested their homes for radon and subsequently taken action to reduce high levels with a certified radon mitigation contractor, will benefit from this final-form rulemaking that assures that radon testing is done properly and that radon mitigation systems are installed according to Department standards.

(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?**

Radiological Health

Instead, this final-form rulemaking will allow better protection during medical procedures involving radiation exposure.

Radon

This final-form rulemaking will not put the Commonwealth at a competitive disadvantage. Regarding radon amendments, Pennsylvania has a wide geographic distribution of radon occurrence, and great potential for radon exposure given a population of 12.5 million. Recently a private home in Pennsylvania was measured with the highest radon value recorded in the world at 6,176 picocuries per liter (pCi/L). This value is over 900 times greater than the EPA guideline value of 4 pCi/L. Nine other states have similar licensing or certification programs for radon testing, mitigation, and laboratory analysis.

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

The Department of Health (DOH) has regulations regarding radiation sources in 28 Pa. Code Chapters 51, 127, and 565 (relating to general information; radiology services; and laboratory and radiology services) that could be affected by this rulemaking. DOH is currently working on a regulatory update. DEP and DOH have held several meetings and have been working together to ensure DOH's regulations are consistent with DEP's regulations.

No other state regulations will be affected by Chapter 240.

(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.)**

This final-form rulemaking was reviewed by the Department's Radiation Protection Advisory Committee (RPAC). The committee represents various stakeholders, including radioactive materials licensees, radiation-producing machine registrants and radon service providers, as well as the general public. In addition, the RPAC formed a Radon Subcommittee, comprised of a mitigator, manufacturer and laboratory representative and led by the radon representative of RPAC, to review the Chapter 240 amendments. The Department presented the draft final regulations and a summary of the comments received on the proposed rulemaking to the RPAC on October 19, 2017. RPAC endorsed moving forward with this final-form rulemaking.

The proposed rulemaking was approved by the EQB on October 18, 2016, and published in the *Pennsylvania Bulletin* on May 13, 2017, with a 45-day public comment period. A webinar was presented for the proposed radiation-producing machines and radiation source regulations on May 31, 2017. Another webinar was presented for the radon certification regulation on May 31, 2017. The Board received comments from 23 commentators during the public comment period and the Independent Regulatory Review Commission (IRRC). These comments were considered and are addressed in the comment and response document that accompanies this final-form rulemaking.

(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?**

See response to #10 above.

This final-form rulemaking affects approximately 11,000 X-ray machine registrants, 825 radioactive material licensees, 150 accelerator licensees, 325 X-ray service providers and 600 entities performing certified radon activities. While the Department does not collect information regarding the size of each business that is an X-ray registrant, licensee, or service provider, the Department considered the vast majority of these entities to be small businesses for the purpose of this rulemaking. All entities performing certified radon activities are considered small businesses for the purposes of this rulemaking.

Radiological Health

A small number of registrants will be affected by the requirement to use a qualified medical physicist, as newly defined in the regulatory amendments. Most 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.

As noted in #10 above, many of the requirements in the final-form rulemaking reflect current industry practice, as discovered through Department inspections and through conversation with industry members. Therefore, these amendments are not expected to impose additional burdens on the regulated community.

Requirements were added for a new technology: electronic brachytherapy. Electronic brachytherapy requires licensure rather than registration because the Department requires designation of a radiation safety officer, as well as a medical physicist and an authorized user, because of the high dose that is administered directly on or near a tumor site during this procedure. Small businesses will not be exempt from any of these requirements because of the health and safety implications associated with the new provisions.

Radon

The general public and businesses could be affected by the radon regulations if they use or provide radon services. The radon amendments in Chapter 240 of this final-form rulemaking generally codify long-standing guidance documents published by DEP, EPA and national organizations, and are considered standard practice.

Added requirements in § 240.310(a)(7) and 310(a)(8) of this final-form rulemaking of two new American National Standards Institute/American Association of Radon Scientists and Technologists (ANSI/AARST) standards to address testing and mitigation of multifamily dwellings may add a small cost of purchasing the standards. Following these standards, however, will ensure more accurate testing and mitigation results to protect health and safety. Documentation requirements added in §§ 240.102(b)(6)(iii) and 112(b)(6)(iii) of this final-form rulemaking regarding initial and ongoing training of employees by the certified individual replaced the more restrictive and costly requirement that was proposed for employees to take an approved course or exam. The documentation requirement

to show how a certified individual will maintain oversight and responsibility of employees replaces the more restrictive and costly previously proposed requirement of limiting the number of firm employees.

Other radon amendments in this final-form rulemaking will reduce the burden on businesses in both paperwork and operations, such as eliminating unnecessary equipment checks and eliminating the requirement to test before mitigation. Benefits to the public include greater consistency in the services provided and improved indoor air quality with subsequent health benefits.

(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 600 entities providing certified radon services that will be required to comply with this final-form rulemaking. X-ray machine registrants include small medical and dental offices and large hospitals. Certified radon service providers include individuals and firms perform radon testing, mitigation, and laboratory analysis. All future registrants, licensees and certified radon service providers must also 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.**

Radiological Health

The benefit of the amendments to the radiological health regulations in this final-form rulemaking include the requirement for users of radiation sources to comply with radiation protection standards that will protect employees and the general public. This final-form rulemaking will ensure that trained professionals are operating these radiation sources so that both the patient and the operator are appropriately protected from the harmful effects of overexposure to radiation.

Other than new license fees in § 218.11(i) for electronic brachytherapy devices and § 218.11(j) for emerging technology devices, which the Department has assessed administratively since 2009 and now codifies in regulation, there are no changes to the fee schedules in Chapter 218 and Chapter 240, Appendix A, in this final-form rulemaking. The annual fee for electronic brachytherapy devices is $1,000 for the first unit (controller) at the facility plus $100 for each additional unit at the facility. Because this fee is existing practice, regulated entities will not experience any additional costs as a result of this final-form rulemaking. As noted in the answers to #10 and #15 above, the requirements for equipment checks, quality control, continuing education and the employment of a qualified medical physicist are already considered standard practice by the industry. Minor costs may be experienced if businesses are not following these standards, but the Department does not foresee this occurring. For example, many of the continuing education requirements can be satisfied through free courses.

Radon Certification

The benefits of the radon certification amendments in this final-form rulemaking include added clarity to the application and reporting requirements, making it easier for the regulated community to understand what is required during each process. For example, if a person is certified as both a tester and a

laboratory, § 240.306 of the final-form rulemaking clarifies that 16 hours of continuing education are required instead of 32 hours. Applicants will no longer be required to repay fees to reinstate a withdrawn certification application; depending on the type of certification, these final-form amendments will save a firm or individual from $450 to $1,125 for each certification. *See* 25 Pa. Code Chapter 240 Appendix A (relating to radon certification fee schedule).

The benefits of the amendments to the testing and mitigation protocols and quality assurance and quality control requirements in this final-form rulemaking include greater detail regarding how these programs should be designed which ensures that radon services provided to the public will more consistently protect the public. The quality assurance and quality control amendments 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 amendment in §§ 240.102(b)(6)(iii) and 112(b)(6)(iii) of this final-form rulemaking to eliminate the requirement to have one year of radon testing experience prior to certification benefits the regulated community by simplifying and shortening the process for an individual to become certified to test for radon.

The language in §§ 240.102(b)(4) and 112(b)(5) of the proposed rulemaking that would have required certified firms to employ one certified individual per five firm employees was deleted in this final-form rulemaking. Therefore, there will be no cost increase associated with this as detailed in the proposed rulemaking. Under §§ 240.102(b)(6)(iii) and 112(b)(6)(iii), the firm's certified individual or a third party may train other employees and provide continuing education, avoiding a potentially large burden on small businesses to pay for outside training.

In terms of other financial impact, the radon regulations codify portions of Department guidance documents. The Department expects that these are already standard practice. Some minor business costs may be experienced if firms are not currently following these guidelines. For example, when testing multi-family buildings, the ANSI/AARST MAMF guidance "Radon Mitigation Standards for Multifamily Buildings" (adopted at the suggestion of public comment) recommends testing every occupied unit in contact with the ground, which might require more test kits than a tester currently uses. Again, the Department expects that these standards are already being followed.

The social impacts of the radon amendments are expected to be positive. 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. Residents of this Commonwealth are at particular risk because the radon levels in this Commonwealth are much more significant than in most other parts of the country. All Commonwealth residents who test their homes for radon and subsequently take action to reduce high levels through a certified radon mitigation contractor will benefit from this final-form rulemaking because this final-form rulemaking assures that testing is done properly and that mitigation systems are installed according to Department standards. The consumers of these services benefit by having improved indoor air quality with reduced exposure to this radioactive gas. Reducing the burdens on mitigators and improving regulatory clarity will ensure that these benefits are realized.

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

There are only minor potential adverse effects associated with this final-form rulemaking. As noted in the answers to questions #10, #15, and #17 above, both the radiological health and radon amendments in this final-form rulemaking codify practices that are understood to be standard in the industry. The radiological health requirements are already imposed by insurance companies or are standards from national organizations. The radon requirements are contained in guidance documents have been implemented successfully by the regulated community. Costs will only be experienced by firms or individuals not currently following industry standards.

The benefits of this final-form rulemaking include protecting employees and the general public by requiring compliance with current radiation protection standards. This final-form rulemaking will ensure that trained professionals are operating radiation sources so that both the patient and the operator are adequately protected. The radiological health updates are partly motivated by recent reported events involving injuries to patients from inadequately trained personnel. The regulations address this risk by codifying standard practices and thereby making them enforceable.

The benefits of the radon certification amendments in this final-form are predicated on the theory that regulatory clarity and codification of best practices can improve the quality of services to the public. The 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 amendments also reduce unnecessary equipment checks and reduce the work experience needed before certification. 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 more consistently protect public health and welfare from the dangers of radon.

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

In terms of costs, as noted in the responses to questions #10, #15, #17, and #18 above, the requirements of the final-form rulemaking are also typically imposed by other entities or are a codification of standards of national organizations and already considered standard practice. Therefore, no additional costs are associated with compliance for either radiological health or radon service providers.

In terms of savings, depending on the type of certification, the amendment in § 240.141 of the final-form rulemaking relating to reinstating a previously withdrawn radon certification application will save a firm or individual $450 to $1,125. (The certification fees are listed in Appendix A of Chapter 240, which has not been amended in this rulemaking). Other savings are less easily quantified, but nonetheless real: removing the requirement of one year's work experience before certification allows a firm to generate business more readily, and removing the requirements to check unused equipment and test for radon prior to mitigation allow a firm to maximize its work time and finish jobs more quickly. (Sections 240.102, 240.604(c)(2)(ii) and (c)(3)(v)(C) and 240.605(c)(1)(ii) and (c)(2)(v)(C) of the final-form rulemaking). See the answers to questions 15 through 18 above.

No legal, accounting or consulting procedures are required by the final-form rulemaking.

(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.**

Several sections of this final-form rulemaking will change various records retention requirements to five years as indicated in the proposed rulemaking. This change was suggested by the Radiation Protection Advisory Committee to promote consistency throughout the radiological health regulations. These records need not be in paper format and may be stored electronically.

This final-form rulemaking adds requirements in §§ 240.102(b)(6)(iii) and 240.112(b)(6)(iii) for certified radon firms and radon firm employees to document continuing education for firm employees. Continuing education records are required to be retained for 5 years. This documentation requirement was added to this final-form rulemaking in exchange for the proposed requirement to limit certified firms to 5 employees, which was aimed at addressing span of control issues and will allow the Department to ensure that certified individuals responsible for firm activities are adequately training firm employees. These records need not be in paper format and may be stored electronically.

Other than these requirements, no legal, accounting or consulting procedures, or additional reporting, recordkeeping or other paperwork are anticipated for implementation of this final-form rulemaking.

(22a) **Are forms required for implementation of the regulation?**

Yes.

(22b) **If forms are required for implementation of the regulation, attach copies of the forms here. If your agency uses electronic forms, provide links to each form or a detailed description of the information required to be reported. Failure to attach forms, provide links, or provide a detailed description of the information to be reported will constitute a faulty delivery of the regulation.**

See attached.

(23) **In the table below, provide an estimate of the fiscal savings and costs associated with**

implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years.

	Current FY 2016/17	FY +1 2017/18	FY +2 2018/19	FY +3 2019/20	FY +4 2020/21	FY +5 2021/22
SAVINGS:	**$**	**$**	**$**	**$**	**$**	**$**
Regulated Community	0	0	0	0	0	0
Local Government	0	0	0	0	0	0
State Government	0	0	0	0	0	0
Total Savings	0	0	0	0	0	0
COSTS:						
Regulated Community	0	0	0	0	0	0
Local Government	0	0	0	0	0	0
State Government	0	0	0	0	0	0
Total Costs	0	0	0	0	0	0
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 Commonwealth's 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 2014/15	FY -2 2015/16	FY -1 2016/17	Current FY 2017-18
Radiation Protection Fund	$11,018,000	$11,628,000	$12,934,000	$14,746,000

(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.

(a) Small businesses covered by the radiological health provisions in this final-form rulemaking include, for example, dentist offices and private medical practices. The exact number of small businesses is not known to the Department, but the Department considered the vast majority of these entities to be small businesses for the purpose of this rulemaking. Radon businesses are generally small businesses, and there are around 600 certified entities in Pennsylvania.

(b) Any additional reporting or recordkeeping required by this final-form rulemaking is already required by other sources such as insurance companies. These amendments merely match regulations to those practices. The radon certification amendments in this final-form rulemaking have reduced administrative costs in several ways, as described in the answer to #17, above.

(c) The radiological health provisions in this final-form rulemaking mainly codify standard industry practice and should have negligible effect on small businesses. Requirements were added for a new technology: electronic brachytherapy. Electronic brachytherapy requires licensure rather than registration because the Department requires designation of a radiation safety officer, as well as a medical physicist and an authorized user because of the high dose that is administered directly on or near a tumor site during this procedure. Because of the health and safety reasons for these requirements, small businesses will not be exempt from any of these requirements. The radon provisions either codify current practice (as embodied in long-standing guidance documents) or reduce operational burdens, such as by removing the requirement to test for radon before installing mitigation equipment and removing the requirement to check unused equipment. Radon businesses should therefore see the same or lower operational costs. See the responses#19 for further examples.

(d) The Department did not analyze alternatives because the objective was to protect public health from unsafe practices regarding radiation by codifying current practice.

(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 need to be developed. For the radiological health provisions, the requirements are either standard practice or added for emerging technologies. Radon businesses are generally small businesses, so the radon provisions were crafted with small businesses in mind.

(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 in this final-form rulemaking because the majority of the amendments are current radiation protection industry practices.

Likewise, for the final radon certification amendments, no alternative regulatory provisions have been considered or rejected because the amendments in this final-form rulemaking are current industry practices and clarifications of current regulations and standard protocols.

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

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

As explained in the response to #24 above, the requirements in this final-form rulemaking as applied to small businesses are either standard practices or added for emerging technologies to appropriately protect public health and safety.

(a) This final-form rulemaking generally reduces reporting requirements when compared to the current regulations.
(b) This final-form rulemaking does not impose new deadlines for compliance or reporting.
(c) The quality assurance and quality control provisions in this final-form rulemaking include greater detail in how these programs should be designed, which simplifies compliance. For radon businesses, which are generally small businesses, this final-form rulemaking removes the requirement that an employee must have one year of work experience before applying for certification. The number of hours of continuing education is clarified in this final-form rulemaking, which will save some firms 50% of their cost due to misinterpretation of the current regulation. The fee to reinstate a withdrawn radon certification application has been removed from this final-form rulemaking.
(d) No new design or operational standards are imposed by this final-form rulemaking, so the substitution of performance standards was not made for small businesses.

It was not necessary or appropriate to exempt small businesses from the requirements contained in the final-form rulemaking for the reasons given above.

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

Radon testing and mitigation data generated by the certified radon industry is reported to DEP 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). 63 P.S. § 2009.

To date, there are approximately 1.57 million radon test results and about 200,000 radon mitigations reported. The testing data highlights the severity of the impact of radon in this Commonwealth. Mitigation data shows that remedial measures are effective at reducing high radon levels.

In this Commonwealth, the average basement radon concentration is 7 pCi/L and the average first floor concentration is 3.5 pCi/L. The 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 for a Zone 1 is greater than 4 pCi/L). The EPA has designated 17 Pennsylvania counties as Zone 2, which is the intermediate designation (predicted average level for a Zone 2 county is 2 to 4 pCi/L), and only one 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 EPA's website, www.epa.gov.

Approximately 6,000 test results have been reported to the Department that are greater than 100 pCi/L, which is 25 times greater than the EPA guideline of 4 pCi/L.

This radon test data supports the continued need for regulations to assure that radon testing and mitigation are being performed accurately and appropriately.

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

A. The length of the public comment period: 45 days

B. The date or dates on which any public meetings or hearings will be held: Webinar – May 31, 2017

C. The expected date of delivery of this final-form regulation: Quarter 3, 2018

D. The expected effective date of this final-form regulation: Quarter 1, 2019

E. The expected date by which compliance with this final-form regulation will be required: Quarter 1, 2019

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

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

The Department will continue to work with RPAC and other stakeholders to evaluate the effectiveness of this final-form rulemaking after its implementation.