

<h1>Regulatory Analysis Form</h1> <p>(Completed by Promulgating Agency)</p> <p>(All Comments submitted on this regulation will appear on IRRC's website)</p>		<p>INDEPENDENT REGULATORY REVIEW COMMISSION</p>
<p>(1) Agency: Environmental Protection</p>		<p>IRRC Number:</p>
<p>(2) Agency Number: 7 Identification Number: 590</p>		
<p>(3) PA Code Cite: 25 Pa. Code Chapters 215, 217, 219, 220, and 230</p>		
<p>(4) Short Title: U.S. Nuclear Regulatory Commission Consistency Rule – Incorporation by Reference</p>		
<p>(5) Agency Contacts (List Telephone Number and Email Address): Primary Contact: Laura Griffin, 717-772-3277, laurgriffi@pa.gov Secondary Contact: Lauren Imgrund, 717-783-8727, limgrund@pa.gov</p>		
<p>(6) Type of Rulemaking (check applicable box):</p> <p><input type="checkbox"/> Proposed Regulation <input type="checkbox"/> Final Regulation <input checked="" type="checkbox"/> Final Omitted Regulation</p>	<p><input type="checkbox"/> Emergency Certification Regulation; <input type="checkbox"/> Certification by the Governor <input type="checkbox"/> Certification by the Attorney General</p>	
<p>(7) Briefly explain the regulation in clear and nontechnical language. (100 words or less)</p> <p>The Commonwealth and the United States Nuclear Regulatory Commission (NRC) entered into an agreement in 2008 in which the Commonwealth agreed to oversee and regulate most types of radioactive materials used in Pennsylvania. As part of that agreement, the Department of Environmental Protection's (Department) radioactive materials program must remain compatible with the NRC's radioactive materials program. The Commonwealth meets this requirement by incorporating the applicable NRC regulations by reference in the Department's regulations. The NRC recently identified provisions of the Federal regulations that should be excluded from the Department's regulations because the regulations can only be implemented by the NRC.</p>		
<p>(8) State the statutory authority for the regulation. Include <u>specific</u> statutory citation.</p> <p>This final-omitted rulemaking authorized under Section 301 of the Radiation Protection Act (RPA) (35 P.S. § 7110.301), which designates the Department as the agency of the Commonwealth responsible for regulation and control of radiation; Section 302 of the RPA (35 P.S. § 7110.302), which grants the Environmental Quality Board (Board) the authority to adopt rules and regulations to accomplish the purposes and carry out the provisions of the RPA; and Section 1920-A of the Administrative Code of 1929 (71 P.S. § 510-20), which grants the Board the authority to adopt rules and regulations for the proper performance of the work of the Department.</p> <p>Notice of proposed rulemaking is omitted under section 204 of the act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. §§ 1102—1208), referred to as the Commonwealth Documents Law (CDL) (45 P.S. §§ 1204). Under section 204(3) of the CDL (45 P.S. § 1204(3)), an agency may omit the notice of</p>		

proposed rulemaking if “the agency for good cause finds...that the [public notice and comment] procedures specified in sections 201 and 202 are in the circumstances impracticable, unnecessary, or contrary to the public interest.”

The amendments in this final-omitted rulemaking are necessary to exclude Federal provisions that the Department’s radioactive materials regulations categorically incorporate by reference, but the Department does not have the legal authority to enforce. The specific provisions that this final-omitted rulemaking addresses have never been enforced by the Department because the enforcement authority resides with the NRC. Review and consideration of public comments on the amendments are unnecessary and contrary to the public interest because public comments would delay the required clarification of the Department’s proper authority under Federal law. It is in the public interest to ensure that the Commonwealth’s regulations accurately reflect the Department’s authority in an expeditious manner so persons holding radioactive material licenses in this Commonwealth can clearly identify which agency, the Department or the NRC, has enforcement authority for specific radioactive materials regulations. Public comments could not alter the need for these amendments or the content of the amendments.

(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 final-omitted rulemaking is mandated by Federal law. Under 42 U.S.C. § 2021(d)(2) (regarding cooperation with States), the Commonwealth’s radioactive materials program is required to remain compatible with the NRC’s radioactive materials program.

(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.

The amendments in this final-omitted rulemaking are necessary for the Commonwealth’s radioactive materials program to remain compatible with the NRC’s program, because the citations to the Federal regulations that the Board is excluding can only be implemented by the NRC. If these amendments are not adopted, the Commonwealth will be at risk of losing the authority it assumed under a 2008 agreement with the NRC for the Department to regulate most types of radioactive materials used in the Commonwealth.

In 2008, the Commonwealth and the NRC entered into an agreement, in which the Commonwealth agreed to oversee and regulate most types of radioactive materials used in the Commonwealth. This agreement gave the Commonwealth status as an “Agreement State.” As part of that agreement, the Commonwealth’s radioactive materials program must remain compatible with the NRC’s radioactive materials program, under 42 U.S.C. § 2021(d)(2). The Commonwealth meets this requirement by incorporating the appropriate NRC regulations in Title 10 of the Code of Federal Regulations (10 CFR) by reference in 25 Pa. Code Part I, Subpart D, Article V (relating to radiological health). The NRC recently identified provisions of 10 CFR that should be excluded from the Commonwealth’s incorporation-by-reference in Chapters 215, 217, 219, 220, and 230.

These sections should have been excluded from the Commonwealth’s incorporation-by-reference of select Federal regulations in the 2008 rulemaking (38 Pa.B. 2243, May 17, 2008), which was promulgated to support the 2008 agreement with the NRC. A few examples of these regulations whose implementation is exclusive to the NRC are 10 CFR 19.14 (relating to presence of representatives of

licensees and regulated entities, and workers during inspections), 10 CFR 20.2203 (relating to reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits) and 10 CFR 70.82 (relating to suspension and operation in war or national emergency). The Department does not have the authority under the Agreement State program to implement these sections and has never enforced them. These amendments clarify the proper authority of the Department and the NRC under their respective regulations.

Finalizing these amendments without public notice and comment is in the public interest because it ensures that the Commonwealth's regulations accurately reflect the Department's authority in an expeditious manner. Likewise, finalizing these amendments without public notice and comment is in the interest of those holding radioactive material licenses in the Commonwealth because the amendments clarify the proper authority of the Department and the NRC under the agencies' respective radioactive materials programs. There are approximately 661 licensees in this Commonwealth.

The fundamental benefit of this final-omitted rulemaking is to ensure that the Commonwealth's regulations do not exceed the Department's authority and that they meet the requirements of the NRC's Agreement State program as required by Federal law. *See* 42 U.S.C. § 2021(d)(2).

(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 in this final-omitted rulemaking more stringent than the Federal standards. This action aligns the Commonwealth's regulations with the Federal program.

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

All Agreement States' radioactive materials programs are required to be compatible with the Federal standards, under 42 U.S.C. § 2021(d)(2). This final-omitted rulemaking allows the Commonwealth to maintain this fundamental and essential compatibility. Therefore, this regulation will not put the Commonwealth nor the radioactive materials licensees in this Commonwealth at a competitive disadvantage.

(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 regulations will be affected.

(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.)

The Department presented the draft final-omitted regulation to the Radiation Protection Advisory Committee (RPAC) at its April 30, 2025, meeting. At that meeting, the RPAC supported the Department's recommendation to move forward with this final-omitted 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?

None of the 661 radioactive materials licensees will be affected by this final-omitted rulemaking, except perhaps to provide clarity regarding the proper Department and NRC legal authority under the agencies' respective radioactive materials programs.

(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.

All radioactive materials licensees must comply with the Federal regulations incorporated by reference in Chapters 215-236. However, this final-omitted rulemaking does not add requirements. It clarifies the list of Federal regulations excluded from incorporation-by-reference because the Commonwealth does not have the authority to implement those regulations.

(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.

There are no financial, economic, or social impacts associated with this final-omitted rulemaking.

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

The fundamental benefit of this final-omitted rulemaking is ensuring that the Commonwealth's regulations meet the requirements of the NRC's Agreement State program as required by federal law. *See 42 U.S.C. § 2021(d)(2).* The Commonwealth will be at risk of losing the authority it assumed under the 2008 agreement to regulate most types of radioactive materials used in the Commonwealth if these amendments are not adopted. Noncompliance could result in suspension or termination of the Department's authority over radioactive materials. Licensees will gain the benefit of clarity regarding the proper Department and NRC legal authority under the agencies' respective radioactive materials programs.

There are no cost or adverse effects associated with this final-omitted rulemaking.

(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.

There are no costs or savings to the regulated community associated with compliance with this final-omitted 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 are no costs or savings to local governments associated with compliance with this final-omitted rulemaking.

(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 are no costs or savings to state government associated with implementation of this final-omitted rulemaking.

(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.

There are no legal, accounting, consulting, reporting, recordkeeping, or paperwork requirements needed to implement this regulation.

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

No forms are required.

(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.

No forms are required.

(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 Year	FY +1 Year	FY +2 Year	FY +3 Year	FY +4 Year	FY +5 Year
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 final-omitted rulemaking will have no effect on program expenditures.

Program	FY -3 2021/22	FY -2 2022/23	FY -1 2023/24	Current FY 2024/25
Radiation Protection Fund	\$12,140,000	\$12,460,000	\$14,917,000	\$15,278,000

(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.**

Not applicable. This final-omitted rulemaking will have no adverse impact on small businesses. No licensees, including small business licensees, will be affected by this final-omitted rulemaking, except by gaining the benefit of clarity regarding the proper Department and NRC legal authority under the agencies' respective radioactive materials programs. No reporting, recordkeeping or other administrative costs are associated with this final-omitted rulemaking. No less intrusive or less costly alternatives exist to achieve the purpose of this final-omitted rulemaking.

(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 are needed.

(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 because the regulatory changes are required for the Commonwealth to maintain its Agreement State status.

(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.**
- e) The exemption of small businesses from all or any part of the requirements contained in the regulation.**

This final-omitted rulemaking will not have any adverse impact on small businesses.

(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.

Data is not the basis for this regulation.

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

- A. The length of the public comment period:** Not Applicable
- B. The date or dates on which any public meetings or hearings will be held:** Not Applicable
- C. The expected date of delivery of the final-form regulation:** Quarter 3, 2025
- D. The expected effective date of the final-form regulation:** Upon publication in the Pennsylvania Bulletin
- E. The expected date by which compliance with the final-form regulation will be required:** Not Applicable
- F. The expected date by which required permits, licenses or other approvals must be obtained:** Not Applicable

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

An implementation and evaluation plan for this rulemaking is not necessary, as no change will occur once this rulemaking is effective. These amendments are needed for the Department to meet its obligations under Federal law.