

<h1 style="margin: 0;">Regulatory Analysis Form</h1> <p style="margin: 0;">(Completed by Promulgating Agency)</p>		<p><i>INDEPENDENT REGULATORY REVIEW COMMISSION</i></p>
<p>(All Comments submitted on this regulation will appear on IRRC's website)</p>		
<p>(1) Agency</p> <p>Department of Environmental Protection</p>		<p>IRRC Number:</p>
<p>(2) Agency Number:</p> <p>Identification Number: 7-550</p>		
<p>(3) PA Code Cite: 25 Pa. Code Part I, Subpart D, Article V. Radiological Health, Chapter 215 (General Provisions); Chapter 217 (Licensing of Radioactive Material); Chapter 230 (Packaging and Transportation of Radioactive Material); and Chapter 232 (Licenses and Radiation Safety Requirements for Irradiators). 25 Pa. Code §§ 215.1, 217.131, 217.151, 217.171, 217.181, 230.3, and 232.2.</p>		
<p>(4) Short Title: U.S. Nuclear Regulatory Commission (NRC) Consistency Rule</p>		
<p>(5) Agency Contacts (List Telephone Number and Email Address):</p> <p>Primary Contact: Laura Edinger, 783-8727, ledinger@pa.gov Secondary Contact: Jessica Shirley, 783-8727, jessshirley@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 NRC entered into an agreement in 2008 in which the Commonwealth agreed to oversee and regulate most types of radioactive materials used in the Commonwealth. As part of that agreement, the Commonwealth's radioactive materials program must remain compatible with NRC's radioactive materials program, under 42 U.S.C. § 2021(d)(2) (relating to cooperation with States). The Commonwealth meets this requirement by incorporating the appropriate NRC regulations 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 25 Pa. Code Chapters 215, 217, 230 and 232. These amendments are necessary for the Commonwealth to remain compatible with NRC's program, because the citations to 10 CFR that the Board is excluding 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 is being made under the following statutory authority: Section 301 of the Radiation Protection Act (RPA), 35 P.S. § 7110.301, which designates the Department of Environmental Protection (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</p>		

purposes and carry out the provisions of the RPA; and Section 510-20(b) of the Administrative Code (P.L. 177, No. 175), as amended, 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.

Notice of proposed rulemaking is omitted under section 204 of the Commonwealth Documents Law (CDL). 45 P.S. § 1204. Section 204(3) of the CDL provides that an agency may omit the notice of 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.” 45 P.S. § 1204(3). The amendments in this final-omitted rulemaking are necessary to exclude Federal provisions that purport to give the Department legal authority that it does not have. The specific provisions that this final-omitted rulemaking addresses have never been enforced by the Department because the enforcement authority resides with the Nuclear Regulatory Commission (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. Public comments could not alter the need to make these amendments and there is no need to alter the formatting 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), the Commonwealth’s radioactive materials program is required to remain compatible with 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 NRC’s program, because the citations to 10 CFR that the Board is eliminating 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 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 NRC’s radioactive materials program, under 42 U.S.C. § 2021(d)(2). The Commonwealth meets this requirement by incorporating the appropriate NRC regulations 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, 230 and 232.

The failure to exclude these sections from the Commonwealth’s incorporation-by-reference of select Federal regulations was a mistake in the 2008 rulemaking (38 Pa.B. 2243, May 17, 2008) promulgated to support the 2008 agreement with the NRC. Examples of Federal provisions excluded by these

amendments are: portions of the definitions of terms such as “construction” and “commencement of construction” dealing with national defense; provisions involving the sale and distribution of radioactive material in certain industrial devices across state lines; regulations concerning high concentration of radioactive source material or special nuclear material, such as uranium and plutonium; and provisions regarding the transportation and distribution of exempt consumer materials. 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.

In addition, the amendments add an exception regarding notifications, reports and correspondence to be directed to the Department.

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 825 licensees in this Commonwealth.

The fundamental benefit of this final-omitted rulemaking is ensuring that the Commonwealth’s regulations do not exceed the Department’s authority and that they meet the requirements of 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 is aligning 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 this 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 discussed the need for regulatory revisions with its Radiation Protection Advisory Committee (RPAC) at RPAC’s October 19, 2017 meeting. At that meeting, RPAC endorsed moving 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?

No 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, 217, 230, and 232. 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 the 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 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. 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 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 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 will be 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 will be 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 requirements for any group or entity identified in items (19) - (21), above, resulting from this final-omitted rulemaking.

(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.

Not applicable.

(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 2017/18	FY +1 2018/19	FY +2 2019/20	FY +3 2020/21	FY +4 2021/22	FY +5 2022/23
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 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.**

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.

(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.

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 final-omitted rulemaking.

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

- A. The length of the public comment period: _____ N/A _____
- B. The date or dates on which any public meetings or hearings will be held: _____ N/A _____

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|---|------------------------|
| C. The expected date of delivery of the final-omitted regulation: | <u>Quarter 3, 2018</u> |
| D. The expected effective date of the final-omitted regulation: | <u>Quarter 3, 2018</u> |
| E. The expected date by which compliance with the final-omitted regulation will be required: | <u>Quarter 3, 2018</u> |
| F. The expected date by which required permits, licenses or other approvals must be obtained: | <u>N/A</u> |

(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.