

<h2 style="margin: 0;">Regulatory Analysis Form</h2> <p style="margin: 0;">(Completed by Promulgating Agency)</p> <p style="margin: 0; font-size: small;">(All Comments submitted on this regulation will appear on IRRC's website)</p>	<p style="margin: 0;">INDEPENDENT REGULATORY REVIEW COMMISSION</p> <div style="border: 2px solid black; padding: 5px; width: fit-content; margin: 0 auto;"> <p style="margin: 0; font-size: 2em; font-weight: bold;">RECEIVED</p> <p style="margin: 5px 0 0 0;">JUL 16 2018</p> <p style="margin: 0; font-size: small;">Independent Regulatory Review Commission</p> </div> <p style="margin: 5px 0 0 0;">IRRC Number: 3208</p>
<p>(1) Agency</p> <p>Department of Environmental Protection</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</p> <p><input type="checkbox"/> Final Regulation</p> <p><input checked="" type="checkbox"/> Final Omitted Regulation</p>	<p><input type="checkbox"/> Emergency Certification Regulation;</p> <p><input type="checkbox"/> Certification by the Governor</p> <p><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

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.

FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE
BUREAU

(Pursuant to Commonwealth Documents Law)



DO NOT WRITE IN THIS SPACE

Copy below is hereby approved as to form and legality.
Attorney General

By: _____
(Deputy Attorney General)

DATE OF APPROVAL

Check if applicable
Copy not approved. Objections attached.

Copy below is hereby certified to be true and
correct copy of a document issued, prescribed or
promulgated by:

DEPARTMENT OF ENVIRONMENTAL
PROTECTION
ENVIRONMENTAL QUALITY BOARD

(AGENCY)

DOCUMENT/FISCAL NOTE NO. 7-550

DATE OF ADOPTION JUNE 19, 2018

BY

TITLE PATRICK MCDONNELL
CHAIRMAN

EXECUTIVE OFFICER CHAIRMAN OR SECRETARY

Copy below is hereby approved as to form and legality
Executive or Independent Agencies

BY
JUL 13 2018

DATE OF APPROVAL

(Deputy General Counsel)
(~~Chief Counsel - Independent Agency~~)
(Strike inapplicable title)

Check if applicable. No Attorney General Approval
or objection within 30 days after submission.

NOTICE OF FINAL-OMITTED RULEMAKING

DEPARTMENT OF ENVIRONMENTAL PROTECTION
ENVIRONMENTAL QUALITY BOARD

U.S. Nuclear Regulatory Commission (NRC) Consistency Rule

25 Pa. Code Chapters 215, 217, 230, and 232

**FINAL-OMITTED RULEMAKING
ENVIRONMENTAL QUALITY BOARD
[25 PA. CODE CHS. 215, 217, 230 AND 232]
U.S. Nuclear Regulatory Commission (NRC) Consistency Rule**

The Environmental Quality Board (Board) amends Chapters 215, 217, 230 and 232 to exclude specific provisions of Title 10, Section I (relating to Nuclear Regulatory Commission) of the Code of Federal Regulations (CFR) from incorporation-by-reference in these Chapters. These amendments are set forth in Annex A.

Notice of proposed rulemaking is omitted under section 204 of the act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. § 1204), known as the Commonwealth Documents Law (CDL). 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 of Environmental Protection (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. Finalizing these amendments without public notice and comment is in the public interest to ensure 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. No changes to any radioactive material license will result from this final-omitted rulemaking.

This final-omitted rulemaking was adopted by the Board at its meeting of June 19, 2018.

A. Effective Date

This final-omitted rulemaking will be effective upon publication in the *Pennsylvania Bulletin*.

B. Contact Persons

For further information, contact John Chipppo, Program Manager, Division of Radiation Control, P.O. Box 8469, Rachel Carson State Office Building, Harrisburg, PA 17105-8469, (717) 787-2480; or Keith Salador, Assistant Counsel, Bureau of Regulatory Counsel, P.O. Box 8464, Rachel Carson State Office Building, Harrisburg, PA 17105-8464, (717) 783-8075. Persons with a disability may use the AT&T Relay Service, (800) 654-5984 (TDD users) or (800) 654-5988

(voice users). This final-omitted rulemaking is available on the Department's website at www.dep.pa.gov (Select "Public Participation," then "Environmental Quality Board (EQB)").

C. Statutory Authority

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 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 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.

D. Background and Purpose

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. 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) (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 the Commonwealth's incorporation-by-reference in Chapters 215, 217, 230 and 232. These amendments 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 excluding can only be implemented by the NRC.

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 2008 agreement 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.

The Department presented this final-omitted rulemaking to the Radiation Protection Advisory Committee (RPAC) at its October 19, 2017 meeting. At that meeting, the RPAC recommended that DEP move forward with this final-omitted rulemaking.

E. Summary of the Final-Omitted Rulemaking

References to the provisions of Title 10 of the CFR that are now being eliminated from incorporation-by-reference in Chapters 215, 217, 230 and 232 in this final-omitted rulemaking are outlined, by section, in the table below:

25 Pa. Code Section Amended	10 CFR Provision Excluded from Incorporation-by-Reference
§§ 215.1(e)(3) and 217.131(b)	Paragraph 2 of the definition of “commencement of construction” and Paragraph 9(ii) of the definition of “construction” in § § 30.4
§§ 215.1(e)(5) and 217.151(b)	§§ 32.1(c)(1), 32.30, 32.31, and 32.32
§ 215.1(e)(9) and § 232.2(b)	Paragraph 2 of the definition of “commencement of construction” and Paragraph 9(ii) of the definition of “construction” in § 36.2
§ 215.1(e)(12)	§§ 40.13(c)(5)(iv), 40.52, 40.53, Part 40 Appendix A Criterion—11 A-F and Criterion—12, and Paragraph 2 of the definition of “commencement of construction” and Paragraph 9(ii) of the definition of “construction” in § 40.4.
§ 215.1(e)(13)	§§ 70.74, Part 70 Appendix A, and Paragraph 2 of the definition of “commencement of construction” and Paragraph 9(ii) of the definition of “construction” in § 70.4
§ 215.1(e)(14)	The definitions of “certificate holder” and “certificate of compliance (CoC)” in Section 71.4. The term “applicant” when used in 10 CFR Part 71.
§ 217.171(b)	§§40.13(c)(5)(iv), 40.52, 40.53, and Paragraph 2 of the definition of “commencement of construction” and Paragraph 9(ii) of the definition of “construction” in § 40.4
§ 217.181(b)	§§ 70.74, Part 70 Appendix A, and Paragraph 2 of the definition of “commencement of construction” and Paragraph 9(ii) of the definition of “construction” in § 70.4
§ 230.3(b)	The definitions of “certificate holder” and “certificate of compliance (CoC)” in § 71.4. The term “applicant” when used in 10 CFR Part 71.

In addition, this final-omitted rulemaking amends Section 215.1(h)(5) to add an exception in 10 CFR § 71.17(c)(3) (relating to general license: NRC-approved package) regarding notifications, reports and correspondence that would otherwise be directed to the Department.

F. Benefits, Costs and Compliance

Benefits

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). If these amendments are not adopted, the Commonwealth will be at risk of losing the authority it assumed as an Agreement State under the 2008 agreement to regulate most types of radioactive materials used in the Commonwealth.

Compliance Costs

The amendments will create no compliance costs. No additional financial, economic or social impact will result from these amendments.

Compliance Assistance Plan

No compliance assistance is necessary for implementation of this final-omitted rulemaking because the regulated community remains subject to the requirements deleted from the Commonwealth's regulations at the Federal level.

Paperwork Requirements

This final-omitted rulemaking will not revise paperwork requirements.

G. Pollution Prevention

Pollution prevention is not applicable to this rulemaking.

H. Sunset Review

The Board is not establishing a sunset date for these amended regulations because the amendments are needed for the regulations to accurately reflect the Department's legal authority and for the Department to meet its obligations under Federal law.

I. Regulatory Review

Under section 5.1(c) of the Regulatory Review Act (71 P. S. § 745.5a(c)), on July 16, 2018, the Department submitted a copy of this final-omitted rulemaking and a copy of the Regulatory Analysis Form to the Independent Regulatory Review Commission (IRRC) and the Chairpersons of the House and Senate Environmental Resources and Energy Committees. On the same date, this final-omitted rulemaking was submitted to the Office of Attorney General for review and approval under the Commonwealth Attorneys Act (71 P.S. §§ 732-101--732-506).

Under section 5.1(j.2) of the Regulatory Review Act, on _____, this final-omitted rulemaking was deemed approved by the House and Senate Committees. Under section 5.1(e) of the Regulatory Review Act, IRRC met on _____ and approved this final-omitted rulemaking.

J. Findings of the Board

The Board finds that:

- (1) The amendments as set forth in Annex A are appropriate to remain compatible with the requirements of the NRC's Agreement State program.
- (2) Use of the omission of notice of proposed rulemaking procedure is appropriate because the proposed rulemaking procedures specified in sections 201 and 202 of the CDL (45 P.S. §§1201 and 1202) are, in this instance, "impracticable, unnecessary, or contrary to the public interest."
- (3) No radioactive licensees are affected by this final-omitted rulemaking.
- (4) These amendments are necessary and appropriate for administration and enforcement of the authorizing acts identified in Section C of this order and are in the public interest.

K. Order of the Board

The Board, acting under the authorizing statutes, orders that:

- (a) The regulations of the Department, 25 Pa. Code Chapters 215, 217, 230, and 232, are amended to read as set forth in Annex A.
- (b) The Chairperson of the Board shall submit this order and Annex A to the Office of General Counsel and the Office of Attorney General for review and approval as to legality and form, as required by law.
- (c) The Chairperson of the Board shall submit this order and Annex A to IRRC and the Senate and House Environmental Resources and Energy Committees as required by the Regulatory Review Act (71 P.S. §§ 745.1—745.14).
- (d) The Chairperson of the Board shall certify this order and Annex A, as approved to legality and form, and deposit them with the Legislative Reference Bureau, as required by law.
- (e) This order shall take effect immediately upon publication in the *Pennsylvania Bulletin*.

PATRICK McDONNELL,
Chairperson

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

CHAPTER 215. GENERAL PROVISIONS

§ 215.1. Purpose and scope.

(a) This article establishes requirements for the protection of public health and safety as related to radiation sources and implements the requirements of the act.

(b) This article, except as otherwise specifically provided in the act, applies to persons who use, manufacture, produce, transport, transfer, receive, acquire, possess, own or dispose of a radiation source.

(c) A person who, when required, fails to register or obtain a license for radiation sources in the possession or control of the person, shall comply with the act or with this article.

(d) This article does not apply to the extent the person is subject to regulation by the NRC.

(e) Title 10 Chapter I (Nuclear Regulatory Commission) Parts 19, 20, 30, 31, 32, 33, 34, 35, 36, 37, 39, 40, 70, 71 and §§ 150.1, 150.2, 150.3, 150.11 and 150.20 of the CFR are incorporated by reference with the exceptions set forth in paragraphs (1)—(14). Notwithstanding the requirements incorporated by reference, nothing in this article relieves or limits a person from complying with the laws of the Commonwealth, including the act and the Low-Level Radioactive Waste Disposal Act (35 P. S. §§ 7130.101—7130.905).

(1) Sections 19.4, 19.5, 19.8, 19.30 and 19.40 are not incorporated.

(2) Sections 20.1006, 20.1009, 20.2206(a)(1), (3), (4) and (5), 20.2401 and 20.2402 are not incorporated.

(3) Sections 30.5, 30.6, 30.8, 30.21(c), 30.34(d) and (e)(1) and (3), 30.41(b)(6), 30.55, 30.63 and 30.64 are not incorporated. **Paragraph 2 of the definition of “commencement of construction” and Paragraph 9(ii) of the definition of “construction” in Section 30.4 are not incorporated.**

(4) Sections 31.4 and 31.14 are not incorporated.

(5) Sections **32.1(c)(1)**, 32.8, 32.14, 32.15, 32.16, 32.18, 32.19, 32.20, 32.21, 32.22, 32.23, 32.25, 32.26, 32.27, 32.28, 32.29, **32.30, 32.31, 32.32** and 32.40 are not incorporated.

(6) Sections 33.8, 33.21 and 33.23 are not incorporated.

(7) Sections 34.5, 34.8, 34.121 and 34.123 are not incorporated.

(8) Sections 35.8, 35.4001 and 35.4002 are not incorporated.

(9) Sections 36.5, 36.8, 36.91 and 36.93 are not incorporated. **Paragraph 2 of the definition of “commencement of construction” and Paragraph 9(ii) of the definition of “construction” in Section 36.2 are not incorporated.**

(10) Sections 37.3(b)(2), 37.13, 37.73(d) and (e), 37.107 and 37.109 are not incorporated.

(11) Sections 39.5, 39.8, 39.101 and 39.103 are not incorporated.

(12) Sections 40.6, 40.8, 40.12(b), **40.13(c)(5)(iv)**, 40.23, 40.27, 40.28, 40.31(k) and (i), 40.32(d), (e) and (g), 40.33, 40.38, 40.41(d), (e)(1) and (3) and (g), 40.51(b)(6), **40.52, 40.53, 40.64, 40.66, 40.67, 40.81, [and] 40.82 and 10 CFR Part 40 Appendix A Criterion—11 A-F and Criterion—12** are not incorporated. **Paragraph 2 of the definition of “commencement of construction” and Paragraph 9(ii) of the definition of “construction” in Section 40.4 are not incorporated.**

(13) Sections 70.1(c), (d) and (e), 70.5, 70.6, 70.8, 70.13, 70.13a, 70.20a, 70.20b, 70.21(a)(1), (c), (f), (g) and (h), 70.22(b), (c), (f), (g), (h), (i), (j), (k), (l), (m) and (n), 70.23(a)(6), (7), (8), (9), (10), (11) and (12) and (b), 70.23a, 70.24, 70.25(a), 70.31(c), (d) and (e), 70.32(a)(1), (4), (5), (6) and (7), 70.32(b)(1), (3) and (4), (c), (d), (e), (f), (g), (h), (i), (j) and (k), 70.37, 70.40, 70.42(b)(6), 70.44, 70.51(c), (d) and (e), 70.52, 70.53, 70.54, 70.55(c)(1), (2) and (3), 70.56(c) and (d), 70.57, 70.58, 70.59, 70.62, 70.71[and], 70.72, **70.74, and 10 CFR Part 70 Appendix A** are not incorporated. **Paragraph 2 of the definition of “commencement of construction” and Paragraph 9(ii) of the definition of “construction” in Section 70.4 are not incorporated.**

(14) Sections 71.2, 71.6, 71.14(b), 71.19, 71.31, 71.33, 71.35, 71.37, 71.38, 71.39, 71.41, 71.43, 71.45, 71.51, 71.55, 71.59, 71.61, 71.63, 71.64, 71.65, 71.71, 71.73, 71.74, 71.75, 71.77, 71.99, 71.100, 71.101(c)(2), (d) and (e), 71.107, 71.109, 71.111, 71.113, 71.115, 71.117, 71.119, 71.121, 71.123 and 71.125 are not incorporated. **The definitions of “certificate holder” and “certificate of compliance (CoC)” in Section 71.4 are not incorporated. The term “applicant” when used in 10 CFR Part 71 is not incorporated.**

(f) If a provision of the CFR incorporated by reference in this article includes a section which is inconsistent with this title, this title controls to the extent Federal law does not preempt Commonwealth law. If a provision of the CFR incorporated by reference in this article is beyond the scope of authority granted the Department under statute, or is in excess of the statutory authority, the provisions shall be and remain effective only to the extent authorized by the Pennsylvania law.

(g) Appropriate parts of 10 CFR (relating to energy) may be obtained from the following:

(1) The United States Government Printing Office, Book Store, Room 118, Federal Building, 1000 Liberty Avenue, Pittsburgh, Pennsylvania 15222, (412) 664-2721.

(2) The United States Government Printing Office, Book Store, 100 North 17th Street, Robert Morris Building, Philadelphia, Pennsylvania 19103, (215) 597-0677.

(3) The United States Superintendent of Documents, United States Government Printing Office, Washington, D.C. 20402, (202) 783-3238.

(h) To reconcile differences between this chapter and the incorporated sections of Federal regulations and to effectuate their joint enforcement, the following words and phrases shall be substituted for the language of the Federal regulations:

(1) A reference to "NRC" or "Commission" means Department.

(2) A reference to "NRC or agreement state" means Department, NRC or agreement state.

(3) The definition of "sealed source" includes NARM.

(4) A reference to "byproduct material" includes NARM.

(5) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR shall be directed to the Department, except as noted in 10 CFR 37.27 (relating to requirements for criminal history records checks of individuals granted unescorted access to category 1 or category 2 quantities of radioactive material) **and in 10 CFR 71.17(c)(3) (relating to general license: NRC-approved package).**

CHAPTER 217. LICENSING OF RADIOACTIVE MATERIAL

* * * * *

§ 217.131. Incorporation by reference.

(a) Except as provided in this subchapter, the requirements of 10 CFR Part 30 (relating to rules of general applicability to domestic licensing of byproduct material) are incorporated by reference.

(b) Notwithstanding the requirements incorporated by reference, 10 CFR 30.5, 30.6, 30.8, 30.21(c), 30.34(d), (e)(1) and (3), 30.41(a)(6), 30.55, 30.63 and 30.64 are not incorporated by reference. **Paragraph 2 of the definition of "commencement of construction" and Paragraph 9(ii) of the definition of "construction" in Section 30.4 are not incorporated.**

* * * * *

§ 217.151. Incorporation by reference.

(a) Except as provided in this subchapter, the requirements of 10 CFR Part 32 (relating to specific domestic licenses to manufacture or transfer certain items containing byproduct material) are incorporated by reference.

(b) Notwithstanding the requirements incorporated by reference, 10 CFR 32.1(c)(1), 32.8, 32.14, 32.15, 32.16, 32.18, 32.19, 32.20, 32.21, 32.22, 32.23, 32.25, 32.26, 32.27, 32.28, 32.29, 32.30, 32.31, 32.32 and 32.40 are not incorporated by reference.

* * * * *

§ 217.171. Incorporation by reference.

(a) Except as provided in this subchapter, the requirements of 10 CFR Part 40 (relating to domestic licensing of source material) are incorporated by reference.

(b) Notwithstanding the requirements incorporated by reference, 10 CFR 40.6, 40.8, 40.12(b), 40.13(c)(5)(iv), 40.23, 40.27, 40.28, 40.31(k) and (i), 40.32(d), (e) and (g), 40.33, 40.38, 40.41(d), (e)(1) and (3) and (g), 40.51(b)(6), 40.52, 40.53, 40.64, 40.66, 40.67, 40.81 and 40.82 are not incorporated by reference. Paragraph 2 of the definition of “commencement of construction” and Paragraph 9(ii) of the definition of “construction” in Section 40.4 are not incorporated.

* * * * *

§ 217.181. Incorporation by reference.

(a) Except as provided in this subchapter, the requirements of 10 CFR Part 70 (relating to domestic licensing of special nuclear material) are incorporated by reference.

(b) Notwithstanding the requirements incorporated by reference, 10 CFR 70.1(c), (d) and (e), 70.5, 70.6, 70.8, 70.13, 70.13a, 70.20a, 70.20b, 70.21(a)(1), (c), (f), (g) and (h), 70.22(b), (c), (f), (g), (h), (i), (j), (k), (l), (m) and (n), 70.23(a)(6), (7), (8), (9), (10), (11) and (12) and (b), 70.23a, 70.24, 70.25(a), 70.31(c), (d) and (e), 70.32(a)(1), (4), (5), (6) and (7) and (b)(1), (3) and (4) and (c), (d), (e), (f), (g), (h), (i), (j) and (k), 70.37, 70.40, 70.42(b)(6), 70.44, 70.51(c), (d) and (e), 70.52, 70.53, 70.54, 70.55(c)(1), (2) and (3), 70.56(c) and (d), 70.57, 70.58, 70.59, 70.62, 70.71, [and] 70.72, 70.74 and 10 CFR Part 70 Appendix A are not incorporated by reference. Paragraph 2 of the definition of “commencement of construction” and Paragraph 9(ii) of the definition of “construction” in Section 70.4 are not incorporated.

CHAPTER 230. PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

* * * * *

§ 230.3. Incorporation by reference.

(a) Except as provided in this chapter, the requirements of 10 CFR Part 71 (relating to packaging and transportation of radioactive material) are incorporated by reference.

(b) Notwithstanding the requirements incorporated by reference, 10 CFR 71.2, 71.6, 71.14(b), 71.19, 71.31, 71.33, 71.35, 71.37, 71.38, 71.39, 71.41, 71.43, 71.45, 71.51, 71.55, 71.59, 71.61, 71.63, 71.64, 71.65, 71.71, 71.73, 71.74, 71.75, 71.77, 71.99, 71.100, 71.101(c)(2), (d) and (e), 71.107, 71.109, 71.111, 71.113, 71.115, 71.117, 71.119, 71.121, 71.123 and 71.125 are not incorporated by reference. **The definitions of “certificate holder” and “certificate of compliance (CoC)” in Section 71.4 are not incorporated. The term “applicant” when used in 10 CFR Part 71 is not incorporated.**

**CHAPTER 232. LICENSES AND RADIATION SAFETY REQUIREMENTS FOR
IRRADIATORS**

* * * * *

§ 232.2. Incorporation by reference.

(a) Except as provided in this chapter, the requirements of 10 CFR Part 36 (relating to licenses and radiation safety requirements for irradiators) are incorporated by reference.

(b) Notwithstanding the requirements incorporated by reference, §§ 36.5, 36.8, 36.91 and 36.93 are not incorporated by reference. **Paragraph 2 of the definition of “commencement of construction” and Paragraph 9(ii) of the definition of “construction” in Section 36.2 are not incorporated.**

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David Sumner
Executive Director
Independent Regulatory Review Commission
333 Market Street, 14th Floor
Harrisburg, PA 17120

Re: Final Rulemaking: Radiological Health (#7-499)
Final-Omitted Rulemaking: U.S. Nuclear Regulatory Commission Consistency Rule (#7-550)

Dear Mr. Sumner:

Pursuant to Section 5(a) of the Regulatory Review Act, please find enclosed copies of one final-form rulemaking and one final-omitted rulemaking for review by the Independent Regulatory Review Commission (IRRC). The Environmental Quality Board (Board) adopted these rulemakings at its June 19, 2018 meeting.

The **Radiological Health (#7-499)** final-form rulemaking amends Chapters 215-221, 223-228, 230, 232, and 240 to establish and maintain adequate radiation protection standards and oversight due to significant technological advances in the use of radiation sources, based on standards set by current recognized accrediting bodies and national organizations. Further, this rulemaking clarifies radon certification application requirements and reporting requirements for certified radon service providers. The rulemaking also amends testing and mitigation protocol requirements and quality assurance and quality control requirements to provide greater detail regarding program design and goals. Amendments included in this rulemaking also remove Agreement State transitional language and outdated requirements.

The Radiation Protection Act (RPA), 35 P.S. §§ 7110.101-7110.703, requires the Department of Environmental Protection (Department) to establish and maintain a comprehensive program of radiation protection including registration, licensing, regulation and control of radiation, radiologic procedures, radiation sources and users of radiation sources. The Radon Certification Act (RCA), 63 P.S. §§ 2001-2014, requires the Department to establish and implement a program of certification of persons who perform radon testing or carry out radon mitigation activities.

Changes to Radiological Health chapters from the proposed rulemaking include:

- reversing units of radiation doses to be consistent with PA and national standards;
- raising peak skin dose from 3 gray (Gy) to 15 Gy for dose criteria in the definition of “medical reportable event for radiation-producing diagnostic or interventional X-ray procedures”;
- clarifying exemptions, evaluation intervals, Computed Tomography Dose Index (CTDI_w) definition, and CT X-ray systems when surveys need to be performed;

- clarifying the distance appropriate persons may be from the radiation-producing device in a veterinary medicine facility during radiographic exposure; and
- eliminating Agreement State transitional language.

Changes in Chapter 240 (Radon) from the proposed rulemaking include:

- clarifying the types of radon testing devices;
- deleting Department approval for scientific research;
- deleting definitions for terms either used once or not at all in the regulations;
- clarifying definitions;
- deleting the limit on the number of firm certified individuals and employees and a firm's certified individuals' disallowance to also be firm employees;
- adding a demonstration that a certified individual will maintain adequate span of control of employees;
- changing the requirement for firm employees to pass a Department-approved course or exam for initial training and continuing education requirements;
- deleting the birth date requirement;
- deleting the requirement to wear a Department-issued identification badge while performing services;
- adding a requirement that a building owner or occupant is to receive test results;
- clarifying reporting requirements to the client and post-mitigation tests;
- deleting the need to perform radon tests prior to mitigation installation;
- deleting duplicative continuing education requirements;
- clarifying mitigation standards;
- adding a requirement to notify the client of malfunctioning mitigation system during the test period;
- clarifying the use of anti-tampering devices;
- clarifying testing timeframe requirements;
- deleting unnecessary tracking of serial numbers, calculating control and warning levels, and electret voltage drift testing.

These amendments affect approximately 11,000 x-ray machine registrants, 825 radioactive materials licensees, 150 accelerator licensees, 325 service providers, and approximately 600 radon service providers.

A small number of registrants will be affected by the new requirement to use a qualified medical physicist (QMP). Most registrants already employ the services of a QMP, or a person with the same qualifications. 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 final-form rulemaking reflect current industry practices due to Medicare and the insurance industry requirements and therefore are not expected to impose additional requirements on the regulated community.

The public and businesses could be affected by the radon regulations if they use or provide radon mitigation services. The increased requirements for businesses are merely a codification of long-standing guidance documents published by the Department and U.S. Environmental Protection

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Agency (EPA) and are considered standard practice. Other amendments in this rulemaking eliminate some current requirements of the radon industry such as testing prior to mitigation and unnecessary equipment checks and tests.

Users of radiation sources are required to comply with radiation protection standards that would not only protect employees but also the public. The final-form rulemaking ensures that trained professionals are operating these radiation sources so that both the patient and the operator are adequately protected. Because the requirements reflect current practices, this rulemaking is not expected to result in additional costs to the regulated community.

This final-form rulemaking clarifies the radon certification application and reporting requirements, making it easier for the regulated community to understand what is required during each process. Most of the new provisions will reduce the burden on businesses in both paperwork and operations, such as eliminating unnecessary equipment checks. The elimination of the requirement to pay certification fees a second time to reinstate a previously withdrawn application saves the firm or individual anywhere from \$450 to \$1,125. Benefits to the public include greater consistency in the services provided, improved indoor air quality with subsequent health benefits, and increased home value. Documentation requirements added in Chapter 240 in 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.

The proposed rulemaking was adopted by the Board on October 18, 2016, and published with a 45-day public comment period on May 13, 2017. A webinar was held for the Radiological Health chapters on May 31, 2017. A separate webinar was also held on that date for Chapter 240 (Radon). Further outreach and implementation support will be provided by regional inspectors and technical staff.

Common themes raised in comments are as follows. Concerns were raised regarding the dose criteria in the definition of "medical reportable event for radiation-producing diagnostic or interventional X-ray procedures." The Department revised the dose criteria as suggested.

Several commentators requested that continuing education hours be codified. The final-form rulemaking was not revised to accommodate this request due to the confusion often occurring when applying education units or contact hours to continuing education requirements.

Several commentators recommended not limiting the number of radon firm certified individuals and employees. These limits were removed as suggested.

A concern was raised regarding firm employees being required to complete a Department-approved course or exam. These requirements have been revised to allow the training of the firm employees to be conducted by the certified individual.

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Several commentators questioned the need to include the date of birth on applications for employees. This requirement has been deleted in the final-form rulemaking.

One commentator noted a possible overlap between the Department and the Department of Health's (DOH) regulations regarding radiology. DOH is currently working on a regulatory update. The Department and DOH have held several meetings and have been working together to ensure DOH's regulations are consistent with the Department's regulations.

All comments were considered and are addressed in the comment and response document that accompanies this final-form rulemaking.

The public comments and regulatory revisions were reviewed in detail with RPAC on October 19, 2017. Following discussion, RPAC members suggesting adding flexibility for the evaluation of spot films by adding "or digital acquisition modes" in § 221.35a(c). RPAC also suggested adding the term "high risk" into the definition of "FGI—fluoroscopic guided interventional procedures" to avoid unnecessary regulatory burdens for low risk FGI procedures. Both suggested amendments were made in the final-form rulemaking.

The U.S. Nuclear Regulatory Commission Consistency (#7-550) final-omitted rulemaking amends Chapters 215, 217, 230 and 232 (relating to general provisions; licensing of radioactive materials; packaging and transportation of radioactive material; and licenses and radiation safety requirements for irradiators) to exclude specific provisions of Title 10, Chapter I (relating to Nuclear Regulatory Commission) of the Code of Federal Regulations (CFR) from incorporation-by-reference in these chapters.

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 this 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 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. This final-omitted rulemaking is 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 excluding can only be implemented by the NRC.

The failure to exclude these sections from the Commonwealth's incorporation-by-reference of select Federal regulations was an oversight 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: 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 2008 agreement to

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implement these sections and has never enforced them. The amendments included in this rulemaking clarify the Department's and the NRC's legal authority under their respective regulations.

Review and consideration of public comments on the amendments is unnecessary because public comments could not alter the need to make these amendments. Finalizing these amendments without public notice and comment is in the public interest to ensure that the Commonwealth's regulations accurately reflect the Department's authority. 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. No changes to any radioactive material license will result from this final-omitted rulemaking.

References to the provisions of Title 10 of the CFR being eliminated from incorporation-by-reference in this final-omitted rulemaking are outlined, by section, in the table below:

25 Pa. Code Section Amended	10 CFR Provision Excluded from Incorporation-by-Reference
§§ 215.1(e)(3) and 217.131(b)	§ 30.4
§§ 215.1(e)(5) and 217.151(b)	§§ 32.1(c)(1), 32.30, 32.31, and 32.32
§ 215.1(e)(9) and § 232.2(b)	§ 36.2
§ 215.1(e)(12)	§§ 40.4, 40.13(c)(5)(iv), 40.52, 40.53 and Part 40 Appendix A Criterion - 11 A-F and Criterion - 12
§ 217.171(b)	§§ 40.4, 40.13(c)(5)(iv), 40.52, 40.53
§ 215.1(e)(13)	§§ 70.4, 70.74 and Part 70 Appendix A
§ 215.1(e)(14)	§§ 71.17, 71.21, 71.70, 71.85(a), (b) and (c), 71.91(c) and (d), 71.101(a), (b), and (c)(1), 71.103(a), 71.106 and 71.135
§ 217.181(b)	§§ 70.4, 70.74 and Part 70 Appendix A
§ 230.3(b)	§§ 71.17, 71.21, 71.70, 71.85(a), (b) and (c), 71.91(c) and (d), 71.101(a), (b) and (c)(1), 71.103(a), 71.106 and 71.135

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.

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.

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

Mr. David Sumner, Executive Director - 6 -

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law. *See* 42 U.S.C. § 2021(d)(2). If these amendments are not adopted, the Commonwealth will be at risk of losing the authority it assumed as an Agreement State under the 2008 agreement to regulate most types of radioactive materials used in the Commonwealth.

The amendments will create no compliance costs. No additional financial, economic or social impact will result from these amendments.

The Department presented this final-omitted rulemaking to the Radiation Protection Advisory Committee (RPAC) at its October 19, 2017 meeting. At that meeting, the RPAC recommended that the Department move forward with this final-omitted rulemaking.

The Department will provide assistance as necessary to facilitate IRRC's review of the enclosed rulemakings under Section 5.1(e) of the Regulatory Review Act.

Please contact me by e-mail at ledinger@pa.gov or by telephone at 717.783.8727 if you have any questions or need additional information.

Sincerely,



Laura Edinger
Regulatory Coordinator

Enclosures

**TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO
 THE REGULATORY REVIEW ACT**

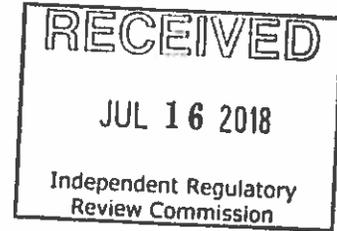
I.D. NUMBER: 7-550

SUBJECT: U.S. Nuclear Regulatory Commission Consistency Rule

AGENCY: DEPARTMENT OF ENVIRONMENTAL PROTECTION

TYPE OF REGULATION

- Proposed Regulation
- Final Regulation
- Final Regulation with Notice of Proposed Rulemaking Omitted
- 120-day Emergency Certification of the Attorney General
- 120-day Emergency Certification of the Governor
- Delivery of Tolled Regulation
 - a. With Revisions
 - b. Without Revisions



FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
<u>7/16/18</u>	<u>Melley K. Weaver</u>	Majority Chair, HOUSE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY <u>Representative John Maher</u>
<u>7/16/18</u>	<u>Richard S. Fox</u>	Minority Chair, HOUSE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY <u>Representative Mike Carroll</u>
<u>7/16/18</u>	<u>Patricia E. Conroy</u>	Majority Chair, SENATE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY <u>Senator Colne Yaw</u>
<u>7/16/18</u>	<u>J. Chi</u>	Minority Chair, SENATE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY <u>Senator John Yudichak</u>
<u>7/16/18</u>	<u>K. Cooper</u>	INDEPENDENT REGULATORY REVIEW COMMISSION <u>David Sumner</u>
<u>7/16/18</u>	<u>Mary Mummert</u>	ATTORNEY GENERAL (for Final Omitted only) <u>Amy Elliott</u>
_____	_____	LEGISLATIVE REFERENCE BUREAU (for Proposed only)

