| Regulatory Analysis Form (Completed by Promulgating Agency) | | INDEPENDENT REGI REVIEW COMMIS | 200 |
|--|-------------------------------------|--|---------------------|
| (All Comments submitted on this regulation will appear on IRRC's w | rebsite) | V. | S 20 |
| (1) Agency | fox | | <u> </u> |
| Department of Environmental Protection | DOMENTAL III | o of elfine — Too | RRC PM |
| (2) Agency Number: | | | w E |
| Identification Number: 7-493 | O 1 , 4 12 15 | IRRC Number: 3090 | W |
| (3) PA Code Cite: 25 Pa. Code Article V. Radiological H | ealth, Chapter 2 | 215, General Provisions | F = 10 +C = 0 |
| (4) Short Title: Security Rule for Radioactive Material | THE PART IN | in the self of the residence of the self o | ter a second |
| (5) Agency Contacts (List Telephone Number and Email | Address): | | |
| Primary Contact: Laura Edinger, 783-8727, ledinger@ Secondary Contact: Patrick McDonnell, 783-8727, pm | | gov | * |
| (6) Type of Rulemaking (check applicable box): | | 77H | |
| ☐ Proposed Regulation ☐ Final Regulation ☐ Final Omitted Regulation | Certif | gency Certification Regulatication by the Governor ication by the Attorney General Control of the Control of th | entra de mar |
| (7) Briefly explain the regulation in clear and nontechnical | al language. (10 | 00 words or less) | |
| The Bureau of Radiation Protection incorporates by reference the U.S. Nuclear Regulatory Commission (NRC) Code of protection. Recently NRC implemented new security-relevants are required to adopt by March 2016. The program of the protection of th | f Federal Regul ated regulations | ations (CFR) relating to racs, known as 10 CFR Part 3 | diation 7, which |
| (8) State the statutory authority for the regulation. Includ | e specific statut | tory citation. | |
| Radiation Protection Act, act of July 10, 1984 (P. 7110.301 and 35 P.S. Sec. 7110.302. Section 1920-A of the Administrative Code, Aparamended, 71 P.S. Sec. 510-20. | , | ,, | |
| (9) Is the regulation mandated by any federal or state law any relevant state or federal court decisions? If yes, cite deadlines for action. | | , | I |
| The regulation is mandated by federal regulation. Comprequirement for Agreement States. | patibility of Sta | ate and NRC regulations is | s a |

On March 31, 2008, Pennsylvania licensees received a security order issued under NRC's common defense and security authority; the order will remain in place until compatible requirements are issued.

On March 19, 2013, the NRC published the new 10 CFR Part 37 final rule in the Federal Register (78 FR 16922). The new regulation establishes security requirements for the use and transport of the most risk-significant quantities of radioactive materials (i.e., International Atomic Energy Agency (IAEA) Category 1 and Category 2 quantities of radioactive materials), as well as for shipments of small amounts of irradiated reactor fuel. The Category 1 and Category 2 quantities of radioactive materials are thresholds established by the IAEA in its Code of Conduct on the Safety and Security of Radioactive Sources. The objective of 10 CFR Part 37 is to provide reasonable assurance of preventing the theft or diversion of Category 1 and Category 2 quantities of radioactive materials. The final rule incorporates lessons learned by NRC and the Agreement States in implementing the post-September 11th security measures, as well as stakeholder input on the proposed rule. The new 10 CFR Part 37 was effective on May 20, 2013, and NRC licensees had to be in compliance with the requirements by March 19, 2014. Agreement States have until March 19, 2016, to issue compatible requirements for their licensees.

(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 public and radiation workers benefit through the prevention of unnecessary radiation exposure.

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

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

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

Every state is required to be compatible with the federal standards. Incorporating these standards by reference allows Pennsylvania to maintain compatibility. Therefore, this regulation will not put Pennsylvania 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 their March 6, 2014 meeting. At its June 12, 2014 meeting, RPAC endorsed moving forward with the proposed rulemaking. At its June 4, 2015 meeting, RPAC endorsed moving forward with

the final rulemaking. Current IC licensees are being informed by DEP during annual inspections that the orders they are required to comply with will be codified in Pennsylvania regulation with the promulgation of this rulemaking.

This final rulemaking will not be discussed with the Small Business Compliance Advisory Committee because the rulemaking codifies a practice that has been in place since 2005 and does not further impact small businesses in Pennsylvania.

(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?

Currently Pennsylvania has 66 IC licensees. These licensees, primarily made up of broad scope medical facilities and industrial radiographers, have been following NRC orders that were implemented on November 14, 2005. These orders will now be codified into Pennsylvania regulation; the final rulemaking will not affect the current operations of these facilities.

(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.

See response for (15). All licensees will be required to comply and have been complying since the NRC security orders were issued in 2005. Of the 66 IC licensees, 12 qualify as small business entities.

(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.

No additional financial, economic or social impact will result from this regulation. Benefits of the regulation are prevention of unnecessary radiation exposure to the public and radiation workers.

No change in the current fee schedule is included with this final rulemaking.

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

There are no adverse effects and costs associated with the regulation, as the licensees are already implementing the provisions as required by the NRC orders upon which the final-form regulation is based. The benefit of the prevention of unnecessary radiation exposure to the public and radiation workers cannot be quantified.

(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 will be no costs and/or savings to the regulated community associated with compliance with the final rulemaking. No change in the current fee schedule is included with this final-form rulemaking.

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

There will be no costs and/or savings to the local governments associated with compliance with this regulation, as local governments do not possess radioactive material licenses.

(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 and/or savings to the state government associated with compliance. Ensuring compliance with the regulation is and has been part of DEP's annual inspection program since becoming an Agreement State on March 31, 2008.

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

The NRC orders require licensees to secure, from unauthorized removal or access, licensed materials that are stored in controlled or unrestricted areas, as well as control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage. The NRC also issued orders imposing fingerprinting and criminal history records check requirements for unescorted access to certain radioactive material. No additional recordkeeping or other paperwork will be required by this proposed regulation.

(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.

This amendment will have no effect on fiscal savings and costs.

| - 82 ш - W - 2 (-) | Current FY Year | FY +1 Year | FY +2 Year | FY +3 Year | FY +4 Year | FY +5 Year |
|---------------------|--|---------------|---------------|---------------|---------------|---------------|
| SAVINGS: | \$ 1111111111111111111111111111111111111 | \$ | \$ | \$ | \$ 4 | \$ 1000 |
| 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: | | -1.6- | | | | |
| 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 (-2.11 = 112.1 | 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 1 1 1 | 0 1 | 0 | 0 | 0 | 0 |
| Total Revenue Losses | 0 | 0 | 0 | 0 | 0 | 0 |

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

This amendment will have no effect on program expenditures.

| Program | FY -3 2012/2013 | FY -2 2013/2014 | FY -1 2014/2015 | Current FY 2015/2016 |
|---------------------------|--------------------|--------------------|--------------------|----------------------|
| Radiation Protection Fund | \$10,460,000 | \$11,113,000 | \$12,384,000 | \$14,109,000 |

- (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.

No groups of persons will be adversely affected by the regulation.

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

No special provisions needed to be developed.

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

No special 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 performing standards for small businesses to replace design or operational standards required in the regulation; and
- e) The exemption of small businesses from all or any part of the requirements contained in the regulation.

The amendment 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 n | ot the basis for this proposed regulation. | |
|-----------|--|----------------|
| (29) Inch | ude a schedule for review of the regulation including: | |
| A. | The date by which the agency must receive public comments: | N/A |
| В. | The date or dates on which public meetings or hearings will be held: | <u>N/A</u> |
| C. | The expected date of promulgation of the proposed regulation as a final-form regulation: | Quarter 3 2015 |
| D | The expected effective date of the final-form regulation: | Quarter 1 2016 |
| | The date by which compliance with the final-form regulation will be required: | Quarter 1 2016 |
| F. | The 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.

No specific program implementation change will occur after the regulation is implemented. IC licensees will continue to be inspected on an annual basis.

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FACE SHEET FOR FILING DOCUMENTS WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

RECEIVED

2015 NOV -6 PM 3: 37

DO NOT WRITE IN THIS SPACE

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

Ву:

(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. 7-493

DATE OF ADOPTION September 15, 2015

TITLE JOHN QUIGLEY
CHAIRPERSON

EXECUTIVE OFFICER CHAIRMAN OR SECRETARY

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

OCT 1 5 2015

DATE OF APPROVAL

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

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

NOTICE OF FINAL RULEMAKING

DEPARTMENT OF ENVIRONMENTAL PROTECTION ENVIRONMENTAL QUALITY BOARD

Security Rule for Radioactive Material

25 Pa. Code, Chapter 215

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NOTICE OF FINAL RULEMAKING DEPARTMENT OF ENVIRONMENTAL PROTECTION ENVIRONMENTAL QUALITY BOARD [25 PA CODE CHAPTER 215]

Security Rule for Radioactive Material

The Environmental Quality Board (Board) by this order amends Chapter 215 (relating to general provisions) to read as set forth in Annex A. Chapter 215 is amended to include a reference to the new 10 CFR Part 37 Nuclear Regulatory Commission (NRC) security regulation. The Bureau of Radiation Protection incorporates by reference all applicable NRC radiation protection and control of radioactive materials regulations from Title 10 of the Code of Federal Regulations (CFR).

This final-form rulemaking was adopted by the Board at its meeting on September 15, 2015.

A. Effective Date

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

B. Contact Persons

For further information, contact Joseph Melnic, Chief, Division of Radiation Control, P.O. Box 8469, Rachel Carson State Office Building, Harrisburg, PA 17105-8469, (717) 783-9730, 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 by calling 1-800-654-5984 (TDD users) or 1-800-654-5988 (voice users). This final-form rulemaking is available electronically through the Department of Environmental Protection's (Department) Web site at www.dep.state.pa.us (select Public Participation, then select Environmental Quality Board).

C. Statutory Authority

This final-form rulemaking is authorized by the Radiation Protection Act, July 10, 1984 (P.L. 688, No. 147), 35 P.S. Sec. 7110.301 and 35 P.S. Sec. 7110.302, and Section 1920-A of the Administrative Code, April 9, 1929 (P.L. 177, No. 175), as amended, 71 P.S. Sec. 510-20.

D. Background and Purpose

When then-Governor Rendell signed the Agreement with the Chairman of the NRC in March 2008 to oversee and regulate licensure of radioactive materials for Pennsylvania entities, Pennsylvania committed to being compatible with the NRC regulations. The Department fulfills this requirement by incorporating by reference NRC regulations. Currently, Pennsylvania licensees are following security orders issued by the NRC in November 2005 following the terrorist attacks of September 11, 2001. The orders were re-issued by the Department in 2008, after Pennsylvania became an Agreement State, for security controls, also referred to as Increased Controls (IC), for these high-activity licensees. The

orders were used to develop the 10 CFR Part 37 regulations that were implemented by the NRC in March 2014. The orders require licensees to secure, from unauthorized removal or access, licensed materials that are stored in controlled or unrestricted areas, as well as control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage. The orders also impose fingerprinting and criminal history records check requirements for unescorted access to certain radioactive material.

E. Summary of Regulatory Requirements

The following discussion outlines the regulatory requirements that have been affected by the final-form regulations and describes the basis for the amendments.

Section 215.1 – Purpose and Scope

Subsection (e) includes a reference to Title 10 Chapter I (Nuclear Regulatory Commission) for Part 37, incorporating by reference this new Part.

Subsection (e)(10) designates the Part 37 sections that are not being incorporated, such as Sections 37.3(b)(2) (relating to imports and exports of category 1 or category 2 quantity of radioactive material); 37.13 (relating to information collection requirements contained in this part to the Office of Management and Budget (OMB)); 37.73(d) and (e) (relating to licensees that import or export); 37.107 (relating to violations); and 37.109 (relating to criminal penalties). These sections are not being incorporated because they apply to the NRC only. Subsequent paragraphs are proposed to be appropriately renumbered.

Subsection (h)(5) deletes the transitional language that had been added in anticipation of Pennsylvania becoming an Agreement State. In addition, language has been added codifying the requirement for licensees to send criminal history records to the NRC.

F. Summary of Comments and Responses on the Proposed Rulemaking

On March 21, 2015, the Board published a *Pennsylvania Bulletin* notice of proposed rulemaking and written public comment period on the proposed amendments to Chapter 215. The comment period closed on April 20, 2015, and no comments on the proposed rulemaking were received. The Independent Regulatory Review Commission (IRRC) reviewed the proposed rulemaking and did not have any objections, comments, or recommendations.

G. Benefits, Costs and Compliance

Benefits

Codifying orders into regulation will result in optimizing compliance authority. Benefits of the regulation are prevention of unnecessary radiation exposure to the public and radiation workers from terrorist acts using large quantities of radioactive material.

Compliance Costs

No additional financial, economic or social impact will result from this regulation.

Compliance Assistance Plan

Current IC licensees are being informed by DEP during annual inspections that the orders they are required to comply with will be codified in Pennsylvania regulation with the promulgation of this rulemaking. DEP has recently notified all IC licensees through a written Information Notice that Part 37 is anticipated to be incorporated by March 19, 2016. In addition, a series of workshops were conducted in September 2014 in which the National Nuclear Security Administration of the US Department of Energy participated to provide technical assistance.

Paperwork Requirements

The final-form rulemaking will not revise the current paperwork requirements.

H. Pollution Prevention

N/A

I. Sunset Review

This regulation will be reviewed in accordance with the sunset review schedule published by the Department to determine whether the regulations effectively fulfill the goals for which they were intended.

J. Regulatory Review

Under Section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), on March 9, 2015, the Department submitted a copy of this proposed rulemaking, published at 45 Pa.B. 1367 (March 21, 2015), to the Independent Regulatory Review Commission (IRRC) and the Chairpersons of the House and Senate Environmental Resources and Energy Committees for review and comment.

Under section 5(c) of the Regulatory Review Act, IRRC and the House and Senate Committees were provided with copies of the comments received during the public comment period, as well as other documents when requested. In preparing the final rulemaking, the Department has considered all comments from IRRC and the public.

Under section 5.1(j.2) of the Regulatory Review Act (71 P. S. § 745.5a(j.2)), on _______, 2015, these final-form regulations were deemed approved by the House and Senate Committees. Under section 5.1(e) of the Regulatory Review Act, IRRC met on ______, 2015, and approved the final-form regulations.

K. Findings of the Board

The Board finds that:

- (1) Public notice of the proposed rulemaking was given under sections 201 and 202 of the act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. §§ 1201 and 1202) and regulations promulgated thereunder at 1 Pennsylvania Code §§ 7.1 and 7.2.
- (2) A public comment period was provided as required by law, and all comments were considered.
- (3) These regulations do not enlarge the purpose of the proposal published at 45 Pennsylvania Bulletin 1367 (March 21, 2015).
- (4) These regulations are necessary and appropriate for the administration and enforcement of the acts identified in Section C of this order.

L. Order of the Board

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

- (a) The regulations of the Department of Environmental Protection, 25 Pennsylvania Code, Chapter 215, 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.
- (d) The Chairperson of the Board shall certify this order and Annex A and deposit them with the Legislative Reference Bureau, as required by law.
- (e) This order shall take effect immediately.

John Quigley Chairperson Environmental Quality Board

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)—([13]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([a]**b**)(6), 30.55, 30.63 and 30.64 are not incorporated.
 - (4) Sections 31.4 and 31.14 are not incorporated.
- (5) Sections 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 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.

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

- ([10]11) Sections 39.5, 39.8, 39.101 and 39.103 are not incorporated.
- ([11]12) Sections 40.6, 40.8, 40.12(b), 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), 40.64, 40.66, 40.67, 40.81 and 40.82 are not incorporated.
- ([12]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 are not incorporated.
- ([13]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.
- (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[and, for NRC licenses, to the NRC until agreement state status is in effect], 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).



November 6, 2015

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

Re: Final Rulemaking: Security Rule for Radioactive Material (#7-493)

Dear Mr. Sumner:

Pursuant to Section 5.1(a) of the Regulatory Review Act, please find enclosed the Security Rule for Radioactive Material final rulemaking for review and comment by the Independent Regulatory Review Commission (IRRC). The Environmental Quality Board (EQB) adopted the final rulemaking at its September 15, 2015 meeting.

The enclosed final-form rulemaking amends 25 *Pa. Code*, Chapter 215, to incorporate by reference selected U.S. Nuclear Regulatory Commission (NRC) regulations relating to radiation protection and control of radioactive materials from Title 10 of the Code of Federal Regulations (CFR).

Pennsylvania radioactive material licensees who possess Category 1 or Category 2 sources have been following security orders issued by the NRC on November 14, 2005, following the terrorist attacks of September 11, 2001. The orders address security controls, also referred to as Increased Controls (IC), for these high-activity licensees. Specifically, the orders require licensees to secure, from unauthorized removal or access, licensed materials that are stored in controlled or unrestricted areas, as well as control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage. The orders also impose fingerprinting and criminal history records check requirements for unescorted access to certain radioactive material. The orders were re-issued by the Department of Environmental Protection (DEP) in March 2008, after Pennsylvania became an Agreement State.

The NRC security orders were used to develop the codified federal regulation as Part 37, which was implemented by the NRC in March of 2014. The DEP orders will remain in place until compatible Pennsylvania regulations are issued. Pennsylvania is obligated to have 10 CFR Part 37 equivalent requirements in effect by March 19, 2016.

All Pennsylvania IC licensees will be required to comply with these regulations and are already doing so under the security orders. Presently, DEP has 680 specific licensees, of which 66 are considered IC licensees. No new entities will be affected by this regulation.

In July of 2014, DEP issued an Information Notice (BRP IN 2014-01) to all DEP licensees authorized to possess Category 1 or 2 radioactive sources regarding the impending implementation of 10 CFR Part 37. DEP held three radioactive materials security workshops in Pittsburgh, Harrisburg, and Philadelphia in September of 2014. DEP is currently providing, and will continue to provide, compliance assistance during routine facility permitting activities and inspections.

The proposed rulemaking was approved by the EQB on October 21, 2014. On March 21, 2015, the Board published a *Pennsylvania Bulletin* notice of proposed rulemaking and public comment period on the proposed amendments to Chapter 215. The comment period closed on April 20, 2015, and no comments on the proposed rulemaking were received. The Independent Regulatory Review Commission (IRRC) reviewed the proposed rulemaking and did not have any objections, comments, or recommendations. The Radiation Protection Advisory Committee endorsed moving forward with the final rulemaking at its June 4, 2015 meeting. IRRC noted that if the Board delivers the final-form regulation to the Commission without revisions, and the Committees do not take any action on the final rulemaking, the regulation will be deemed approved by the Commission.

The Department will provide assistance as necessary to facilitate IRRC's review of the enclosed final-form rulemaking 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.

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Sincerely,

Laura Edinger

Regulatory Coordinator

Enclosures



COMMONWEALTH OF PENNSYLVANIA DEPARTMENT OF ENVIRONMENTAL PROTECTION POLICY OFFICE

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

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TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

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