

Regulatory Analysis Form

(Completed by Promulgating Agency)

**INDEPENDENT REGULATORY
REVIEW COMMISSION**

(All Comments submitted on this regulation will appear on IRRC's website)

(1) Agency

Department of Environmental Protection

(2) Agency Number:

Identification Number: 7-493

IRRC Number: **3090**

(3) PA Code Cite: 25 Pa. Code Article V. Radiological Health, Chapter 215, General Provisions

(4) Short Title: Security Rule for Radioactive Material

(5) Agency Contacts (List Telephone Number and Email Address):

Primary Contact: Laura Edinger, 783-8727, ledinger@pa.gov

Secondary Contact: Patrick McDonnell, 783-8727, pmcdonnell@pa.gov

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

- Proposed Regulation
 Final Regulation
 Final Omitted Regulation

- Emergency Certification Regulation;
 Certification by the Governor
 Certification by the Attorney General

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

The Bureau of Radiation Protection incorporates by reference selected regulations from Title 10 Chapter I of the U.S. Nuclear Regulatory Commission (NRC) Code of Federal Regulations (CFR) relating to radiation protection. Recently NRC implemented new security-related regulations, known as 10 CFR Part 37, which Pennsylvania is required to adopt by March 2016. The purpose of this amendment is to reference the new Part 37.

(8) State the statutory authority for the regulation. Include specific statutory citation.

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

(9) Is the regulation mandated by any federal or state law or court order, or federal regulation? Are there any relevant state or federal court decisions? If yes, cite the specific law, case or regulation as well as, any deadlines for action.

The regulation is mandated by federal regulation. Compatibility of State and NRC regulations is a requirement for Agreement States.

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.

| | Current FY Year | FY +1 Year | FY +2 Year | FY +3 Year | FY +4 Year | FY +5 Year |
|----------------------------|------------------------|-------------------|-------------------|-------------------|-------------------|-------------------|
| SAVINGS: | \$ | \$ | \$ | \$ | \$ | \$ |
| Regulated Community | 0 | 0 | 0 | 0 | 0 | 0 |
| Local Government | 0 | 0 | 0 | 0 | 0 | 0 |
| State Government | 0 | 0 | 0 | 0 | 0 | 0 |
| Total Savings | 0 | 0 | 0 | 0 | 0 | 0 |
| COSTS: | | | | | | |
| Regulated Community | 0 | 0 | 0 | 0 | 0 | 0 |
| Local Government | 0 | 0 | 0 | 0 | 0 | 0 |

| | | | | | | |
|-----------------------------|---|---|---|---|---|---|
| State Government | 0 | 0 | 0 | 0 | 0 | 0 |
| Total Costs | 0 | 0 | 0 | 0 | 0 | 0 |
| REVENUE LOSSES: | | | | | | |
| Regulated Community | 0 | 0 | 0 | 0 | 0 | 0 |
| Local Government | 0 | 0 | 0 | 0 | 0 | 0 |
| State Government | 0 | 0 | 0 | 0 | 0 | 0 |
| Total Revenue Losses | 0 | 0 | 0 | 0 | 0 | 0 |

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

This amendment will have no effect on program expenditures.

| Program | FY -3 2011/2012 | FY -2 2012/2013 | FY -1 2013/2014 | Current FY 2014/2015 |
|---------------------------|----------------------------|----------------------------|----------------------------|---------------------------------|
| Radiation Protection Fund | \$9,442,000 | \$10,460,000 | \$12,585,000 | \$13,475,000 |

(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 not the basis for this proposed regulation.

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

- A. The date by which the agency must receive public comments: N/A
- B. The date or dates on which public meetings or hearings will be held: N/A
- C. The expected date of promulgation of the proposed regulation as a final-form regulation: December 2015
- D. The expected effective date of the final-form regulation: January 2016
- E. The date by which compliance with the final-form regulation will be required: January 2016
- F. The date by which required permits, licenses or other approvals must be obtained: N/A

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

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