

Results of the NRC's Section 610 Review of the Physical Protection of Byproduct Material

September 19, 2024

I. Section 610 of the Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), as amended,¹ requires that agencies consider the impact of their rulemakings on small entities and, consistent with applicable statutes, consider alternatives to minimize these impacts on the businesses, organizations, and government jurisdictions to which they apply. Section 610 of the RFA requires agencies to conduct a review within 10 years of issuance of those regulations that have or will have a significant economic impact on a substantial number of small entities. The NRC undertakes these reviews to decide whether the provisions that could affect small entities should be continued without change, or whether they should be rescinded or amended to minimize adverse economic impacts on small entities. As part of the Section 610 review, NRC considers the following factors: (1) the continued need for the rule; (2) the nature of complaints or comments received concerning the rule; (3) the complexity of the rule; (4) the extent to which the rule overlaps, duplicates, or conflicts with other Federal, State, or local government rules; and (5) the degree to which the technology, economic conditions or other factors have changed in the area affected by the rule. The NRC also solicits public comments on these factors/the Section 610 review.

On March 19, 2013, the U.S. Nuclear Regulatory Commission (NRC) issued “Physical Protection of Byproduct Material” (78 FR 16922), establishing security requirements for the use and transport of category 1 and category 2 quantities of radioactive material. Subsequently, on September 30, 2014, the NRC issued “Safeguards Information—Modified Handling Categorization; Change for Materials Facilities” (79 FR 58664), to protect security-related information for large irradiators, manufacturers and distributors, and for the transport of category 1 quantities of radioactive material, using the information protection requirements in 10 CFR Part 37.

At the time NRC developed the rulemaking for physical protection of byproduct material, that NRC determined the rule would have a significant economic impact on a substantial number of small entities.² As discussed below, the NRC has completed its Section 610 review of the part 37 requirements for the physical protection of byproduct material and concluded that no changes to the rule are warranted.

II. Background

The final rule, “Physical Protection of Byproduct Material.” established generically applicable security requirements for the protection of category 1 and category 2 quantities of radioactive materials possessed by certain NRC and Agreement State licensees. The NRC considered these quantities to be risk significant enough to warrant additional protection. The rule established reasonable assurance of preventing the theft or diversion of category 1 and category 2 quantities of radioactive material. These security requirements are similar to the

¹ 5 U.S.C. 601 et seq.

² The U.S. Nuclear Regulatory Commission (NRC) has established standards for determining which NRC licensees qualify as small entities (10 CFR 2.810, “NRC size standards”). These size standards were based on the Small Business Administration’s most common receipts-based size standards and include a size standard for business concerns that are manufacturing entities.

requirements imposed on these licensees through security orders issued by the NRC after the terrorist attacks of September 11, 2001. The NRC determined that it is preferable to regulate through rulemaking rather than order because notice and comment rulemaking is an open and transparent process that facilitates public participation. In developing the final rule, the NRC considered, among other things, the various orders, lessons-learned during implementation, the recommendations from the Independent Review Panel and the Materials Working Group, and stakeholder comments.

Licensees are required to: (1) develop procedures for implementation of the security provisions; (2) develop a security plan that describes how security is being implemented; (3) conduct training on the procedures and security plan; (4) conduct background investigations (including fingerprinting) for those individuals permitted access to category 1 or category 2 quantities of radioactive material; (5) coordinate with local law enforcement agencies (LLEAs) so the LLEAs would be better prepared to respond in an emergency; (6) conduct preplanning and coordination activities before shipping radioactive material; and (7) implement security measures for the protection of the radioactive material. Licensees also are required to promptly report any attempted or actual theft or diversion of the radioactive material. Licensees are required to keep copies of the security plan, procedures, background investigation records, training records, and documentation that certain activities have occurred.

Several U.S. Government programs involve fingerprinting and an FBI identification and criminal history records check. These include the National Agency Check; Transportation Worker Identification Credentials in accordance with 49 CFR 1572; Bureau of Alcohol, Tobacco, Firearms, and Explosives background check and clearances in accordance with 27 CFR 555; Health and Human Services security risk assessments for possession and use of select agents and toxins in accordance with 42 CFR 73; Hazardous Material security threat assessment for hazardous material endorsement to a commercial driver's license in accordance with 49 CFR 1572; and Customs and Border Protection's Free and Secure Trade Program. Any individual that has favorably undergone the background investigation required by these programs would be relieved from the fingerprinting and FBI criminal history records check element of the final rule as long as the licensee has appropriate documentation. Any individual who has an active Federal security clearance would also be relieved assuming appropriate documentation is provided.

The Department of Transportation requires security plans for the transport of highway route control quantities of radioactive material in accordance with 49 CFR 172.800. This provision covers only a small portion of the category 1 and category 2 quantities of radioactive material covered by the rule.

Some of the licensees impacted by the rule are small businesses. The rule does impose the minimum requirements that the NRC believes are necessary to adequately protect the public health and safety and the common defense and security. The rule provides some flexibility in the particular measures that a licensee can choose to employ.

III. Discussion of the Five Statutory Factors

As discussed below, the NRC has reviewed the rule with respect to the five factors set forth in Section 610 of the RFA.

IV. Continued need for the rule

One of the factors that must be considered in a Section 610 review is the continued need for the rule under review. The NRC finds that there is a continued need for the rule because the rule addresses radioactive source protection and security. The terrorist attacks of September 11, 2001, heightened concerns about the use of risk-significant radioactive materials in a malevolent act. Such an attack is of particular concern because of the widespread use of radioactive materials in the United States by industrial, medical, and academic institutions. The theft or diversion of risk-significant radioactive materials could lead to their unauthorized use in a radiological dispersal device or a radiological exposure device.

Commission regulations provide requirements for the safe use, transport, and control of licensed material. A licensee's loss of control of risk-significant radioactive material, whether it is inadvertent or through a deliberate act, could result in significant adverse impacts that could reasonably constitute a threat to the public health and safety or the common defense and security of the United States. After the attacks of September 11, 2001, the Commission determined that certain licensed material should be subject to enhanced security provisions and safeguarded during transport, and that individuals with unescorted access to risk-significant radioactive material should be subject to background investigations.

V. Nature of complaints or comments received concerning the rule

The NRC did not receive any comments during the public comment period for the Section 610 review. In addition, there have been no complaints from small entities during the 10 years the rule has been in effect.

VI. Complexity of the rule

In a Section 610 review, the complexity of the rule under review must be considered. Although establishing the security requirements for the use and transport of category 1 and category 2 quantities of radioactive material rule resulted in a number of regulatory requirements, the rule also includes a number of provisions aimed at easing the burden of compliance for affected licensees. The NRC carefully considered the various requirements and worked with stakeholders to facilitate implementation. The NRC finds that the rule is as complex as it needs to be to provide effective security requirements for the use and transport of category 1 and category 2 quantities of radioactive material.

VII. Extent to which the rule overlaps, duplicates, or conflicts with other Federal, State, or local government rules

In this review of part 37, the NRC has not found any overlap, duplication, or conflict with other similar programs administered by the NRC or Federal, State, or local agencies.

VIII. The degree to which technology, economic conditions, or other factors have changed in the area affected by the rule

NRC has examined the degree to which technology, economic conditions, or other factors have changed in the area affected by part 37 and has found no changes in technology over the period of time after promulgation of the rule nor general economic fluctuations that affect

radioactive source protection and security and have introduced significant additional burden on small entities subject to the rule.

IV. Conclusion

Based on NRC's Section 610 review of the 2013 final rule, "Physical Protection of Byproduct Material," as discussed in this document, the NRC has concluded that the final rule provides for establishing security requirements for the use and transport of category 1 and category 2 quantities of radioactive material without undue burden on small entities and that no changes to the rule are warranted at this time. As part of any future rulemakings related to security requirements for the use and transport of category 1 and category 2 quantities of radioactive material, the Agency will continue to work with small entity representatives to minimize any potential unfavorable impacts while meeting the objectives of applicable statutes.

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