



Report to Congress
under Public Law 113-235

Effectiveness of Part 37 of Title 10 of the *Code of Federal Regulations*

Submitted by: The U.S. Nuclear Regulatory Commission

Executive Summary

This report provides the results of a program review conducted pursuant to Section 403 of Public Law 113-235, "Consolidated and Further Continuing Appropriations Act, 2015," (Appropriations Act). This act required that the U.S. Nuclear Regulatory Commission (NRC) assess the effectiveness of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material," 2 years following its implementation by NRC licensees. The effectiveness evaluation for Agreement State licensees will be conducted separately by the Government Accountability Office as required by the Appropriations Act.

The NRC took steps to strengthen the security of risk-significant radioactive materials after the terrorist attacks of September 11, 2001, by issuing a series of security Orders to its licensees to implement interim security measures. Subsequently, the NRC published 10 CFR Part 37 on March 19, 2013 (78 FR 16922), to establish security requirements for the use and transport of Category 1 and 2 quantities of radioactive material. This final rule replaced the security Orders.

The review of the rule's effectiveness, which is documented in this report, was conducted through an analysis of events and inspection findings related to the security of risk-significant radioactive materials. This review was supplemented by an integrated assessment of the clarity and effectiveness of the rule, associated guidance documents, and implementation thereof conducted by NRC staff and expert Independent Assessment Consultants. In totality, these activities formed the basis for assessing the adequacy of the regulatory infrastructure for security of these radioactive materials.

The assessment showed that the requirements in Part 37 are effective in ensuring the security of risk-significant radioactive materials during use, storage, and transport when implemented appropriately by licensees. However, the assessment did identify a number of implementation issues due to licensees' incomplete understanding of differences between requirements in the rule and requirements in the Orders issued by the NRC to strengthen the security of risk-significant radioactive materials after the terrorist attacks of September 11, 2001.

Additionally, the NRC identified potential enhancements to the rule and guidance that could improve the clarity of the rule and consistency in its implementation.

Table of Contents

1.0	Introduction	1
2.0	Background – Statutory Authority and Evolution of Radioactive Source Security.....	1
2.1	Atomic Energy Act of 1954, as amended	1
2.2	Energy Reorganization Act of 1974	1
2.3	Energy Policy Act of 2005	2
2.4	Evolution of Regulatory Framework for Radioactive Source Security	2
2.4.1	Control of Radioactive Material	2
2.4.2	Enhanced Security	2
2.4.3	Security and Control Requirements for Category 1 and 2 Materials	3
3.0	Oversight of Risk-significant Radioactive Material	4
3.1	NRC’s Licensing and Oversight Process.....	4
3.1.1	Pre-licensing Activities	4
3.1.2	Inspection	5
3.1.3	Enforcement.....	5
3.2	Overview of NRC Source Security Program Features.....	6
3.2.1	Threat Assessment	6
3.2.2	Information Technology Applications	7
4.0	NRC Assessment of 10 CFR Part 37	8
4.1	Inspection Results	8
4.2	Events.....	13
4.3	Additional Assessment Activities	16
5.0	Conclusion	18
	Appendix A: Acronyms and Abbreviations.....	20

1.0 Introduction

Section 403 of Public Law 113-235, “Consolidated and Further Continuing Appropriations Act, 2015,” (Appropriations Act) required the U.S. Nuclear Regulatory Commission (NRC) to evaluate the effectiveness of the requirements of Part 37 of Title 10 of the *Code of Federal Regulations* (10 CFR), “Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material,” and determine whether those requirements are adequate to protect “high-risk radiological material.”¹ This report fulfills that directive to assess the effectiveness and consider “inspection results and event reports from the first 2 years of implementation of the requirements in 10 CFR Part 37 for NRC licensees.” Discussion on the Agreement State program is provided in this report in brief. The effectiveness evaluation for Agreement State licensees will be conducted separately by the Government Accountability Office (GAO) as required by the Appropriations Act.

2.0 Background – Statutory Authority and Evolution of Radioactive Source Security

2.1 Atomic Energy Act of 1954, as amended

Under the Atomic Energy Act of 1954, radioactive sources generally fall within the definition of byproduct material, and are therefore subject to licensing under 10 CFR Part 30, “Rules of General Applicability to Domestic Licensing of Byproduct Material,” of NRC’s regulations and to compliance with other applicable regulatory requirements, such as 10 CFR Part 20, “Standards for Protection Against Radiation.”

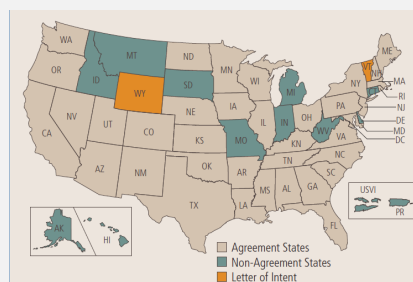
2.2 Energy Reorganization Act of 1974

The NRC was established in 1974, as an independent agency, from a portion of the former Atomic Energy Commission, to regulate the civilian use of byproduct material, source material, and special nuclear material to protect public health and safety, to promote the common defense and security, and to protect the environment. The NRC meets this mission

AGREEMENT STATE PROGRAM

The Atomic Energy Act authorizes the NRC to relinquish to individual states portions of its regulatory authority to license and regulate byproduct materials. The mechanism for the transfer of NRC’s authority to a state is an agreement signed by the governor of the state and the Chairman of the NRC. Such states are thus referred to as “Agreement States,” of which there are currently 37.

The NRC’s Integrated Materials Performance Evaluation Program ensures the protection of public health and safety through routine evaluation of Agreement States’ regulatory oversight of licensees under their jurisdiction and provides NRC and Agreement State management with a systematic and integrated approach to evaluate the strengths and weaknesses of their nuclear material licensing and inspection programs.



¹ Although the legislation uses the term “high risk,” the Radiation Source Protection and Security Task Force and the NRC use the term “risk-significant.” Risk-significant quantities of radioactive material are defined as those meeting the thresholds for Category 1 and Category 2 as included both in the International Atomic Energy Agency (IAEA) Code of Conduct on the Safety and Security of Radioactive Sources and in Part 37.

through licensing, inspection, and enforcement of its regulatory requirements.

2.3 Energy Policy Act of 2005

The Energy Policy Act of 2005 created the Radiation Source Protection and Security Task Force (Task Force). The Task Force is charged with evaluating the security of radiation sources in the U.S. from potential terrorist threats, including acts of sabotage, theft, or use of a radiation source in a radiological dispersal device or a radiation exposure device, and recommending regulatory or legislative changes as appropriate to the President and the U.S. Congress. The Task Force is comprised of representatives from 14 Federal agencies and one State organization, and is led by the Chairman of the NRC (or designee). The Task Force is in its 12th year and continues to meet routinely to work toward closure of open recommendations and to address additional concerns, such as any changes in the threat level related to radiological materials that may arise over time.

2.4 Evolution of Regulatory Framework for Radioactive Source Security

2.4.1 Control of Radioactive Material

Since the establishment of the NRC, it has been a requirement, that licensees, including those who possess Category 1 and 2 quantities of radioactive material, must control access to areas where licensed material is either used or stored to prevent the unnecessary exposure of members of the public, and to prevent theft. This is commonly achieved by posting signs, locking devices, locking areas where licensed materials are stored, and maintaining constant control and continuous surveillance of areas where materials are used. Every licensee is required to develop operating and emergency procedures that include steps for authorized users to ensure that access to licensed materials is controlled for the types of operations that will be performed. These requirements are found in Parts 20 and 30.

2.4.2 Enhanced Security

After the terrorist attacks of September 11, 2001, the NRC determined that there was a need for heightened awareness and focus on ensuring the prevention of intentional unauthorized access to radioactive materials to carry out potential malicious acts. As a result, the NRC imposed additional security controls to supplement the existing regulatory requirements in order to ensure adequate protection of, and minimize danger to, the public health and safety and the common defense and security. The additional security requirements were consistent with the International Atomic Energy Agency's (IAEA) *Code of Conduct on the Safety and Security of Radioactive Sources* Category 1 and Category 2 thresholds. These thresholds were separately reaffirmed by the Task Force to warrant the greatest level of control since they present the greatest risk for potential use in a radiological dispersal device. The requirements for Category 1 or 2 quantities of radioactive materials encompassed background checks, fingerprinting, access control, physical security during use, and physical security during transport.

The requirements were imposed by order to different classes of licensees, phased in from highest to lowest risk. The initial set of Orders were issued to specific licensees under the common defense and security provisions of the Atomic Energy Act, the enforcement of which was only by the NRC. These Orders applied to NRC and Agreement State licensees operating panoramic irradiators with more than 370 Terabecquerels (10,000 curies) of radioactive material; certain licensees authorized to manufacture or distribute Category 1 or 2 quantities of radioactive material; and licensees transporting Category 1 quantities of radioactive material. The Orders required licensees to implement compensatory measures, additional security measures, or increased controls to enhance the protection of radioactive materials in quantities

CATEGORY 1 AND 2 RADIOACTIVE MATERIALS

	Category 1 (TBq)	Category 1 (Ci)	Category 2 (TBq)	Category 2 (Ci)
Americium-241	60	1,620	0.6	16.2
Americium-241/Be	60	1,620	0.6	16.2
Californium-252	20	540	0.2	5.40
Cobalt-60	30	810	0.3	8.10
Curium-244	50	1,350	0.5	13.5
Cesium-137	100	2,700	1	27.0
Gadolinium-153	1,000	27,000	10	270
Iridium-192	80	2,160	0.8	21.6
Plutonium-238	60	1,620	0.6	16.2
Plutonium-239/Be	60	1,620	0.6	16.2
Promethium-147	40,000	1,080,000	400	10,800
Radium-226	40	1,080	0.4	10.8
Selenium-75	200	5,400	2	54.0
Strontium-90	1,000	27,000	10	270
Thulium-170	20,000	540,000	200	5,400
Ytterbium-169	300	8,100	3	81.0

Category 1 and 2 thresholds from Appendix A of 10 CFR Part 37. Terabecquerel (TBq) values are the regulatory standard; curie (Ci) values specified are obtained by converting from the TBq value.

of concern. The Orders also required licensees to require fingerprinting and FBI criminal history records checks for unescorted access to risk-significant quantities of radioactive material at their facilities. Following the implementation of these Orders, the NRC and Agreement States subsequently issued Orders and legally-binding license conditions pursuant to the

public health and safety provisions of the Atomic Energy Act to the remaining licensees authorized to possess Category 1 and 2 quantities of radioactive materials (e.g., medical facilities, academic institutions, research facilities, and other facilities). The additional security requirements imposed by the Orders and lessons learned from their implementation were used as the starting basis for the development of Part 37, which was published on March 19, 2013. The NRC licensees were required to implement the rule requirements no later than March 19, 2014, while Agreement States implemented Part 37-compatible requirements on or before March 19, 2016. The Orders discussed above have been rescinded as the Part 37 requirements, Agreement State regulations, or equivalent legally binding requirements, took effect for licensees.

2.4.3 Security and Control Requirements for Category 1 and 2 Materials

In addition to the requirements of Part 20, Part 30, and other specific regulatory requirements, licensees that possess aggregated² Category 1 and 2 materials must implement security measures in accordance with the requirements of Part 37. Key requirements of Part 37 include:

- Conducting background checks, including (1) fingerprinting to help ensure that individuals with unescorted access to risk-significant radioactive materials are trustworthy and reliable and (2) protection of certain information from unauthorized disclosure.
- Controlling personnel access to areas where risk-significant radioactive materials are stored and used.

² As defined in 10 CFR Part 37, radioactive materials are “aggregated” if the breach of a single physical barrier would allow access to radioactive material in any form, including any devices that contain the radioactive material, when the total activity equals or exceeds a Category 2 quantity of radioactive material.

- Documenting security programs that are designed with defense in depth to detect, assess, and respond to actual or attempted unauthorized access events.
- Planning of coordination and response between the licensee and local law enforcement agency (LLEA).
- Coordinating and tracking of radioactive materials shipments.
- Using security barriers to discourage theft of portable devices.
- Timely reporting of events to LLEA and the regulatory authority.

As required by the AEA, Agreement State programs must be compatible with the Commission's regulatory program. Therefore, as mentioned above, all Agreement States have implemented regulations or legally binding license conditions on or before March 19, 2016, to be compatible with Part 37.

3.0 Oversight of Risk-significant Radioactive Material

The NRC and Agreement States regulate the facilities, personnel, program controls, and equipment involved in the civilian use of radioactive materials in medical, academic, and industrial settings. The licensing and inspection oversight provided by the NRC and Agreement States, consistent with the regulatory framework provided in the *Code of Federal Regulations*, ensures the safety of the public, patients, the environment, and workers who might be exposed to radiation from those materials.

The physical security requirements of Part 37 apply to all licensees that possess radioactive material that aggregates to or exceeds a Category 2 quantity. For some facilities, radioactive material may not be in the form of a discrete radioactive source. For example, material made radioactive inside a nuclear reactor, such as reactor vessel internal components, would be subject to the requirements of Part 37 if it met or exceeded the Category 2 threshold. Security for radioactive material at reactor and fuel cycle facilities is maintained consistent with both Part 37 and the security plans and procedures required by relevant sections of Part 73, "Physical Protection of Plants and Materials."

3.1 NRC's Licensing and Oversight Process

The NRC protects public health and safety, promotes the common defense and security, and protects the environment through a comprehensive process of reviewing licensing applications against the agency's regulations, by performing routine and reactive inspections to assess licensee compliance with those regulations, and through the enforcement program. The NRC performs policy-setting activities including rulemaking and associated guidance development to ensure that the regulatory framework is commensurate with the risk associated with licensed activities. The NRC seeks to perform these activities in an open and transparent manner, sharing information with the public to the maximum extent possible, and performing frequent outreach to licensees and communication with stakeholders.

3.1.1 Pre-licensing Activities

Prior to issuing a materials license, the NRC conducts a pre-licensing review. The purpose of this review is to:

- Screen all unknown applicants to determine their legitimacy;

- Screen existing licensees (beyond the review conducted in the initial application) that increase possession limits to a Category 2 or higher quantity of radioactive material;
- Conduct site visits at applicant facilities to assure that radioactive material will be used as specified on the license application; and
- Forward suspicious applications to the appropriate authority for follow-up.

Pre-licensing activities also include the use of a checklist to address requests for authority to possess risk-significant radioactive material. The essential objective of the checklist is to identify those applicants and licensees that require implementation of the security requirements in Part 37. An onsite security review or an initial security inspection is conducted to verify that applicants or licensees requesting authority to possess aggregated Category 1 or 2 quantities of radioactive material are prepared to implement the applicable security requirements before taking possession of those materials.

3.1.2 Inspection

A primary component of the NRC's oversight involves an established inspection program for licensees authorized to possess, use, transfer, and dispose of radioactive material. This program is documented in NRC Inspection Manual Chapter (IMC) 2800, "Materials Inspection Program." Associated with IMC 2800 are specific inspection procedures that are used to verify that licensees are effectively implementing NRC requirements.

3.1.3 Enforcement

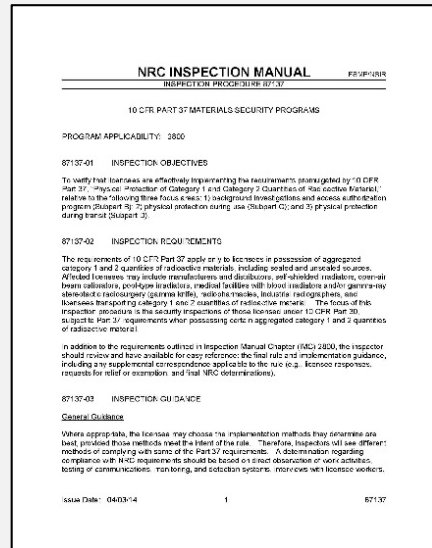
Another important aspect of NRC's oversight in this area is NRC's enforcement program. The NRC assesses the significance of licensee violations of NRC requirements by assigning a severity level to all violations. The assessment considers:

- actual safety or security consequences,
- potential safety or security consequences,
- potential for impacting the NRC's ability to perform its regulatory function, and
- any willful aspects of the violation.

Severity level designations reflect different degrees of significance and include Severity Levels I, II, III, and IV and minor violations.

NRC INSPECTION PROGRAM

All NRC materials licensees that possess radioactive material are inspected on a routine basis. Licensees that possess Category 1 and 2 quantities of radioactive material are inspected to ensure compliance with 10 CFR Part 37 and other regulatory requirements. Inspection frequency for these licensees varies depending on the risk associated with the licensed materials and activities.



Documents pertaining to the NRC's Inspection Program are publicly available at: <http://www.nrc.gov/reading-rm/doc-collections/insp-manual/>

Severity Level I (SLI) violations are of the highest significance. SLI violations are those that resulted in, or could have resulted in, serious safety or security consequences. These violations involve, for example, the theft, diversion, or sabotage of a Category 1 quantity of radioactive material that results from the failure to establish or implement one or more regulatory requirements.

Severity Level II (SLII) violations are those that resulted in or could have resulted in significant safety or security consequences; for example, the theft, diversion, or sabotage of a Category 2 quantity of radioactive material resulting from the failure to establish or implement one or more regulatory requirements.

Severity Level III (SLIII) violations are those that resulted in or could have resulted in moderate safety or security consequences.

Severity Level IV (SLIV) violations are those that are less serious, but are of more than minor concern, that resulted in no or relatively inappreciable potential safety or security consequences.

Minor violations are those that are less significant than a SLIV violation. While such violations must be corrected, minor violations do not warrant enforcement action and are not normally documented in inspection reports.

3.2 Overview of NRC Source Security Program Features

The oversight of licensees that possess Category 1 and 2 quantities of radioactive material is facilitated by two critical elements of the NRC's source security program: (1) an ongoing assessment of the threat level to determine if changes are needed to the measures enacted for protecting radiological materials; and (2) a comprehensive suite of data management tools that enable the tracking of Category 1 and 2 licenses and the sources held under those licenses, and enable the license verification function to ensure the validity of material transfers.


3.2.1 Threat Assessment

The NRC continually monitors intelligence information to keep abreast of foreign and domestic events and to maintain a real-time awareness of the capabilities of potential adversaries. The NRC uses this information, and other sources, to determine the physical protection requirements for source security regulations.

The NRC's Office of Nuclear Security and Incident Response conducts daily official liaison with the Intelligence and Law Enforcement Communities on intelligence and threat matters. The NRC works closely with the intelligence community, and other Federal agencies, as appropriate,

NRC ENFORCEMENT PROGRAM

The NRC applies the guidance in the NRC Enforcement Policy when assessing the significance of licensee violations. The Policy includes examples of violations for different licensee types and severity levels.



The NRC's Enforcement Policy is publicly available at:
<http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>.

to ensure the timely transfer of relevant intelligence information. The NRC staff performs prompt assessment of security threats to licensees and regulated activities.

As part of the Task Force, the NRC collaborates with its Federal and State partners to perform a periodic review of the types and quantities of radioactive materials in use. In accordance with the Task Force charter, the Task Force periodically reevaluates the list of radioactive sources that warrant enhanced security and protection to assess its adequacy in light of the evolving threat environment, and consistent with current National consequences of concern (e.g., prompt fatalities, land contamination, economic consequences). In preparation for the 2014 Task Force report, the Task Force reviewed information from the intelligence community regarding the current threat of terrorist organizations using radioactive sources or other radioactive materials against the U.S., along with isotope production and usage information, in order to determine whether changes to the radioactive sources list or threshold levels were needed. The Task Force is not aware of any specific threat against a specific target. In addition, the global use of radioactive sources has remained stable both in isotopes and quantity such that the Task Force determined that additional radionuclides or changes in thresholds for the existing list is not justified at this time.

3.2.2 Information Technology Applications

The Integrated Source Management Portfolio (ISMP) is a suite of information technology tools that supports the NRC radioactive material security program and related radioactive materials licensing and tracking activities. The key systems that comprise the ISMP include the National Source Tracking System (NSTS), the Web-Based Licensing (WBL) System and the License Verification System (LVS). The integration of these systems ensures the security and control of radioactive material by tracking information related to the NRC and Agreement State licensees.

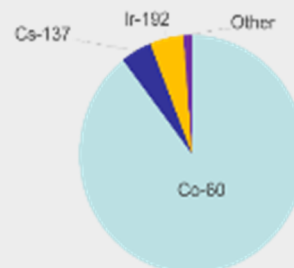
National Source Tracking System. NSTS is a secure, national system that tracks and accounts for Category 1 and Category 2 sources licensed by the NRC or Agreement States from the time they are manufactured or imported through the time of their disposal, decay, or export. The NSTS pre-existed the relatively recent Part 37 rulemaking. Requirements to report information into the NSTS are governed by NRC regulations in Part 20. The NSTS tracks and accounts for over 77,000 Category 1 and 2 sources held by 1,400 NRC and Agreement State licensees and processes 7,500 – 10,000 transactions per month. This tracking system enhances the agency's ability to detect and act upon inventory discrepancies, respond to emergencies, and verify the legitimate use and transfer of sources. It has also helped the NRC to

CATEGORY 1 AND 2 SOURCE TRANSACTIONS

The National Source Tracking System tracks transactions associated with more than 77,000 Category 1 and 2 sources nationwide. Of those transactions, manufacture (23%), transfer (38%), and receipt (27%) are the most common transactions, followed by export (11%) and import and disposal (<1% each).



Of the total sources, roughly 90% are cobalt-60; 5% are cesium-137, and 4% are iridium-192.



locate and ensure the safety of radioactive materials after natural events such as hurricanes and tornadoes.

Category 1 and 2 sources are evenly represented in NSTS, with Category 1 sources comprising 50 percent of the sources in the database and Category 2 comprising the remaining 50 percent. The isotopes within the system are less evenly distributed, with the majority of the sources in the system being cobalt-60. Used in industrial irradiators, panoramic irradiators, and external beam radiation therapy units, cobalt-60 sources are replaced approximately every 5 years. While the cobalt-60 sources are the largest inventory item in NSTS, the majority of transactions occur with iridium-192. This isotope is used in radiography, and the source decays below usefulness in about 3 months. The iridium-192 source transactions, which include manufacture, transfer, and receipt, make up 97 percent of the transactions reported.

Web-Based Licensing System. WBL is a repository of all Category 1 and 2 radioactive materials licenses nationwide. The system is used solely by regulatory bodies. In addition to its use by the NRC, it is available for use by Agreement State regulators to enable them to use the same licensing and information platform as the NRC. License information stored in WBL, when paired with data from NSTS, serves as the basis for license verification.

License Verification System. LVS is an integrated service designed to provide access to Category 1 and Category 2 license information maintained by the NRC and Agreement States. LVS is used by licensees to confirm that a license is valid and accurate and that a licensee is authorized to acquire quantities and types of radioactive materials being requested. LVS performs automated verification checks using data that resides in WBL and NSTS in order to verify that Category 1 and 2 possession limits are not exceeded by licensees.

4.0 NRC Assessment of 10 CFR Part 37

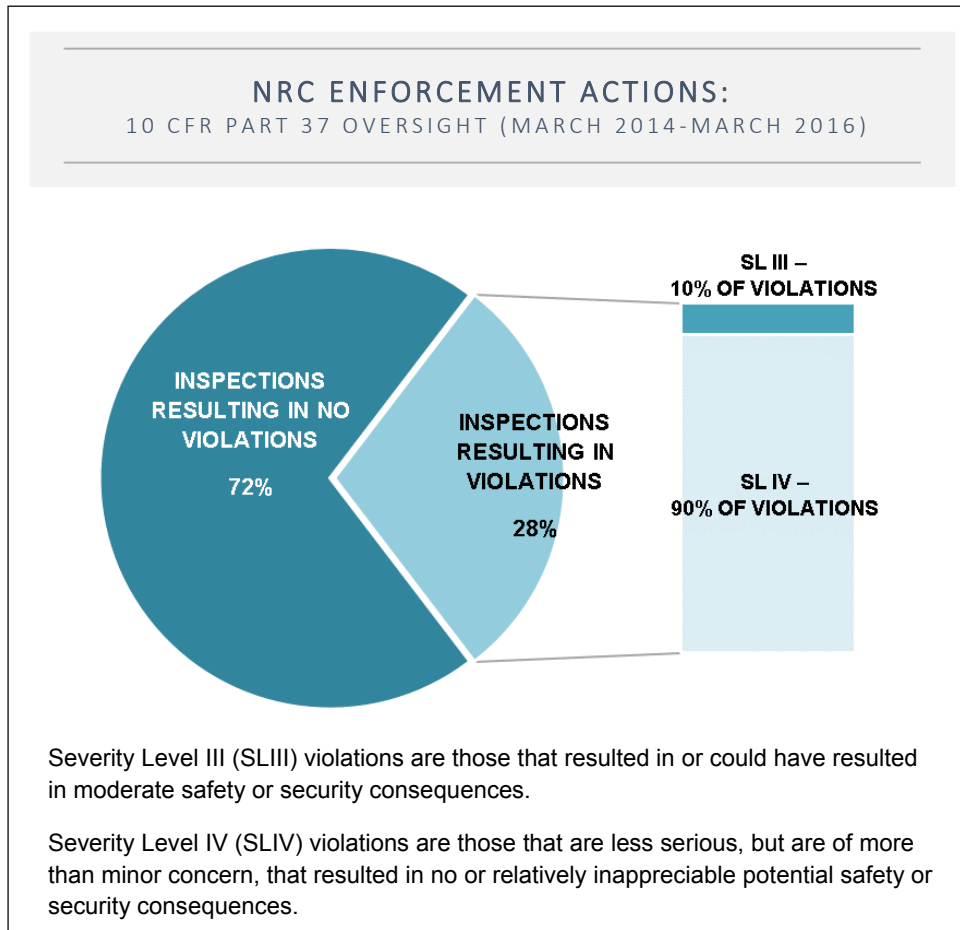
The NRC performed an assessment of the effectiveness of the requirements in Part 37 as mandated by the Appropriations Act. This assessment evaluated events reported by licensees in accordance with the rule as well as the results of inspections conducted to verify NRC licensee compliance with Part 37 requirements. In the interest of performing a complete and thorough analysis, the NRC expanded the assessment activities to include a more comprehensive evaluation of additional topical areas such as trustworthiness and reliability, stakeholder feedback on the rule, and observations made by independent consultants regarding the effectiveness of Part 37. The NRC also expanded the assessment to evaluate events that occurred while the Orders were in place to identify any potential opportunities to enhance the rule to ensure its suitability to address loss and theft events.

4.1 Inspection Results

From March 2014 to March 2016, the NRC performed 255 inspections to confirm NRC licensee compliance with the requirements of Part 37. The majority of inspections, 184 or 72 percent, resulted in no violations. The remaining 71 inspections resulted in 189 specific violations issued to 61 licensees. Given that there are approximately 1,400 Agreement State and NRC licensees implementing Part 37, these inspections account for 17 percent of Category 1 and 2 licensees in the United States.

The NRC staff closely tracked the results of the Part 37 inspections. Additionally, the staff tracked precedent setting violations and examples. To better analyze the clarity and effectiveness of the Part 37 requirements, general citations such as “10 CFR 37.3 – failure to comply with the requirements of Part 37” were not acceptable. The staff, including but not limited to, inspectors, security specialists and attorneys, discussed root cause of the violations

and agreed upon the appropriate regulatory citation(s). The staff conducted an in-depth analysis of the violations cited during inspections to determine if the issues demonstrated any problems with the regulation itself. Minor violations (i.e., less than SLIV) were not evaluated as part of the assessment because, consistent with the NRC Enforcement Policy, these violations constitute minor safety or security concerns that, although they must be corrected, generally do not warrant enforcement action or documentation in inspection reports.



Violations were cited against requirements contained in each of the four Subparts of Part 37: Subparts A, B, C, and D. Subpart A, “General Provisions,” provides definitions for key terms, requirements for transmitting communications and reports concerning the regulations, and requirements for submitting exemptions to the rule. Subpart B, “Background Investigations and Access Authorization Programs,”

contains requirements for implementation of an access authorization program. Subpart C, “Physical Protection Requirements During Use,” includes requirements for establishment, implementation, and maintenance of a security program. Finally, Subpart D, “Physical Protection in Transit,” provides requirements for transferring a Category 1 or 2 quantity of radioactive material.

Of the 189 total violations cited against the rule during the first 2 years of implementation for NRC licensees, 187 of the violations were cited against Subparts B and C, one violation was cited against Subpart A and one against Subpart D. In cases where a licensee received a notice of violation that identified multiple examples (i.e., a SLIV “problem” with four separate violations listed), each violation was counted individually.

Subpart A – General Provisions

One violation of Subpart A was identified for a licensee failing to revise the security plan required by Part 73 to include activities related to Category 2 radioactive material stored in the same room as the licensee’s research and test reactor.

Subpart B – Background Investigations and Access Control Program

A total of 75 violations of Subpart B of Part 37 were cited. In the majority of cases where licensees failed to meet the requirements in Subpart B, licensees did not fully document how their security program complied with Part 37. For example, licensees failed to provide Reviewing Official oath and affirmations to the NRC, complete informed consent forms, or have a documented basis for trustworthiness and reliability determinations. The documentation was suitable for compliance with post-September 11 security Orders, but was not updated or revised to reflect the requirements of Part 37. The most prevalent violations of Subpart B, failure to meet the requirements in 10 CFR 37.23, “Access Authorization Program Requirements,” accounted for 21 percent of all violations cited against the rule. Generally, these violations represented programmatic issues such as the lack of procedures for and documentation associated with the access authorization program.

In some cases where a failure to implement certain provisions of Subpart B was cited, licensees performed incomplete evaluations of individuals with access to security information. Specifically, licensees did not properly consider that information technology staff could potentially access protected security information.

VIOLATIONS BY SUBPART:
10 CFR PART 37 OVERSIGHT (MARCH 2014-MARCH 2016)

During the first two years of NRC licensee implementation of Part 37, a total of 189 violations were cited against the provisions of the rule during inspection activities. More than half of these violations resulted from licensees’ failure to appropriately transition from the requirements of the Orders to those in the rule.

SUBPART A OF 10 CFR PART 37	
Requirement Not Met	Total Violations
37.11, <i>Specific Exemptions</i>	<1%
SUBPART B OF 10 CFR PART 37	
Requirement Not Met	Total Violations
37.21, <i>Personnel Access Authorization requirements for Category 1 and 2</i>	3%
37.23, <i>Access authorization program requirements</i>	21%
37.25, <i>Background investigations</i>	9%
37.31, <i>Protection of Information</i>	2%
37.33, <i>Access authorization Program Review</i>	5%
SUBPART C OF 10 CFR PART 37	
Requirement Not Met	Total Violations
37.41, <i>Security program</i>	3%
37.43, <i>General security program requirements</i>	33%
37.45, <i>LLEA coordination</i>	5%
37.47, <i>Security zones</i>	4%
37.49, <i>Monitoring, detection, and assessment</i>	5%
37.51, <i>Maintenance and testing</i>	2%
37.53, <i>Requirements for mobile devices</i>	<1%
37.55, <i>Security program review</i>	5%
37.57, <i>Reporting of events</i>	1%
SUBPART D OF 10 CFR PART 37	
Requirement Not Met	Total Violations
37.71, <i>Physical Protection in Transit</i>	<1%

Subpart C – Physical Protection Requirements During Use

A total of 112 violations of Subpart C were cited. In the majority of violations where licensees failed to meet the requirements in Subpart C, as was the case for violations against Subpart B, licensees did not fully document how their security program complied with Part 37. For example, licensees failed to fully develop and provide training to staff that have security responsibilities, document annual coordination with the LLEA, ensure detection and communication in the event of loss of primary power source, adequately document and implement the annual maintenance and testing program, adequately implement and document their annual security program review, report suspicious activities within the required timeframe, and report unsuccessful coordination with LLEA. For many inspections citing violations, it was noted that the licensee had continued to implement the Orders as opposed to implementing the requirements in Part 37, which included more planning, procedural, and process elements than the previously-in-force Orders. Violations cited against Section 37.43 of Subpart C, “General Security Program Requirements,” represented the most frequent violation of 10 CFR Part 37. These violations represented 33 percent of the total violations issued in the first 2 years of the Part 37 rule implementation.

Subpart D – Physical Protection in Transit

The NRC inspectors identified one violation of Subpart D, resulting from a licensee’s failure to perform license verification prior to the transfer of a Category 2 quantity of radioactive material. The violation resulted from a failure to comply with 10 CFR 37.31(b), which requires licensees to verify with the NRC’s LVS or the license issuing authority that the transferee’s license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred.

Discussion

In analyzing the violations of Part 37, the NRC assessed the significance of violations as well as their prevalence. No SLI or SLII violations were cited, which indicates that there were no violations with actual safety or security consequences. The majority of the violations (90 percent) were SLIV violations, which indicates that the violations resulted in no or relatively inappreciable potential safety or security consequences. The remaining 10 percent of violations were SLIII, which are those that resulted in or could have resulted in moderate safety or security consequences.

Of the SLIII violations, about 74 percent were related to a violation of Subpart C. The remaining SLIII violations were of Subpart B. No SLIII violations of Subparts A or D were cited. As noted previously, when multiple violations were cited in a single notice of violation (i.e., when multiple violations that share commonality are identified and grouped as a “problem”), the specific violations were counted individually in order to ensure appropriate assessment of non-compliances. In fact, ten of the total 19 SLIII violations were cited in a notice of violation issued to one individual licensee. Consequently, of the 61 licensees that received violations during the evaluation period, only six of the licensees received SLIII violations. The SLIII violations were consistent with the overall trends in violations of the rule in that many were the result of inadequate understanding of certain rule requirements by licensees.

Examples of the SLIII violations included failure to continuously monitor and detect without delay all unauthorized entries into the licensee’s security zone when staff members, who were relied upon to provide the continuous monitoring and detection via direct visual surveillance, were not working due to observance of holidays; failure to develop a written security plan and procedures to document how the security plan will be met; failure to have two independent

physical controls that form tangible barriers against unauthorized removal when a mobile device is not under direct control and constant surveillance (mobile device was stored overnight next to, but not inside, a storage vault); failure to provide an alternative data transmission and processing capability, in the event of a loss of the primary means of data transmission, as a result of only being able to communicate with an offsite central alarm system via a single phone line; and failure to coordinate with LLEA annually.

None of the SLIII violations were cited as a result of actual safety or security consequences (i.e., theft of Category 1 or 2 radioactive material). Rather, the violations were indicative of licensee failures to adequately restrict access to or provide security for Category 1 or 2 radioactive material such that moderate safety or security consequences could have resulted had the violations been combined with circumstances such as adversarial intent.

The majority of the violations of the rule were cited against Subparts B and C and shared a common theme; they resulted from a lack of transition to the requirements of Part 37 from the previously-in-force Orders. In these cases, the licensees had documentation and physical security measures in place that were suitable for compliance with the Orders but did not update or change documentation to reflect the requirements of the new regulation. This generally resulted in two distinct violations against Subpart B and C. Common terms used in inspection reports included that licensees: “misunderstood,” “didn’t fully understand,” “didn’t consider fully,” “displayed a lack of thoroughness,” or “had an incomplete knowledge and understanding,” of the Part 37 requirements.

While some of the violations resulted from a failure to follow requirements that the staff determined to be clear and readily understood (e.g., failure to properly secure a source); a significant number of the violations resulted from a lack of understanding of the requirements, or from a lack of development of the program infrastructure (e.g., plans and policies, annual program reviews) that is required under the Part 37 rule, but had not been required by the Orders.

Only one violation of Subpart A was cited and only one violation of Subpart D was cited. A low incidence of violations of Subpart A is consistent with the nature of the section. Subpart A provides general provisions for the rule, including the scope, definitions, and exemptions. As such, failures to comply with Subpart A should be limited to instances of inadequate implementation of the exemptions allowed by 10 CFR 37.11, which is the portion of the rule that was cited in the one violation identified in Subpart A.

The low number of violations (one) of Subpart D for the protection of materials in transit could be because the majority of large manufacturer and distribution companies that consistently ship Category 1 and 2 radioactive materials are licensed by Agreement States. This assessment only looked at NRC licensees. Additionally, for licensees that transport their own sources, the security requirements for transportation are largely the same as they had been under the Orders or that exist for compliance with safety requirements, so the requirements are well-understood.

Overall, the two most frequent violations (including SLIII and SLIV) of the rule were violations related to procedures. There were 26 violations of 10 CFR 37.23(f), which requires that access authorization program requirements of Subpart B be documented in procedures. Similarly, there were 25 violations of 10 CFR 37.43(b)(1), which requires that security program requirements in Subpart C be documented in procedures.

In total, more than 25 percent of all cited violations were failures to adequately document program requirements in procedures. Licensees were not required to have documented

security programs under the Orders; however, under Part 37, licensees have the responsibility to develop, document, and implement security plans and access authorization programs that satisfy specific requirements set forth by the rule. The analysis of inspection results from early implementation of the rule demonstrates that licensees have had issues implementing new planning, procedure, and documentation requirements. Conversely, for protective measures that remained unchanged between the Orders and the rule, licensees demonstrated a high level of compliance.

Inspection Results Assessment Outcome

The NRC determined that, although substantial guidance has been issued on the new rule and the differences between the Orders and the rule, further outreach is necessary. When paired with the March 2016 deadline for Agreement State implementation of Part 37-compatible requirements, it is evident that communication to licensees regarding the inspection experience obtained and resources available to licensees to aid in the transition from the Orders to the rule is warranted. The NRC plans to prepare a generic communication to ensure licensee awareness of inspection experience in the implementation of Part 37 as well as the availability of reference material such as the crosswalk between the Orders and Part 37 requirements.

4.2 Events

Reporting theft or loss of radioactive material is an important requirement for NRC and Agreement State licensees to ensure the regulatory authority is notified as soon as possible of events regarding radioactive material. These reporting requirements are found under 10 CFR Part 20, Subpart M³. For Category 1 and 2 radioactive materials, Part 37 imposes reporting requirements⁴ beyond those of Part 20 related to attempted or actual theft, sabotage, or diversion of radioactive material. The NRC collects the information related to these event reports within the Nuclear Material Events Database (NMED). The staff searched NMED specifically for reports of theft of Category 1 and 2 radioactive materials. In order to facilitate this analysis, the staff expanded the scope of the review to include Agreement States and to include the entire time period during which the Orders were in effect⁵. Since May 2006 (when the security Orders went into effect), there have been no thefts of Category 1 radioactive materials and six thefts of Category 2 radioactive materials. Prior to the security Orders, from 1990 to April 2006, there had been 20 reported thefts of a total of 33 sources/devices⁶ that ranged in quantity (e.g., Category 2 or Category 3). Three of the events involved multiple sources/devices, with zero thefts totaling up to a Category 1 quantity of radioactive material.

³ 10 CFR 20, Subpart M, requires licensees to report to the NRC immediately when the occurrence of any lost, stolen, or missing licensed material becomes known to the licensee. Category 1 and 2 materials are included in the quantities of licensed material subject to this reporting requirement.

⁴ 10 CFR 37.57 requires licensees to (1) immediately notify the LLEA after determining that an unauthorized entry resulted in an actual or attempted theft, sabotage, or diversion of a Category 1 or Category 2 quantity of radioactive material and (2) assess any suspicious activity related to possible theft, sabotage, or diversion of Category 1 or Category 2 quantities of radioactive material and notify the LLEA as appropriate. For events or activities in which the LLEA is notified, licensees are required to make a report to the NRC within 4 hours.

⁵ The Orders were issued in November 14, 2005, and licensees were given 6 months to come into compliance with the requirements. 10 CFR Part 37 was issued in March 2013. The NRC licensees had until March 2014 to come into compliance, and Agreement States had until March of 2016 to implement compatible, legally binding requirements for their licensees.

⁶ Reports from 1990-2006 used different conventions for reporting the theft of radioactive material. For example, a report might state that 6 radiography cameras were stolen totaling X Ci of iridium-192. Such reports did not specify the individual activity of the sources, so correlating the theft event to specific Categories of material (e.g., Category 2 or Category 3) for individual sources was not possible.

INDUSTRIAL RADIOGRAPHY

Industrial radiography is a common application of Category 2 quantities of radioactive material. Of the events that are required to be reported, radiography events constitute the majority of the events reported due to the mobile nature of the work which often leads to human error in controlling the materials while in use, storage, and transit.



Top:
Radiography Camera



Bottom:
Truck used for
industrial
radiography field
work

The six reported thefts of Category 2 radioactive materials since 2005 were of radiography cameras containing iridium-192. The events all occurred in Agreement States, with the two 2015 events occurring in an Agreement State that had not yet implemented Part 37-compatible requirements. Of the six reported thefts, five of the sources were recovered and returned to the licensee. The device that was not recovered quickly decayed below the threshold deemed risk-significant. Following an event, the NRC or Agreement State authority conducts an assessment to determine the appropriate response, and, for instances of loss or theft of risk-significant radioactive materials, typically conducts a reactive inspection. The events listed above were investigated by the licensee's regulator at the time of occurrence, and appropriate enforcement actions were taken against the licensees. The staff reviewed the circumstances of these cases against the safety and security requirements in the *Code of Federal Regulations* to evaluate whether there are any "gaps" in the requirements that would have allowed these events to occur had the licensees been in compliance with Part 37 at the time of the event and found none. On the contrary, the staff found a number of requirements that would have prevented such events from occurring. Note that 10 CFR Part 20, Part 30, and other related requirements have been, and continue to be, in effect for the safe and secure use of these materials, and that the requirements of Part 37 provide an enhanced level of protection.

Besides the theft of material, other security-related events must be reported to the NRC, such as suspicious activities and any attempts at unauthorized access. Although some of the reported incidents contain details that demonstrate the ability of security measures to deter or hamper efforts to gain access to sources, the majority describe more general concerns, such as people taking pictures of facilities or unknown persons requesting tours of facilities. The NRC evaluates each report to ensure that appropriate law enforcement and intelligence agencies are notified, and to use combined agency resources and systems to track trends in activities that could lead to actual malicious activities against the United States. There has been no overall increase in the number or types of suspicious activities tracked by the NRC that are related to the use of radioactive materials at such facilities. The staff actively monitors suspicious activities to ensure adequate protection of these materials in a fluid threat environment.

Other events that can impact public health and safety but do not involve criminal or suspicious activity are also reported and tracked. This additional reporting includes incidents where sources have fallen off/out of a truck, been left at a job site, left in a vehicle, lost by the shipping company, or otherwise unattended. Although a common perception may be that sources being left unattended occurs frequently, given the number of radioactive sources in use and in transit in the United States, these incidents are actually not very common. Not including the six actual

CASE STUDY: PROTECTION AGAINST THEFT

Of the six instances of theft of risk-significant radioactive material that occurred from 2006-2016, five were the result of theft of a source that was stored on a truck, or theft of a truck that had a source onboard. The following regulatory requirements in Title 10 of the *Code of Federal Regulations* currently apply to protection of this material and could have prevented the thefts, had they been implemented:

- *20.1801, Licensee required to secure licensed material from unauthorized removal.*
- *20.1802, Licensee required to control and maintain constant surveillance of licensed material not in storage.*
- *34.23, Licensees required to lock radiography devices, storage containers, and source changers when not under direct surveillance.*
- *37.43, Licensees required to establish a security plan and implementing procedures for its specific operations. Licensees required to ensure that individuals implementing the security program understand and are capable of implementing such duties and provide refresher training annually.*
- *37.49, Licensees required to establish and maintain the ability to detect without delay unauthorized entries into security zones. Licensee required to establish a means to immediately detect unauthorized removal of Category 1 or 2 material from the security zone.*
- *37.53, Licensees are required, with limited exceptions, to immobilize the vehicle when devices are not under direct control and surveillance by licensee.*

The analysis demonstrates that the current regulatory infrastructure provided by Parts 20, 34, and 37 for these materials is robust, and if followed, capable of protecting against theft.

thefts discussed above, since implementation of the Orders, there were 29 incidents reported that involved Category 1 and 2 quantities of radioactive material. Some of these reports were of instances where devices were inadvertently left unattended for some period of time (e.g., left at a jobsite, or left unlocked in storage) but were retrieved. More commonly though, they resulted from shipments that were not received when anticipated but were ultimately located and delivered correctly. This was the case in 13 of the 29 events. Of this population of events, there were only two that involved Category 1 quantities of radioactive materials, both of which were shipping errors; the remaining events were associated with Category 2 quantities of radioactive material. None of these events were security-related.

Events Assessment Outcome

In all the events, it is clear that carelessness or human error contributed to the thefts and that, had the existing regulatory requirements in effect for the storage and control of licensed material been followed, the thefts could have been prevented.

The analysis of events from 1990 until implementation of the Orders showed, similarly, that a robust regulatory infrastructure has existed for decades to ensure the protection and security of sources, and that thefts are generally infrequent in nature and occur as the result of crimes of opportunity enabled by inadequate implementation of existing requirements. The augmenting of specific security practices, as required by Part 37, provides an enhanced level of protection against theft of the sources by minimizing the opportunity for theft to occur.

4.3 Additional Assessment Activities

In order to support the analysis of inspection outcomes and events and to provide a holistic and integrated assessment of the effectiveness of Part 37, the NRC performed a comprehensive evaluation of the rule and associated guidance. Referred to as the “program review,” this effort involved not only the evaluation of events, incidents, and inspection results, but also analyzed the specific concerns raised in the 2012 and 2014 GAO audits; GAO-12-925 “Nuclear Nonproliferation: Additional Actions Needed to Improve Security of Radiological Sources at U.S. Medical Facilities,” and GAO-14-293, “Nuclear Nonproliferation: Additional Actions Needed to Increase the Security of U.S. Industrial Radiological Sources.” As a result, the program review also considered the following topics:

- Trustworthiness and reliability program;
- Collocation of well logging sources;
- Enhanced tracking and accounting of radioactive sources; and
- Training for NRC and Agreement State inspectors.

In addition to evaluating specific facets of the Part 37 security program requirements and infrastructure described above, the staff conducted a comparison of Part 37 radioactive material security requirements and associated guidance with other international recommendations and material security programs. This consisted of reviewing national material security programs that are comparable to Part 37 regulatory requirements and identifying any differences in the security programs used by other nations and the International Atomic Energy Agency. Observations in which security requirements and practices differed between the United States and other nations were evaluated and considered by the NRC staff as part of the program review.

The program review also entailed extensive stakeholder outreach. Specifically, the staff conducted numerous outreach activities to seek feedback from stakeholders regarding the clarity and effectiveness of the rule and associated guidance documents. These activities included issuance of a *Federal Register* notice requesting public comments on a series of questions regarding the effectiveness and clarity of the rule and guidance as well as holding four webinars and a public meeting at NRC Headquarters to gather feedback on stakeholder experiences, perspectives, and challenge areas. Each public comment received was considered by the NRC staff to determine if follow-up action, such as considering changes to the rule or guidance, was warranted.

Finally, the program review sought to incorporate feedback regarding the rule through the analysis of observations and recommendations made by external Independent Assessment Consultants (IACs). In October 2014, the NRC Office of Nuclear Material Safety and Safeguards appointed three consultants with specific expertise to assist in the program review. Each consultant had extensive knowledge of radioactive material safety and security and evaluated a specific topic associated with the program review. The IACs assessed:

- Clarity of the requirements set forth in Part 37, including implementing guidance and best practices documents;
- Completeness and thoroughness of staff’s efforts to assess the clarity of the Part 37 rule and guidance; and

- The NRC's rollout of Part 37, considering training and guidance for inspection, communication to stakeholders (licensees and Agreement States), and Agreement State rollout of compatible requirements.

The extensive nature of the program review enabled the NRC to obtain implementation information as well as stakeholder feedback related to the rule, which helped to inform the overall conclusions regarding the rule's effectiveness. As described below, the analysis of inspection experience, when paired with the other program review activities, identified numerous enhancements that could improve the clarity of the rule and associated guidance and, subsequently, result in a more robust national program for the security of Category 1 and 2 radioactive materials.

The program review activities resulted in the analysis of over 200 observations and recommendations, including recommendations made by the IACs; comments and questions provided by stakeholders; results from GAO reports; and observations identified by NRC staff during review of the rule, guidance, and inspection experience. Based on the program review, the NRC determined that the requirements of Part 37 are effective in preventing the theft or diversion of risk-significant quantities of radioactive materials. The NRC also concluded that potential rule clarifications and guidance initiatives could help to enhance the clarity and effectiveness of the rule, ensure better understanding of security expectations, and allow for more complete and adequate implementation. Highlights from the analysis of these issues are described below:

- Challenges in the rollout of Part 37 were noted by the IACs, further emphasizing the need for additional outreach beyond that already provided by the NRC during the transition process to ensure licensee understanding of the requirements.
- Significant differences in views among stakeholders were heard during the analysis and discussion of reinvestigation periodicity for trustworthiness and reliability determinations. The staff ultimately recommended retaining a 10-year periodicity while conducting further evaluation of potential strategies for insider mitigation, such as requiring self-reporting of legal actions and periodic behavioral observation of individuals to identify potential behaviors adverse to the trustworthiness and reliability determination in between the reinvestigations.
- Assessment of the potential need to revise the definition of "aggregation" resulted in recommendations to revise the pre-licensing activities performed by the NRC for well logging licensees that are capable of aggregating above a Category 2 quantity of radioactive material to ensure a thorough evaluation of their strategies for controlling radioactive material.
- Stakeholder feedback showed that there was confusion over certain security terminology in the rule that will require a thorough analysis and consideration and subsequent review in guidance to ensure clarity and consistency in use and application.
- Consideration of adding disqualifying criteria to the rule for making trustworthiness and reliability determinations was an item of interest for stakeholders, IACs, GAO, and the NRC, that generated a multitude of diverse perspectives. The NRC determined that further evaluation of the subject would be needed in order to adequately analyze the results of Temporary Instruction (TI) 2800/042, "Evaluation of Trustworthiness and Reliability Determinations," which was completed in November 2016. The NRC will

make a decision regarding disqualifying criteria after analyzing the results from TI 2800/042.

- The assessment of NRC requirements against international guidance and standards, as well as the IACs' review, identified differences between U.S. standards and requirements of other countries. Substantial changes were not recommended regarding areas such as inclusion of Category 3 material under the provisions of 10 CFR Part 37, because there has been no change in use, availability, or threat directed toward Category 3 material.
- Public feedback and other program review analyses indicated a need for guidance to address provisions for performing background investigations of foreign nationals; expectations for licensees for coordination with LLEA and what to do if coordination fails; reporting requirements when a licensee's security force is also the LLEA; sharing of trustworthiness and reliability information among licensees; reporting of Category 1 shipments to the NRC and/or Agreement State; what constitutes an adequate barrier; and implementation of Part 37 requirements for reactors in different phases of operation and decommissioning. It also identified the need to consider rulemaking to clarify if certain information in the license should be protected information under Part 37 and to make administrative changes to clarify portions of the rule and ensure internal consistency.
- Inspection experience and public feedback indicated a need for guidance to address need-to-know and trustworthiness and reliability determination requirements for certain individuals who have access to protected information as a corollary to their job functions, such as information technology personnel and security service providers.

5.0 Conclusion

The analysis of events and inspection results, combined with the additional assessment activities performed during the program review, demonstrated that Part 37 provides a strong regulatory framework to ensure the security of Category 1 and 2 radioactive materials.

The requirements of Part 37 have increased the security of risk-significant radioactive materials and have heightened licensee awareness of the need to protect these materials and be vigilant in monitoring and controlling them. Provisions such as background investigations assure that individuals are thoroughly assessed for trustworthiness and reliability prior to gaining access to materials. The development of security plans and coordination with LLEA provide readiness to respond to actual or potential events and individuals' awareness of the need to be alert for suspicious activity. Finally, stringent requirements for monitoring the materials when in use, storage, or transport and controlling access to the materials restricts the potential for loss, theft, or diversion and subsequent malicious use.

Part 37 incorporated over a decade of lessons learned by NRC and the Agreement States in implementing enhanced security controls provided in the Orders, and built upon those initial requirements to ensure that licensees implement a robust security program for the protection of Category 1 and 2 radioactive materials. Although the NRC intends to pursue specific outreach actions to communicate relevant information to stakeholders, enhance the clarity of implementing guidance, and even consider rulemaking in limited areas where the regulations could be strengthened or administratively clarified, the overall assessment of Part 37 determined that the regulation itself is effective in achieving its objective: "provide reasonable

assurance of the security of Category 1 or Category 2 quantities of radioactive material by protecting these materials from theft or diversion.”

Appendix A: Acronyms and Abbreviations

CFR	<i>Code of Federal Regulations</i>
Ci	Curie
DHS	Department of Homeland Security
FBI	Federal Bureau of Investigation
FDA	Food and Drug Administration
GAO	Government Accountability Office
IACs	Independent Assessment Consultants
IAEA	International Atomic Energy Agency
IMC	Inspection Manual Chapter
ISMP	Integrated Source Management Portfolio
LLEA	Local Law Enforcement Agency
LVS	License Verification System
NMED	Nuclear Material Events Database
NRC	Nuclear Regulatory Commission
NSTS	National Source Tracking System
SL	Severity Level
Task Force	Radiation Source Protection and Security Task Force
TI	Temporary Instruction
WBL	Web-based Licensing