

**SUMMARY OF NRC STAFF
PROGRAM REVIEW OF 10 CFR PART 37**

**Program Review Team
United States Nuclear Regulatory Commission**

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1.0 Purpose

The purpose of this report is to summarize the results of the program review performed by the Program Review Team (PRT) 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 2 Quantities of Radioactive Material," as directed by the Congress of the United States in Section 403 of Public Law 113-235, "Consolidated and Further Continuing Appropriations Act, 2015" (Appropriations Act); and to fulfill commitments made to the Government Accountability Office (GAO) and the Commission.

2.0 Objectives, Scope, and Methodology

2.1 Objectives

The objectives of the 10 CFR Part 37 program review were to address:

- *H.R. 83, Public Law 113-235, "Consolidated and Further Continuing Appropriations Act, 2015," which states in Section 403:*
 - (a) "Securing Radiological Material. No later than 2 years from enactment of this Act, the Nuclear Regulatory Commission shall provide a report to the Committees on Appropriations of the House of Representatives and the Senate that evaluates the effectiveness of the requirements of 10 CFR Part 37 and determines whether such requirements are adequate to protect high-risk radiological material. Such evaluation shall consider inspection results and event reports from the first two years of implementation of the requirements in 10 CFR Part 37 for NRC licensees."
 - (b) "No later than 2 years after the completion of the NRC evaluation required in subsection (a), the Government Accountability Office, with assistance from an independent group of security experts, shall provide a report to Congress on the effectiveness of the requirements of 10 CFR Part 37 for NRC and Agreement State licensees and recommendations to further strengthen radiological security."
- *NRC Report on Security of Radiation Sources used by Medical Facilities as requested in the Senate Report accompanying the Energy and Water Development and Related Agencies Appropriations Act for Fiscal Year 2014*

As required by Public Law 113-76, the "Consolidated Appropriations Act, 2014," the NRC submitted a report to address NRC actions to strengthen the agency's security requirements for radiation sources used by hospitals and medical facilities. This report was requested following the findings of the GAO report GAO-12-925, "Nuclear Nonproliferation: Additional Actions Needed to Improve Security of Radiological Sources at U.S. Medical Facilities." In this report, the NRC agreed to track the inspections of NRC licensees during the first 1 to 2 years post-implementation [2015–2016], and use that information to conduct a preliminary review of the effectiveness of 10 CFR Part 37. Based on this review, staff committed to submit recommendations to the Commission for consideration as appropriate.

- *NRC Response to GAO-14-293, "Nuclear Nonproliferation: Additional Actions Needed to Increase the Security of U.S. Industrial Radiological Sources," dated June 12, 2014*

The NRC committed to evaluate the following GAO recommendations as part of the 10 CFR Part 37 program review:

- Consider whether the definition of collocation should be revised for well logging facilities that routinely keep radiological sources in a single storage area but secured in separate storage containers.
 - Conduct an assessment of the trustworthiness and reliability (T&R) process by which licensees approve employees for unescorted access to Category 1 and 2 radioactive material to determine if it provides reasonable assurance against insider threats, including; 1) determining why criminal history information concerning convictions for terroristic threats was not provided to a licensee during the T&R process to establish if this represents an isolated case or a systemic weakness in the T&R process; and 2) revising, to the extent permitted by law, the T&R process to provide specific guidance to licensees on how to review an employee's background. The GAO also recommended that NRC consider whether certain criminal convictions or other indicators should disqualify an employee from T&R or trigger a greater role for the NRC.
 - Assess the effectiveness of NUREG-2166, "Physical Security Best Practices for the Protection of Risk Significant Radioactive Material," during the first one to two years following implementation of Part 37 to determine if any revisions to this document are needed, and make revisions accordingly using the public participation process.
- *Enhanced Tracking and Accounting of Radioactive Sources*

The review in this area updates the Commission in accordance with commitments made in SECY-16-0021, "Discontinuation of Rulemaking Activities" (Agencywide Documents Access and Management System (ADAMS) Accession No. ML15336A324). In SECY-16-0021, the staff committed to consider, as part of the program review, whether additional measures are warranted for Category 3 sources and to submit a rulemaking plan to the Commission if the staff determined that the National Source Tracking System (NSTS) should be expanded to include Category 3 sources. NSTS is a computer system that accounts for Category 1 and 2 radioactive sealed sources from the time they are manufactured or imported through their disposal or export, or until they decay below the Category 2 threshold. In SRM-SECY-16-0021, the Commission approved the staff's recommendation.

The consideration of including Category 3 sources in NSTS was intended to encompass an evaluation of the results of an ongoing GAO Engagement, Code 361565, "NRC Licensing of Radioactive Materials," which was, at that time, expected to be issued in early 2016. GAO did not complete its final report on radioactive materials licensing in early 2016, when NRC staff expected it, but instead issued the report in July 2016. In order to ensure the issue of expanding the NSTS to include Category 3 sources was informed by the latest information, that issue was not addressed by this 10 CFR Part 37 program review. Instead, it is being addressed by a working group established in response to this latest GAO report.

As part of the review of enhanced tracking and accounting measures, the PRT evaluated the functionality and user satisfaction with NSTS. Specifically, the PRT considered measures to improve NSTS and enhance its functionality.

2.2 Scope

The PRT reviewed NRC activities related to the development, implementation and oversight of 10 CFR Part 37 as part of the program review. The regulations went into effect for NRC licensees beginning in March 2014; therefore, the majority of information evaluated was for the period from March 2014 to March 2016, consistent with the mandate from Congress. Additional information extending back to the implementation of the Orders was included as appropriate to enhance the utility of the analysis.

The 10 CFR Part 37 program review entailed the following nine assessment activities: (1) analysis of 10 CFR Part 37 inspection results from the first 2 years of rule implementation; (2) review of events from the Nuclear Material Events Database (NMED) and Security Information Database; (3) evaluation of the 10 CFR Part 37 T&R program; (4) consideration of the definition of aggregation as it applies to well logging sources; (5) assessment of the adequacy of the materials security training program for NRC and Agreement State inspectors; (6) evaluation of enhanced tracking and accounting of radioactive sources; (7) conduct of a comparison to identify and evaluate differences between 10 CFR Part 37 and international standards and guidance; (8) assessment of separate, independent aspects of 10 CFR Part 37 by three external independent assessment consultants (IACs); and (9) consideration of comments, questions, and recommendations made during stakeholder outreach efforts.

The program review charter (ADAMS Accession No. ML15254A374) was developed to include the scope identified above in order to ensure sufficient analysis was conducted to address the Congressional mandate that was codified in the Appropriation Act; satisfy commitments made in response to GAO audits (GAO-12-925 and GAO-14-293); and meet commitments made in SECY-16-0021.

2.3 Methodology

The PRT examined data from a multitude of sources in order to gather the widest possible amount of data on the implementation of security measures for protecting Category 1 and 2 radioactive materials from theft and diversion. These sources included guidance for implementing the requirements of 10 CFR Part 37, such as NUREG-2155, "Implementation Guidance for 10 CFR Part 37, Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material," and NUREG-2166, "Physical Security Best Practices for the Protection of Risk-Significant Radioactive Material." The members of the PRT debated issues internally to reach consensus, then brought recommendations to a Steering Committee consisting of senior managers from the Office of Nuclear Material Safety and Safeguards (NMSS), the Office of Nuclear Security and Incident Response (NSIR), the Office of Nuclear Reactor Regulation, Region III, and the Office of the General Counsel, for direction or approval. This section describes the data gathered and how it was utilized for the evaluation.

2.3.1 10 CFR Part 37 Inspection Results

The PRT reviewed inspection reports documenting the results of inspections performed in the first 2 years of 10 CFR Part 37 implementation for NRC licensees and assessed the number,

type, and severity of violations. The data was also evaluated for trends that may be indicative of needing to enhance the rule or guidance, or taking another action such as issuing a generic communication or conducting training. The PRT membership included a materials inspector from NRC Region III to ensure that sufficient inspection experience and expertise was embedded in the team for consideration of inspection-related issues.

2.3.2 Event Analysis

The PRT evaluated all reports of stolen radioactive material as documented in the NMED, and reports of suspicious activity contained in the Security Information Database. Records were evaluated reaching back to 1990. Since the objective of 10 CFR Part 37 is to prevent the theft and diversion of risk-significant radioactive material, the PRT focused on incidents that were designated or reported as thefts to determine if the incident indicated a gap in the regulatory framework or would have been prevented by implementation of existing regulations. The PRT also analyzed other reportable events, such as losses in shipping events, to assess any potential security nexus that should be addressed in 10 CFR Part 37.

2.3.3 Trustworthiness and Reliability Program

The PRT conducted an assessment of the T&R process by which licensees approve employees for unescorted access to Category 1 and 2 radioactive material to determine if the T&R process provides reasonable assurance against insider threats, in order to satisfy a commitment to GAO based on a recommendation made in GAO-14-293. The PRT sought to: (1) determine why criminal history information concerning convictions for terroristic threats was not provided to a licensee during the T&R process, to establish if this represents an isolated case or a systemic weakness in the T&R process; (2) consider revision of the T&R process to provide specific guidance to licensees on how to review an employee's background; and (3) consider whether certain criminal convictions or other indicators should disqualify an employee from T&R or trigger a greater role for NRC.

In order to gather relevant information to assess the adequacy of the T&R program established under 10 CFR Part 37, in November 2015 the NRC staff issued Temporary Instruction (TI) 2800/042, "Evaluation of Trustworthiness and Reliability Determinations," to provide direction to inspectors in collecting and documenting specific information regarding the conduct of licensees' trustworthiness and reliability determination processes under 10 CFR Part 37. The TI is performed in accordance with routine security inspections conducted under Inspection Procedure 87137, "10 CFR Part 37 Materials Security Programs," and seeks to gather information regarding: (1) whether licensees have established criteria that would disqualify an individual from unescorted access to Category 1 and Category 2 quantities of radioactive material; (2) whether licensees had either approved and/or denied any individuals for unescorted access and noted a conviction, charge or report involving certain circumstances as part of the determination documentation; and (3) the total number of individuals approved and/or denied unescorted access and the number or individuals approved and/or denied access to a security plan and implementing procedures since the 10 CFR Part 37 implementation date. The TI will close on November 25, 2016.

To conduct its review, the PRT also assessed elements of the T&R process through the review of recommendations made by the IACs, assessment of comments received from stakeholders, and analysis of inspection findings.

2.3.4 Aggregation of Well Logging Sources

The PRT considered whether the definition of collocation should be revised for well logging facilities that routinely keep radiological sources in a single storage area but secured in separate storage containers based on a recommendation made by GAO in GAO-14-293. To conduct the program review, the PRT evaluated licensee configurations for the storage of well logging sources, measures for protecting the sources in storage, and inspector experience regarding aggregation of well logging sources.

2.3.5 Training for NRC and Agreement State Inspectors

During the program review, the PRT examined the existing qualification program for inspectors and evaluated the effectiveness of specific courses and activities that address materials security in order to determine if the training program was effective in preparing inspectors to conduct security inspections for oversight of 10 CFR Part 37 implementation. In a 2012 report, GAO-12-925, GAO recommended that the NRC provide more comprehensive training to the NRC and Agreement State inspectors to improve their security awareness and ability to conduct related security inspections. The NRC reviewed and revised the inspector qualification program for radioactive material security inspections in 2013, prior to the issuance of the 10 CFR Part 37 rule. The PRT's effort evaluated the effectiveness of the revised training program to ensure its suitability for providing inspectors with the skills necessary to perform inspections in accordance with materials security requirements.

2.3.6 Enhanced Tracking and Accounting of Radioactive Sources

The PRT evaluated the measures for tracking and accounting of radioactive materials as part of the program review. Specifically, the PRT considered measures to improve NSTS — a computer system that accounts for Category 1 and 2 radioactive sealed sources from the time they are manufactured or imported through their disposal or export, or until they decay below the Category 2 threshold. The NSTS is part of the NRC's Integrated Source Management Portfolio that also includes the Web-based Licensing (WBL), and the License Verification System modules to enable the security and control of radioactive materials and license information. The review of enhanced tracking and accounting of radioactive sources involved assessing the results of a marketing firm survey and extensive outreach efforts to assess the need for enhancements to NSTS.

2.3.7 Regulatory Comparison

The NRC staff conducted a comparison of 10 CFR Part 37 radioactive material security requirements and associated guidance with other international guidance and material security programs. This consisted of reviewing national material security guidance or requirements that are comparable to 10 CFR Part 37 regulatory requirements (e.g., the International Atomic Energy Agency (IAEA), Australia, Canada, Finland, France, and Spain) and identifying any differences in the security programs used by other nations and the IAEA. Observations where security requirements and practices differ between the U.S. and other nations were evaluated by the PRT. The comparison also evaluated the consistency of the security requirements of the U.S. with the IAEA's *Code of Conduct on the Safety and Security of Radioactive Sources* (Code of Conduct) and Nuclear Security Series guidance documents. In 2004, the U.S. made a political commitment to implement the Code of Conduct, which describes at a high level the control of radioactive materials within each nation.

2.3.8 Independent External Review

The PRT also considered observations and recommendations made by three IACs in order to determine if rule changes, guidance revisions, or other courses of action were necessary to enhance the effectiveness of 10 CFR Part 37. In October 2015, NMSS appointed three consultants with specific expertise to assist in the program review of 10 CFR Part 37. Each consultant had extensive knowledge of radioactive material safety and security and reported directly to the Director of the Division of Material Safety, State, Tribal, and Rulemaking Programs in NMSS. These consultants reviewed separate, independent aspects of 10 CFR Part 37 and documented their observations and recommendations in reports submitted in March 2016. Their reports are available in ADAMS (referenced in the applicable sections below), and their observations and recommendations are summarized in this report.

2.3.9 Stakeholder Outreach

The NRC staff published a *Federal Register* notice (81 FR 13263) that requested public comment on a series of questions regarding the effectiveness and clarity of the 10 CFR Part 37 regulations. To facilitate input, between March and May 2016, the staff conducted a series of four webinars (ADAMS Accession Nos. ML16158A205, ML16158A207, ML16158A208, and ML16158A209) and a public meeting (ADAMS Accession No. ML16158A210) to gather stakeholder experience with 10 CFR Part 37. Additionally, questionnaires were developed and issued to a total of nine non-Federal NRC licensees who possess or did possess at one time Category 1 and/or Category 2 quantities of radioactive materials. Eight of those nine licensees were interviewed. A total of eight Federal licensees were also issued questionnaires and/or participated in interviews. Interviews were also conducted with staff from the NRC, Agreement States, and the Department of Energy National Nuclear Security Administration (NNSA).

3.0 Summary of Findings

This section summarizes the conclusions of the program review activities described in Sections 2.3.1-2.3.9 above.

All the issues evaluated in the program review were deliberated by the PRT and presented to the Steering Committee for alignment and then divided into decision bins according to the type of action recommended to address the issue. These bins included the following actions: consider the recommendation in rulemaking; revise guidance; pursue other course of action; conduct further evaluation; or take no additional action. The items binned in “conduct further evaluation” may require input from outside stakeholders and/or designation of a technical working group to focus on how recommendations will impact licensees. These items will be included in future agency activities (i.e., rulemaking through the rulemaking process, guidance changes developed by NRC and Agreement State working groups, etc.) as appropriate, consistent with business line priorities and budgeted resources.

For the purposes of this evaluation, the “take no additional action” bin includes issues for which existing practice, regulation, or guidance is deemed sufficient, for which activities to address the issue are ongoing or planned already, or for which the NRC does not have explicit regulatory authority. This report summarizes the results of the program review which have generated a recommendation for action.

3.1 Part 37 Inspection Results

From March 2014 to March 2016, a total of 255 inspections were conducted to confirm NRC licensee compliance with the requirements of 10 CFR 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 10 CFR Part 37, these inspections account for 17 percent of the affected licensee population.

The NRC Headquarters and Regional staff closely tracked the results of the 10 CFR Part 37 inspections. To ensure consistent application of enforcement, the NRC's traditional Enforcement Program was used for escalated enforcement activities (severity level (SL) III¹ or higher), and the Security Issues Forum² was used to disposition SLIV³ violations. The Enforcement Policy and experience gained from the Orders was generally applied to the 10 CFR Part 37 inspections; however, given that Part 37 includes new requirements, there were situations not previously addressed. 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 PRT conducted an in-depth analysis of the violations cited during inspections to determine if the issues demonstrated any problems with the regulation itself.

Violations were cited against requirements contained in each of the four Subparts of 10 CFR 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 was identified in Subpart A (10 CFR 37.11(b)) for a licensee failing to revise the security plan required by 10 CFR Part 73 to include activities related to Category 2 radioactive material stored in the same room as the licensee's research and test reactor. 10 CFR 37.11(b)

¹ SLIII violations are those that resulted in or could have resulted in moderate safety or security consequences (e.g., violations that created a potential for moderate safety or security consequences or violations that involved systems not being capable, for a relatively short period, of preventing or mitigating a serious safety or security event).

² The NRC staff applies the Security Issues Forum process to deliberate SLIV violations issued against 10 CFR Part 37 to ensure they are appropriately characterized and consistently cited for significance.

³ 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 (e.g., violations that created the potential of more than minor safety or security consequences).

allows licensees to be exempted from the requirements of Subparts B and C of 10 CFR Part 37 to the extent that the licensee's activities are included in a security plan required by 10 CFR Part 73.

Subpart B — Background Investigations and Access Control Program

A total of 75 violations were cited against Subpart B of 10 CFR Part 37. In the majority of cases, licensees did not fully document how their access authorization program complied with 10 CFR Part 37. For example, licensees failed to provide Reviewing Official (RO) oath and affirmations to the NRC; complete informed consent forms; or have a documented basis for trustworthiness and reliability determinations. Additionally, a few licensees did not consider that information technology (IT) staff could potentially access protected security information.

Subpart C — Physical Protection Requirements During Use

A total of 112 violations were cited against Subpart C of 10 CFR Part 37. In the majority of cases, licensees failed to adequately document how their security program complied with 10 CFR Part 37. Licensee programs and documentation were suitable for compliance with the previously-in-force security Orders but were not updated or revised to reflect the requirements of 10 CFR Part 37. For example, licensees failed to fully develop and provide training to staff that have security responsibilities; document annual coordination with the local law enforcement agency (LLEA); evaluate redundancy of their security system to 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.

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. 10 CFR 37.31(b) requires licensees to verify with the NRC's license verification system 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 cited against implementation of 10 CFR Part 37, the NRC assessed the significance of violations as well as their prevalence. The majority of the violations (90 percent) cited against the rule were SLIV violations, and no SLI or SLII violations were cited, which is representative of the lack of actual safety or security consequences related to the violations of 10 CFR Part 37 implementation (there were no violations for theft of Category 1 or 2 radioactive material as no thefts of such material occurred for NRC licensees since implementation of the new rule). Evaluation of escalated enforcement cases (SLIII) identified that about 74 percent of escalated enforcement issues were related to a violation of Subpart C. The remaining SLIII violations were cited against Subpart B, as no escalated enforcement actions were identified for a violation of Subparts A or D. 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. This is an important detail to consider given that 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 escalated violations.

Examples of the SLIII violations cited against Subparts B and C 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 evaluate the need to know and determine the trustworthiness and reliability of individuals with access to the licensee's security plan and implementing procedures (specifically, IT personnel);
- Failure to provide an alternative data transmission and processing capability in the event of a loss of the primary means of data transmission (licensee was only able to communicate with an offsite central alarm system via a single phone line); and
- Failure to coordinate with LLEA annually.

These violations were consistent with the overall trends in violations cited against the rule in that many were the result of inadequate understanding of certain rule requirements by licensees.

As demonstrated in Subpart-specific discussions above, the distribution of violations cited against licensees for 10 CFR Part 37 implementation were largely focused in Subparts B and C. Only one violation was cited against Subpart A, and only one violation was cited against Subpart D.

A low incidence of violations against 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 against in the one violation identified in Subpart A.

The PRT noted that the low number of violations (one) cited under Subpart D for the protection of materials in transit could be an underrepresentation of the number of violations nationwide in this Subpart because the majority of large manufacturer and distribution companies that consistently ship Category 1 and 2 radioactive materials are licensed by Agreement States. 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.

The majority of the violations issued against 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 10 CFR 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 10 CFR Part 37 requirements.

While some of the violations cited in the analysis resulted from a failure to follow requirements that the PRT 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 10 CFR Part 37 rule, but had not been required as part of the Orders.

3.1.1 Recommendations

The requirements of 10 CFR Part 37 are effective in preventing the theft or diversion of risk-significant quantities of radioactive materials; however, the PRT identified some actions that could clarify security expectations. These items are based upon violations and inspection experience.

3.1.1.1 Pursue Other Course of Action

- Issue Generic Communication to licensees as an additional announcement that the requirements of 10 CFR Part 37 are now in force for all materials licensees nationwide, and provide additional information as appropriate. Include direct links to useful, already-publicly available information available to help with implementation: the “crosswalk” between the Orders and 10 CFR Part 37, NUREG-2155, and NUREG-2166. This additional communication would be intended to counter the prevailing experience with licensees who did not adequately account for the changes in requirements in converting from the Orders to 10 CFR Part 37. The Generic Communication could also describe the results of inspection experience to further enhance licensee understanding of and compliance with the regulations in 10 CFR Part 37.

3.1.1.2 Revise Guidance

- Include more discussion of both primary and backup power supply systems and reliability issues and the implementation of 10 CFR 37.49(a)(3)(i).
- Include direction on the evaluation of routes of incursion as well as the adequacy and continuity of barriers.
- Include guidance regarding licensee use of assumed LLEA response times in the design of security plans, and describe the uncertainty associated with such assumptions due to LLEA prioritization of response demands.
- Clarify the definition of “security zone” and elaborate on the importance and application of the trustworthy and reliable determination in the physical control of the security zone as the basis for the physical security program.
- Revise enforcement guidance to ensure the examples are clear with regard to application to 10 CFR Part 37 requirements.

3.2 Event Analysis: Nuclear Material Events Database and Security Information Database

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 M. For Category 1 and 2 radioactive materials, 10 CFR Part 37 imposes reporting requirements beyond those of 10 CFR 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 NMED. The staff searched NMED specifically for reports of theft of Category 1 and 2 radioactive materials. 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/devices⁴ 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.

The six reported thefts of Category 2 radioactive materials since 2005 were of radiography cameras containing iridium-192. The events all occurred while the Orders were in effect, with the two 2015 events occurring in an Agreement State that had not yet implemented 10 CFR Part 37-compatible requirements. The events were thoroughly 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 of the Orders, 10 CFR Parts 20 and 37, and other applicable requirements to evaluate whether any "gaps" in the requirements exist, and determined that the requirements would have prevented the events had they been implemented in the six reported cases of theft.

Besides the theft of radioactive 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 general concerns of activities that may have a nexus to radioactive material security. These items have been reported, as required by 10 CFR Part 37, out of an abundance of caution. The NRC evaluates each report to determine whether NRC follow-up action is necessary and to ensure that appropriate law enforcement and intelligence agencies are notified. 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 Category 1 and 2 radioactive materials or facilities that are authorized to use such radioactive materials.

Other events that could impact public health and safety are also reported and tracked. Incidents where sources have fallen off/out of a truck, been left at a job site, left in a vehicle, lost by a shipping company, or otherwise unattended are also reported. Given the large number of radioactive sources in use and in transit in the United States, incidents are uncommon in frequency. Specifically, there are approximately 77,000 Category 1 and 2 sources in use in the

⁴ 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.

United States. Many of these sources, such as radiography sources, are used at temporary job sites on a routine basis and are transported in a vehicle as part of their normal use. For the 77,000 nationally tracked sources, approximately 43,000 source transfers occur per year for purposes such as procurement of new sources and source change-outs; this includes sources transported by licensees themselves and sources transported through the use of common carriers. Not including the six actual thefts discussed above, since 2005 there were 29 incidents reported that involved Category 1 and 2 quantities of radioactive material, and 37 incidents reported that involved Category 3 quantities of radioactive material. This represents a low incidence of sources being lost or unaccounted for when viewed in light of the overall frequency the sources are transported or transferred.

3.2.1 Recommendations

The theft events demonstrate that crimes of opportunity can occur when sources are not secured properly. The PRT has not made any recommendations for enhancement to guidance or changes to regulations as a result of event analysis, but recommends that additional communications be provided to licensees about the existence of the regulations in 10 CFR Part 37, as well as the differences between 10 CFR Part 37 and the no-longer-in-force security Orders. Proper compliance with the security requirements in 10 CFR Part 37, had the requirements been in effect at the time of the events, could have prevented the reported events.

3.3 Trustworthiness and Reliability Program

The review in this area addresses GAO concerns pertaining to insider mitigation identified in a 2014 audit (GAO-14-293). The PRT examined the trustworthiness and reliability program and identified recommendations that could strengthen the trustworthiness and reliability process, including rulemaking and additional guidance. Further evaluation of various observations will be combined with feedback from TI 2800/042 to inform the staff's determination of the overall effectiveness of the 10 CFR Part 37 trustworthiness and reliability requirements to mitigate the acts of an insider. Once the actions under the TI are completed, the staff will use the results to determine the appropriate course of action (e.g., additional security measures, guidance documents, rulemaking plan, or licensee outreach). The T&R assessment utilized the following sources of information:

- 10 CFR Part 37 access authorization requirements and associated guidance documents NUREG-2155 and NUREG-2166;
- 10 CFR Part 73 access authorization requirements and associated Regulatory Guide 5.77, "Insider Mitigation Program" ;
- 10 CFR Part 37 regulatory history document, "Technical Basis for Proposed Rulemaking Regarding Fingerprinting and Authorization for Unescorted Access to Radioactive Material" ;
- Transportation Security Administration US Code, Title 49, Part A, Chapter 449, Section 44936, "Employment investigations/ restrictions" ;
- Bureau of Alcohol, Tobacco, Firearms, Explosives US Code, Title 18, Part I, Chapter 10, Section 842, "Unlawful acts" ;
- Centers for Disease Control US Code, Title 18, Part I, Chapter 10, Section 175, "Prohibition with respect to biological weapons" ;
- NRC Temporary Instruction 2800/042, "Evaluation of T&R Determinations" ;
- 10 CFR Part 37 access authorization inspection findings;

- Input from internal and external stakeholders; and
- Recommendations for changes to the T&R program made by the GAO.

The PRT identified 11 issues related to the effectiveness of trustworthiness and reliability requirements for unescorted access to Category 1 and Category 2 quantities of radioactive material and protected information. The 11 issues are summarized below:

- **Gaps in Employment History:** Employment history verification provision in 37.25(a)(3) does not include specific language requiring licensees to determine the activities of individuals while unemployed. Although the guidance in NUREG-2155 states that licensees should determine why these gaps exist, additional guidance should be provided in the NUREG to aid licensees in reviewing periods of unemployment.
- **Requirements for Protected Information:** The “protection of information” provision in 10 CFR 37.43(d)(1) requires licensees to limit access to and unauthorized disclosure of their “security plan, implementing procedures, and the list of individuals that have been approved for unescorted access,” but the other subsections of 37.43(d) omit the last item – the list of individuals approved for unescorted access. This list of individuals that have been approved for unescorted access should be included in each subsection of 37.43(d) that lists information to be protected.
- **Background Reinvestigation Requirements:** Part 37, Subpart B, requires that licensees conduct a reinvestigation every 10 years for any individual with unescorted access to Category 1 and Category 2 quantities of radioactive material. The decision was made to establish a 10-year reinvestigation period instead of 5 years, to be consistent with the Federal Government “L” clearance. The “L” clearance reinvestigation requirement has recently changed to a frequency of every 5 years, prompting a review of this issue.
- **NRC Notification of Individuals on the FBI Terrorist Watch List:** Under 10 CFR Part 37, all applicable NRC and Agreement State licensees are required to submit fingerprints to the NRC for processing. The NRC sends the fingerprints to the FBI, and the results of the criminal history records check are returned to NRC, who forwards the results directly to the licensees. No formal mechanism exists for the FBI to notify the NRC of adverse reports.
- **Trustworthiness and Reliability Disqualifying Criteria:** The NRC has not established disqualifying criteria for access authorizations in 10 CFR Part 37, but does provide guidance in NUREG-2155 and NUREG-2166. The guidance specifies that the included indicators are not meant to be all inclusive nor intended to be disqualifying factors. It is a licensee’s decision as to what criteria it uses for the bases of the T&R determination, and to determine their own disqualifying criteria, if any. Some stakeholders have urged the NRC to establish definitive T&R disqualifying criteria.
- **Insider Mitigation Program (IMP):** Section 73.55, “Requirements for physical protection of licensed activities in nuclear power reactors against radiological sabotage,” has established design requirements to detect, assess, interdict, and neutralize threats up to and including the design basis threat of radiological sabotage (significant core damage or spent fuel sabotage). Reactor licensees must establish and implement an IMP and describe the program in their physical security plans. Part 37 does not have a similar requirement for an IMP.
- **Self-Appointed ROs:** Currently, a small business owner can designate him or herself as the RO without any independent review.
- **Access Authorization for non-Manufacturing and Distribution (M&D) Service Providers:** Rather than requiring that non-M&D service provider licensees establish an access authorization program under Subpart B, 10 CFR Part 37 allows this group of licensees

the option of determining if they want their customer licensees to be able to permit service provider employees unescorted access to Category 1 or Category 2 quantities of radioactive material at customers' facilities. There have been issues with clarity of this provision in terms of the available options for both service providers and for their customers with respect to access authorization.

- **Processing of RO Oath and Affirmations:** 10 CFR Part 37 requires that, after completing the background investigation on the RO, licensees provide under oath or affirmation, certification that the RO is deemed trustworthy and reliable. The regulation and guidance are not consistent as to the submission process for providing oath or affirmation certifications for ROs to the NRC.
- **Unauthorized Access to Protected Information:** There have been a number of inspections where violations have been cited for individuals having access to protected information without a need-to-know and a T&R determination. The violations have primarily involved IT personnel; however, they could also involve security service providers and others. Current guidance does not adequately address need-to-know and T&R determination requirements for these types of individuals.
- **Disclosure of Personal History Information:** 10 CFR Part 37 requires that any individual applying for unescorted access authorization disclose the personal history information that is required for the T&R determination. The guidance in NUREG-2155 is limited regarding the types of information that licensees may want to consider in the T&R determination process (e.g., psychological disorders, drug or alcohol abuse).

3.3.1 Recommendations

The 10 CFR Part 37 T&R requirements have been demonstrated to be effective; however the PRT made recommendations that could strengthen the T&R process.

3.3.1.1 Rulemaking

- Propose adding requirements to 10 CFR 37.43(d) as necessary to add the list of individuals approved for unescorted access to information needing protection. These requirements appear to have been inadvertently excluded from portions of 10 CFR 37.43(d). Revising the rule to include these requirements supports preventing an unauthorized individual from gaining access to a security zone containing Category 1 and Category 2 radioactive material with an altered unescorted access list.

3.3.1.2 Pursue Other Course of Action

- Develop a Memorandum of Understanding (MOU), or other mechanism, with the FBI to notify the NRC when an individual with unescorted access is identified in the FBI Terrorist Screening Database. The NRC currently has an MOU with the FBI to notify the NRC when an individual with unescorted access to a nuclear power plant is identified in the FBI Terrorist Screening Database. The staff should determine if an FBI notification process is also needed for individuals with unescorted access to Category 1 and Category 2 radioactive material, and if so, benchmark the MOU currently in place for reactor licensees. In addition, the staff should develop follow-up actions to take when they receive this notification due to the sensitive nature of this information.

3.3.1.3 Conduct Further Evaluation

The feedback from TI 2800/042 will inform the staff's determination of the overall effectiveness of the 10 CFR Part 37 T&R requirements to mitigate the acts of an insider. Once the TI is completed, the staff will use the results to determine the appropriate course of action (e.g., additional security measures, guidance documents, rulemaking plan, or licensee outreach).

The information obtained through the TI will be used to evaluate the following recommendations:

- Consider adding language to 10 CFR 37.25(a)(3) that directs licensees to determine activities of individuals while unemployed. This would ensure the entire 7-year period of employment history is evaluated by ROs prior to making T&R determinations and could enhance the effectiveness of T&R reviews. Staff should also revise NUREG-2155 to provide clear guidance for the implementation of 10 CFR 37.25(a)(3) to outline steps to investigate gaps in employment.
- Consider adding T&R disqualifying criteria and requirements for a program similar to an IMP to continually monitor employees' T&R when granted unescorted access to Category 1 and Category 2 radioactive materials.
- Consider changing 10 CFR Part 37 and internal processes so that the NRC would approve otherwise-self-appointed ROs, where a small business owner can designate him or herself as the RO without any independent review.

3.3.1.4 Revise Guidance

The PRT identified four T&R observations that would enhance implementation of 10 CFR Part 37 requirements by clarifying or expanding guidance.

- Clarify that non-M&D service provider licensees, who want to have their employees granted unescorted access to Category 1 or Category 2 quantities of radioactive materials under 10 CFR 37.29(a)(13), are required to comply with Subpart B requirements.
- Clarify and add examples of individuals that should not have access to protected information without a need-to-know and a T&R determination.
- Clarify the process for licensees providing to the NRC, the oath or affirmation certification that the RO is deemed T&R.
- Provide examples of methods of listing information required for individuals to disclose when applying for unescorted access authorization. In addition, provide a sample form or template that licensees can use that establishes a clear link to the more extensive indicators, such as psychological disorders and substance abuse, listed in NUREG-2155, Annex A.

3.4 Aggregation of Well Logging Sources

In response to a specific recommendation made by the GAO in GAO-14-293, the NRC included an examination of the definition of aggregation as it pertains to radioactive sources in 10 CFR Part 37, with a specific emphasis on those used in the well logging industry. The program review also considered measures in place to assess stakeholder understanding of aggregation principles and the acceptability of measures in place to secure sources during storage such that aggregation does not occur. In conducting the evaluation, the PRT utilized the following sources of information to evaluate issues with the storage of well logging sources:

- Interviews with the NRC and Agreement State inspectors to determine licensee storage practices and inspection experience.
- License searches to determine the number of well logging licensees whose possession limits allow them to aggregate to Category 2.
- Examination of photographs of various storage practices for well logging sources at licensee facilities.
- Examination of reported events (loss or theft) involving stored well logging sources.
- Examination of inspection reports and enforcement actions involving stored well logging sources.
- Recommendations noted in GAO Report 14-293.
- Inspection practices of the NRC and Agreement States for determining the applicability of 10 CFR Part 37 for aggregation.

3.4.1 Recommendations

The PRT determined that the definition of aggregation is clear and does not need to be changed. In addition, the PRT determined that the security requirements in 10 CFR Part 37 provide adequate protection for well logging sources in storage. However, based on the analysis performed, the PRT made recommendations for enhancements to guidance and additional communications to ensure that the implementation of appropriate security measures is understood by licensees and evaluated accordingly by inspectors.

3.4.1.1 Revise Guidance

- Expand discussion for evaluating potential routes of incursion as well as the adequacy and continuity of barriers. This will include consideration of licensee use of common keys for multiple locks.

3.4.1.2 Pursue Other Course of Action

The PRT identified two actions that would potentially improve oversight of licensees who are authorized to possess quantities of radioactive material that can be aggregated to a Category 2 quantity:

- Revise pre-licensing guidance for risk-significant radioactive materials to direct NRC license reviewers to examine new licenses and amendments and, if necessary, conduct onsite security reviews or initial security inspections to determine whether applicants will aggregate radioactive materials to 10 CFR Part 37 levels and, respectively, to ensure that licensees will implement 10 CFR Part 37 measures as appropriate.
- Perform outreach to inspectors to communicate any changes, and to verify that they understand the licensee's application of security measures for well logging sources in storage.

3.5 Training for NRC and Agreement State Inspectors

Each inspector is required to complete formal training prior to conducting health and safety and security oversight activities. Inspectors complete specific classroom instructor-led training courses, accompany experienced inspectors on radioactive materials inspections, and complete Individual Study Activities before conducting independent 10 CFR Part 37 inspection activities. Normally, a qualified inspector acts as a resource and mentor for individuals that are training to

become a qualified inspector. Supervisors are responsible for: (1) ensuring that inspectors are provided adequate training to complete health and safety and security inspection oversight activities; and (2) accompanying inspectors annually to evaluate their performance.

For this evaluation, the PRT examined the existing qualification program for inspectors as well as the specific courses and activities provided in the training program to address physical security requirements for Category 1 and 2 quantities of radioactive material.

3.5.1 Recommendations

Training for both the NRC and Agreement State inspectors on the security requirements of the Orders and 10 CFR Part 37 have generally been reviewed favorably by inspectors of all experience levels. While the PRT found that security training has improved since its inception, and in the current training program infrastructure, experienced, knowledgeable inspectors provide much of the training, the PRT conducted a thorough analysis of the training program and made recommendations that could further enhance the security training provided.

3.5.1.1 Pursue Other Course of Action

The PRT identified three recommendations for actions that can improve the overall efficacy of the training program:

- The Technical Training Center (TTC) should continue efforts to expand the NRC Materials Control and Security Systems and Principles (S-201) course training capacity by providing additional classes at Sandia National Lab.
- TTC should continue their current extended course feedback pilot program to solicit trainee feedback after the trainee has completed the course and implemented the skills attained during the course of routine work activities. If the pilot is determined to be effective, it should be applied to the S-201 course to obtain feedback from inspectors after the S-201 course has been completed and inspectors have had the opportunity to implement the training skills.
- Training should be developed for project managers, inspectors, and license reviewers for implementation of 10 CFR Part 37 inspection oversight at non-power reactors.

3.6 Enhanced Tracking and Accounting of Radioactive Sources

The review of enhanced tracking and accounting of radioactive sources involved assessing the need for changes to the National Source Tracking System (NSTS) to enhance the functionality of the system. The NSTS was mandated by legislation in the Energy Policy Act of 2005 to track all Category 1 and Category 2 radioactive sources in the United States held in the civilian sector, and licensees began reporting to NSTS in January 2009. Currently, the NSTS contains details on over 77,000 individual sources, and records more than 1,000 transactions per week. Integrated with the Web-based Licensing System (WBL) and the License Verification System (LVS), it forms part of the Integrated Source Management Portfolio (ISMP) which connects licenses and inventories to ensure that possession limits are not exceeded and licenses are not compromised.

The Commission has considered expanding NSTS to include Category 3 sources in the past. The 2006 Radiation Source Protection and Security Task Force report also included an action

item (Action 11-3) for the conduct of a comprehensive analysis on the inclusion of Category 3 sources in the NSTS. A Proposed Rule on Expansion of NSTS was published in 2008.

In June 2009, staff requested Commission approval of the final rule amending 10 CFR Parts 20 and 32 to expand reporting for NSTS to include Category 3 sources. In June 2009, the Commission did not reach a decision (2-2 split vote), and the final rule was not approved (SRM-SECY-09-0068).⁵

As part of the recommendation provided in SECY-16-0021, the staff noted to the Commission that the program review of 10 CFR Part 37 would evaluate the security requirements for Category 1 and 2 sources and submit a rulemaking plan to the Commission if it was determined that additional measures are warranted for Category 3 radioactive materials. As part of the 10 CFR Part 37 program review, in SECY-16-0017, "Staff Activities Related to the Program Review of Part 37 of Title 10 of the *Code of Federal Regulations*," the staff committed to considering the final report from an ongoing GAO audit which was expected to be published in early 2016. Because the 10 CFR Part 37 program review activities had been completed by mid-July, and the results were already under staff review at that time, the issue of whether or not to include Category 3 sources in NSTS was not addressed by this 10 CFR Part 37 assessment effort. Instead, it is being addressed by a working group established in response to this latest GAO report.

In order to conduct the evaluation of possible enhancements to NSTS, the PRT utilized the following sources of information:

- NSTS Integrated Marketing Solutions Report;
- Licensee responses to questionnaires and feedback obtained from interviews;
- Intelligence information related the threats to the security of radioactive material;
- Information regarding the availability and use of radioisotopes; and
- Reports prepared by the Radiation Source Protection and Security Task Force.

The PRT concluded that the current mechanisms for tracking and accounting of sources are effective, but did recommend that minor enhancements could improve the integrity of the data for the information that is currently captured in NSTS.

3.6.1 Recommendations

The NSTS is an effective method of accounting for Category 1 and Category 2 radioactive sources in the United States. Nonetheless, the PRT made one recommendation to improve the efficiency and consistency of the system to reduce human error, as described in Section 3.6.1.1 below.

⁵ Commission voting record can be found at: <http://www.nrc.gov/reading-rm/doc-collections/commission/cvr/2009/2009-0086vtr.pdf>.

3.6.1.1 Pursue Other Course of Action

- Continue efforts to simplify data entry into NSTS by auto-populating data fields, from WBL, such as: licensee name; licensee and source location addresses; and contact information for the Radiation Safety Officer (RSO). This enhancement would provide consistency across the two systems, reduce human error in data entry, and increase efficiency for updates and required annual reporting in accordance with 10 CFR 20.2207(g).

3.7 Regulatory Comparison

With assistance from the Office of International Programs, the PRT conducted a regulatory comparison of the requirements in 10 CFR Part 37 with the IAEA recommendations and with other nations that have implemented recommendations of the IAEA Code of Conduct and associated guidance. The nations chosen for this comparison were Australia, Canada, Finland, France, and Spain. For practicality, the staff chose nations where the regulations were publicly available in English or where staff fluent in the language could assist in translations (e.g., French).

Given that each nation takes a slightly different approach to implementing the Code of Conduct, the comparison was not a straightforward one-for-one comparison. For example, the Code of Conduct recommends two barriers to prevent access to radioactive materials. At first glance, 10 CFR Part 37 appears inconsistent with that recommendation, but upon a more detailed review, that was often not the case. For example, many nations consider the encapsulation or device housing the radioactive material as the first barrier. The second barrier is similar to the 10 CFR Part 37 security zone. Because the NRC does not consider the encapsulation or the device itself a barrier, the NRC requirements for a security barrier are consistent with those of other nations and the Code of Conduct. While a cursory review may appear that the United States is not consistent with recommendations of the Code of Conduct, in this example as with overall security measures, when the full scope of the existing safety and security programs, extensive Federal cooperation, and mature and dependable infrastructure of the United States is considered, it is evident that the United States' regulatory framework is consistent with the Code of Conduct.

Because this review was performed to highlight areas where other nations may be implementing the Code of Conduct in a manner that is different or more stringent than the NRC, this summary will focus on those areas, rather than highlighting where the NRC requirements are more stringent than those of other nations. The primary areas where differences were identified were in designing delay into the physical protection system and in approaches used for background checks.

In general, approaches are very similar and provide for enhanced security for risk-significant sources. The following table provides the observations of noteworthy differences identified in the comparison between the IAEA Security Objectives and/or Measures and 10 CFR Part 37 requirements.

Table 4 - Notable Differences in Security Measures

Notable differences between 10 CFR Part 37, IAEA Code of Conduct, and Nations' Implementation of the Code of Conduct	
	Description of Difference
IAEA	<p>Physical Protection while in Use, Storage and Transport: Security Management Criteria: For Security Level A, which is comparable to Category 1 radioactive material, the suggested security measures are a combination of two or more verification measures (use a swipe card and a PIN, a PIN and a computer password, etc.) For Security Levels B and C, which is comparable to Category 2 and 3, only one verification measure is recommended. The NRC requires no set number or method of access control; however, as safety features, most of the Category 1 devices will already have multiple access requirements.</p>
Australia	<p>Physical Protection while in Use, Storage and Transport: For Category 1 sources, when in use (including sources being transported) and when being stored, the source must be protected by, at a minimum, physical security measures capable of providing sufficient delay to allow immediate detection and assessment of the intrusion, and for a guard or police service to interrupt unauthorized removal of the source. The NRC requires licensees to be able to detect, assess, and respond to any unauthorized access without specifying a specific delay criteria.</p>
	<p>Trustworthiness and Reliability: For Category 1, 2, and 3 sources, a person be endorsed by an assessor accredited for this purpose by the regulatory authority. This applies to transport as well. The NRC requires the licensee to make the determination that an employee is T&R.</p>
Canada	<p>Physical Protection while in Use, Storage and Transport: Maintenance and Testing: For all categories of radioactive material, maintenance and testing is to be conducted at least every 6 months, and written records should be maintained. The NRC's maintenance and testing requirements are based on the manufacturer's suggested frequency or at least annually.</p>
	<p>Trustworthiness and Reliability: For all categories of radioactive material, the T&R check should be updated every five years. NRC requires reinvestigation every 10 years which includes fingerprinting and a criminal history records check.</p>
Finland	<p>Physical Protection while in Use, Storage: For Level A and B radioactive material, if windows provide access to interior areas in proximity to sources, they must be fortified to prevent break-ins (bars, bulletproof glass, or similar). The NRC requires licensees to be able to detect, assess, and respond to any unauthorized access without specifying a specific mechanism to accomplish that task.</p>
France	<p>Physical Protection while in Use, Storage: For Security Level A and B radioactive material, which is comparable to both the Category 1 and 2 radioactive materials, the measure includes a system of at least two layers of barriers (e.g., walls, cages). For Security Level A, which is comparable to Category 1 radioactive material, the suggested security measure for Security Level A radioactive material suggests requiring a combination of two or more verification measures (use a swipe card and a PIN, a PIN and a computer password, etc.). For Security Levels B and C, only one verification measure is recommended. The NRC requires licensees to be able to detect, assess, and</p>

	respond to any unauthorized access without specifying a specific mechanism to accomplish that task.
Spain	<i>Trustworthiness and Reliability:</i> The Ministry of Interior, with the Nuclear Safety Council's collaboration, shall determine which licensees must set up a security department, which shall be led by a head of security who must be authorized by the Ministry of Interior. The Spanish requirements also state those that do not need to set up their own security department must entrust those functions to a security company duly authorized by the Ministry of Interior for that purpose. The NRC requires all licensees who possess aggregated radioactive materials greater than or equal to Category 2 to develop a documented security program, which may be administered by the existing corporate infrastructure of the licensee.

3.7.1 Recommendations

The PRT made seven observations of differences and evaluated them for consideration. The recommendations were considered by the PRT in the relevant evaluation activities (hence the results are not repeated in this section). Specifically:

Two issues were incorporated into the T&R evaluation for consideration:

- Consider increasing the reinvestigation periodicity from 10 to 5 years. The 10-year periodicity was based on the NRC's "L" clearance reinvestigation, which has been changed from 10 to 5 years.
- Consider whether a regulatory requirement should or could be included for the appointment, by the applicable regulatory authority, of an individual responsible for physical protection of radioactive material (similar to what was done under the previous security Orders with the NRC approving/disapproving licensee-nominated ROs).

Four issues were incorporated into the evaluation of inspection results and controls for use, storage and transport for consideration:

- Evaluate the feasibility of adding requirements for protection of radioactive material in 10 CFR Part 37 to provide delay after detection sufficient to interrupt unauthorized radioactive material removal.
- Review effectiveness of requirements for a combination of two or more access control verification measures (e.g., swipe card and PIN; PIN and computer password) for Category 1 radioactive material; review if the security requirement could be enhanced for radioactive material users where multiple interlocks would not be achieved through compliance with current safety requirements. Licensees with multiple interlocks in place to meet safety requirements can take advantage of those measures for security purposes (i.e., additional access control measures). However, some radioactive materials users (e.g., blood irradiators) may not have multiple safety measures in place. Therefore, the staff should review additional access control measures as best practices, not requirements, for those licensees to consider implementing to enhance access control.
- Review current security equipment maintenance and testing periodicity.
- Review if regulatory requirements or guidance should be provided to clarify when windows are suitable barriers to protect security zones.

An observation was identified with regard to differences in coordination activities conducted prior to the transport of radioactive materials; however, it was determined to warrant no further action.

3.8 Independent Assessment Consultant Reports

The program review included consideration of recommendations made by three IACs that evaluated separate elements of the rule, guidance, and implementation. Each IAC provided a separate report of their review area.

3.8.1 Review of 10 CFR Part 37 and Completeness of NRC's Self-Assessment

The Independent Assessment Consultant report, "Review of the NRC's 10 CFR Part 37 Regulations and the Completeness of the NRC's Program Review Team's Review" (ADAMS Accession No. ML16162A099), identified several positive aspects of the 10 CFR Part 37 regulations, including: "the requirements are clear, and provide a balance of performance and prescriptive regulations; there's a good balance between keeping risk-significant radioactive sources secure and keeping regulations from being overly burdensome; and the requirements are generally consistent with international standards and recommendations." The report also noted that most of the violations of 10 CFR Part 37 were generally administrative in nature, such as not having written procedures, rather than actual lapses in source security, and the two major guidance documents on implementing 10 CFR Part 37 (NUREG-2155 and NUREG-2166) are comprehensive, useful and generally well-regarded by licensees and inspectors alike.

Table 5 - Consultant Recommendations: Regulation and Self-Assessment

Consultant Recommendations on 10 CFR Part 37 and Completeness of the NRC's Self-Assessment	
Topic	Recommendation
Consistency with Code of Conduct	Come to a common agreement with the NNSA on threat assessments, potential adversary capabilities and the security standards required to meet these threats. Adjust 10 CFR Part 37 as necessary.
	Revise 10 CFR Part 37 to include all radionuclides for which there are D-values.
	Stay abreast of the development of the revisions to IAEA security documents and take the updates into consideration during any revisions of 10 CFR Part 37 and its guidance.
Category 3 Enhanced Security and Tracking	Revise 10 CFR Part 37 to include graded security measures for Category 3 sources in storage, use and transit and expand the NSTS to include Category 3 sources.
Physical Protection During Use, Storage and Transport	Focus on improving compliance with existing regulations, especially in industrial radiography.
	Revise 10 CFR Part 37 to require a delay greater than the estimated LLEA response time for Category 1 sources.
	Revise 10 CFR Part 37 to require two means of identification and verification for access into a security zone with Category 1 sources.

	Consider adding a two person requirement and checks to prevent insiders from taking tools, material and weapons into a facility to carry out a malicious act for Category 1 sources, at least during higher risk situations such as source transfer and device maintenance.
	Reconsider requiring real-time tracking of mobile sources as device technology develops.
	Critically review and evaluate the regulations and guidance related to the most frequent citations to determine whether the causes are due to lack of clarity in the requirements.
	Continue to analyze the data on violations to try and draw conclusions that may result in further improvements to Part 37 or its guidance.
	Seek feedback from licensees on all aspects of radioactive source location and tracking not just the NSTS (i.e., use of methods such as inventories, bar codes, telemetry, etc.).
	Examine the NRC Security Issues Forum process and its development of enforcement examples with a view to speeding up the decision making process and publication of guidance to the regions.
	Redefine aggregation; not to change the meaning, but to make it better English and thereby clearer.
	Adopt the guidance, training and source management changes recommended by the PRT for well logging licensees and inspectors.
	Include Category 3 sources in Part 37 as previously recommended to eliminate the problems related to aggregation of well logging sources.
Trustworthiness and Reliability	Adjust the scope of background checks in a graduated manner for T&R determinations.
	Analyze the data regarding T&R that comes in from the Technical [sic] Instruction on the subject as it comes in, with a view to informing revised regulations or guidance.
	Seek advice from appropriate government agencies about how to help licensees perform background checks on foreign nationals.
NRC internal	Obtain feedback on the inspector training program from a wider variety of sources.
NRC internal	Continue to seek feedback from inspectors regarding how their guidance, training and tools can be improved.
	Begin planning for the transfer of personnel and resources away from gap training and toward the development of a refresher training module for 10 CFR Part 37.

While the report recommended the inclusion of Category 3 sources in 10 CFR Part 37, the PRT determined that no action was needed in this area. Due to a lack of compelling threat indicators or a change in the use and availability of Category 3 sources, the PRT did not recommend a change to the scope of sources to which the security controls in 10 CFR Part 37 apply. The PRT concluded that the current mechanisms for the control and security of sources as defined

in specific portions of the *Code of Federal Regulations* (e.g., 10 CFR Part 20) are effective in protecting Category 3 radioactive materials.

3.8.2 Consultant Review of NRC 10 CFR Part 37 Regulations and Supporting Guidance

The Independent Assessment Consultant report, “United States Nuclear Regulatory Commission Independent Assessment Consultant’s Review of Title 10 of the *Code of Federal Regulations*, Part 37 Requirements to Protect Risk-Significant Radioactive Material” (ADAMS Accession No. ML16153A211), evaluated the clarity of the regulatory language and the available guidance. This Consultant assessed the clarity of the regulations and guidance since the effectiveness of the regulations depends upon both licensees and regulators having a common understanding of expectations and requirements. In this report, the consultant concluded: “NRC has chosen a risk-informed performance-based security program requirement based on research and experience; NRC uses a defense-in-depth approach, in order that the failure to meet a performance criterion, while undesirable, will not constitute or result in an immediate safety concern”; and “Part 37 is effective in preventing malevolent use of radioactive material.”

The consultant notes that this conclusion is based on a limited amount of data including:

- Results from 179 inspections completed by NRC (or about 13 percent of the NRC and Agreement State licensees with Category 1 and 2 radioactive materials).⁶
- Interviews with the NRC Regional and Agreement State Inspectors.
- Feedback from 11 Federal licensees and 9 private sector licensees.
- Interviews with and documentation provided by the NRC staff about development and implementation of 10 CFR Part 37 and guidance.

Table 6 - Consultant Recommendations: Clarity of Regulations and Guidance

Consultant Recommendations for NRC Part 37 Regulations and Supporting Guidance	
Topic	Recommendation
Physical Protection During Use, Storage and Transport	Revise the Best Practices document (NUREG-2166) to clarify the circumstances when aggregation does not require implementation of 10 CFR Part 37 regulations.
	Expand discussion on security zones in Implementing Guidance (NUREG-2155) to address surveillance challenges for mobile uses of industrial radiography sources. Include narrative of problem and solution in order that licensees may determine relevance to operational needs.
	Include additional background information in the Implementing Guidance (NUREG-2155) such as the purpose of the weekly verification check.
	Add model security plans and procedures by license type to Implementing Guidance (NUREG-2155) to assist licensees with required content.

⁶ Because the independent assessment consultant reports were completed in March 2016, inspection data used in their reviews was truncated prior to the end of the 2-year evaluation period to allow time for analysis.

	Consider methods to share best practices information such as updating Best Practices (NUREG-2166), disseminating lessons learned periodically with generic information notices, or holding a Regulatory Information Conference.
	Include a checklist or “audit” form that could be used to conduct and document the annual security program review required by 10 CFR 37.55 in Implementing Guidance (NUREG-2155).
	Make on-going lessons learned from theft incidents, particularly Category 2 industrial radiography sources, available to licensees and regulators. Emphasize corrective actions that have proven successful at reducing human performance errors.
	Evaluate LVS once the Agreement State licensees have used it for six months.
	<p>The NRC’s PRT should review and evaluate:</p> <ul style="list-style-type: none"> • selection of theft reports from the ITDB (IAEA’s Incident and Trafficking Database), looking particularly at Category 1 or 2 quantities of radioactive material; • inspection reports for inspections with SLIII violations – determine root causes; • inspection reports from Agreement States with theft incidents of Category 2 industrial radiography sources; • results of follow-up interview with Agreement State staff regarding effectiveness of corrective actions for Category 2 theft events; • the Security Information Database; and • results of the surveys received from Agreement States.
Trustworthiness and Reliability	Add text to the Implementing Guidance (NUREG-2155) clarifying that the purpose of the T&R determination is essentially to determine if someone is trustworthy by assessing their truthfulness.
	Add to Best Practices (NUREG-2166) that an industry, such as industrial radiography, develop an information sharing database of individuals approved and denied unescorted access similar to sharing of information in Personnel Access Data System for nuclear power plants.
	Review the results of TI 2800/04211 for examples of the licensee’s basis for making a negative T&R determination. Identify whether the basis is subjective (i.e., an evaluation of truthfulness, or specific criminal offenses). Use this information to develop additional guidance.
	Add detailed information of content needed for access authorization program procedures required by 10 CFR 37.23(f) to implementing guidance (NUREG-2155).
	Include a checklist or “audit” form that could be used to conduct and more uniformly document the annual unescorted access program review required by 10 CFR 37.33(a) to implementing guidance (NUREG-2155).

NRC internal	Consider offering NNSA's Y-12 Oak Ridge, Tennessee, training to licensees who are having difficulty establishing a good working relationship with its LLEA, even if they have not accepted an enhanced security system provided by NNSA.
	Share lessons learned from initial 10 CFR Part 37 inspection experience with Agreement States.

3.8.3 Independent Review of the NRC's Rollout of 10 CFR Part 37

The Independent Assessment Consultant report, "Independent Assessment Contractor's Review of Title 10, *Code of Federal Regulations* (CFR) Part 37 Requirements to Protect High-Risk Radioactive Material" (ADAMS Accession No. ML16162A083), included the conclusion that the NRC made considerable effort to communicate with stakeholders on the new regulatory requirements in 10 CFR Part 37 and conducted a considerable amount of outreach activities to stakeholders to gather feedback when developing and updating regulatory requirements and guidance. However, the Consultant noted there was one exception: the development of NUREG-2166 did not include stakeholder outreach. The NRC staff developed NUREG-2166 with inputs from the Department of Energy/National Nuclear Security Administration. During the development of NUREG-2166, the NRC staff focused on immediately providing best practice guidance to licensee personnel who lacked expertise in developing physical security measures, but were responsible for implementing 10 CFR Part 37 requirements. The PRT received outside stakeholder comments on the effectiveness of NUREG-2166 during stakeholder outreach as part of the 10 CFR Part 37 review. These comments were deliberated by the PRT and presented to the Steering Committee to be incorporate during revision of the guidance document.

Table 7 - Consultant Recommendations Rollout

Consultant Recommendations Regarding the NRC's Rollout of Part 37	
Topic	Recommendation
NRC internal	The NRC should require refresher training for radioactive materials security inspectors at a frequency of at least every 2-3 years.
	The NRC's Integrated Materials Performance Evaluation Program should include a determination of the equivalency of Agreement State Program training in security.
	The NRC has developed a number of effective on-line tools to communicate with stakeholders in a timely and secure manner. Recommend expanding the number of on-line tools, including the development of training videos regarding the WBL System and informing staff of the availability of these training videos.
	It is too early to assess Agreement State Program roll-out of 10 CFR Part 37 compatible requirements to identify best practices for the NRC to implement in the future. Recommend that the NRC perform another review of this area again at a later date.
	Recommend that the NRC analyze and trend the violations being identified in order to determine if there is a common root cause, especially where there are large numbers of violations being issued for a particular section of 10 CFR Part 37.

3.8.4 Recommendations

Many recommendations provided by the IACs aligned with observations that had been considered separately by the PRT as part of the staff's self-assessment activities (e.g., T&R). For instance, numerous IAC recommendations identified that the NRC should consider the establishment of disqualifying criteria and insider mitigation program elements, which will be performed as part of the analysis of the results of TI 2800/042. Recommendations that were not addressed in other sections of the program review were reviewed by the PRT as a team to identify the appropriate course of action.

3.8.4.1 Pursue Other Course of Action

- The NRC will ensure the Enforcement Policy examples are clear with regard to application to 10 CFR Part 37 requirements.

3.8.4.2 Revise Guidance

- Include a sample form or template that licensees can use to establish a clear link to the more extensive T&R indicators, such as psychological disorders and substance abuse.

3.9 Stakeholder Outreach

In order to encourage stakeholder feedback on the rule and associated guidance documents, specific questions were provided in a *Federal Register* Notice (81 FR 13263) that was issued on March 14, 2016. These questions were used to facilitate discussion and solicit comments during four webinars held in March and April 2016 and a public meeting held in May 2016. In total, the NRC received 65 comments from the webinars and public meeting (ADAMS Accession Nos. ML16158A205, ML16158A207, ML16158A208, ML16158A209, and ML16158A210) and 14 comment letters (ADAMS Accession No. ML16162A202) in response to the *Federal Register* Notice.

3.9.1 Recommendations

Recommendations associated with stakeholder feedback are sorted in relation to the rule section or guidance document to which they pertained. Similar to recommendations for other portions of the program review, all comments were reviewed and considered by the PRT as potential recommendations from the program review.

3.9.1.1 Subpart A – General Provisions

The PRT determined that several comments received on Subpart A should be considered for rulemaking. The recommended changes to the rule include:

- Clarify the definition of radioactive waste and exempting radioactive material – the Nuclear Energy Institute (NEI) has included these issues in their petition for rulemaking (PRM) 37-1.
- Clarify the definition of “sabotage.” The intent of the rule is to provide protection against malicious acts involving risk-significant radioactive material. Therefore “sabotage” can be added to the purpose of the rule for clarity.
- Clarify the term “annual” in 10 CFR 37.5 (Definitions).

- Clarify 10 CFR 37.43(c) to differentiate between initial and refresher training requirements.

The PRT determined that revisions to guidance documents related to 10 CFR Part 37 should be considered. The recommended revisions include:

- Clarify what is a reasonable LLEA agreement – 10 CFR 37.45(b) or equivalent State regulation requires the licensee to notify the NRC or Agreement State if the LLEA has not responded to requests or does not plan to coordinate. The NRC or Agreement State does not have the authority over LLEA but could help to facilitate and better understand the reasons for the unwillingness to coordinate.
- Include a link in NUREG guidance to the Directory of Agreement State and Non-Agreement State Directors and State Liaison Officers (which is currently available on the NRC's public website). This link in the NUREG will facilitate access by LLEA to the agency contact information in the event that the licensee is non-responsive during an event.
- Clarify the definition of security zone. Security zones apply to use, storage, and transport by the licensee not using a commercial carrier. Security zones do not apply to transport using a commercial carrier.
- Clarify whether the 10 CFR Part 72 security plan covers the scenario where 10 CFR Part 37 radioactive material is stored next to spent fuel.

One comment received on Subpart A involves a recommendation to conduct further evaluation:

- Clarify terms that are used in the NUREG-2155 guidance document (e.g., direct control, direct supervision, constant surveillance, continuous surveillance) that are not used in the regulation.

In response to this recommendation, the staff will evaluate the current use of terminology and proceed with guidance revision, as appropriate.

3.9.1.2 Subpart B – Background Investigations and Access Control Program

Several comments received on Subpart B involve revising guidance documents related to 10 CFR Part 37. The recommended revisions include:

- Clarify relief for background investigations for current law enforcement officers. Once law enforcement officers cease employment as a sworn law enforcement officer, they are private citizens and thus subject to the background investigation requirements.
- Clarify background investigation requirements for nuclear power plants entering decommissioning. Staff has provided guidance to the nuclear power industry via questions and answers concerning the application of 10 CFR Part 37 requirements to licensees with 10 CFR Part 73 security plans.

Two comments received on Subpart B involve a recommendation to conduct further evaluation. They include:

- Evaluate the ongoing 10 CFR Part 73 rulemaking effort for applicability to 10 CFR Part 37 access authorization programs, specifically whether to revise 10 CFR 37.23(e) requirements to address third party arbitration rulings for RO, T&R determinations.
- Review the results of the TI 2800/042 to formulate a recommendation on whether to establish disqualifying criteria for T&R determinations (also addressed in section 3.3.1.3).

3.9.1.3 Subpart C – Physical Protection Requirements During Use

As a result of this analysis, the staff determined that two comments received on Subpart C should be considered for rulemaking:

- Revise relevant provisions of 10 CFR 37.43(d) so that they are in agreement with 10 CFR 37.43(d)(1) by requiring the list of individuals that have been approved for unescorted access to be stored in a manner to prevent unauthorized access.
- Revise 10 CFR 37.43(d) to include certain information in the license as information to be protected. Consideration of rulemaking will assess how the protection of this information under 10 CFR Part 37 correlates to licensee compliance with other safety requirements, as well as ensuring appropriate public notice is maintained.

Several comments received on Subpart C involve revising guidance documents related to 10 CFR Part 37. The recommended revisions include:

- Clarify the requirement in 10 CFR 37.23(b)(3) for the RO to be given access to Safeguards Information or Safeguards Information-Modified Handling if a licensee possesses that information.
- Clarify if 10 CFR 37.49(a)(3)(ii) requirements can be met through a combination of methods. If licensees use physical checks to verify the presence of Category 2 radioactive material under 10 CFR 37.49(a)(3)(ii) rather than tamper-indicating devices, use, or other means, they would have to determine that the source is present, not just that the device is present.
- Clarify guidance information from Regulatory Issue Summary (RIS), RIS 2005-31, “Control of Security-Related Sensitive Unclassified Nonsafeguards Information Handling by Individuals, Firms, and Entities Subject to NRC Regulations of The Use of Source Byproduct, and Special Nuclear Material” regarding how or if certain information in the license should be protected.
- Clarify requirements in 10 CFR 37.47(d) on the applicability for sufficient personnel to provide surveillance in a temporary zone for Category 2 radioactive material. Licensees using individuals to provide direct supervision or surveillance of Category 2 radioactive materials would need to have sufficient staff for continuous oversight of security zones rather than sources.
- Clarify the security plan training objectives.
- Clarify practices for accepting service providers’ T&R credentials.
- Clarify and provide examples of individuals who do not need to be determined T&R.
- Outline common problems encountered during investigations of foreign nationals and best practices to address them.
- Clarify expectations regarding evaluation of the “claimed period” and how it relates to the 7-year background investigation requirement.
- Expand guidance for the implementation of 10 CFR 37.25(a)(3) that outlines steps to investigate gaps in employment.
- Clarify that licensees could inquire of previous employers as to whether an individual was considered trustworthy and reliable.
- Clarify submittal of the Oath and Affirmation for the RO, to include providing an example form.
- Clarify a licensee’s ability to share T&R information with other licensees.

- Clarify whether the use of “individual” covers employees and contractors (e.g., clarify T&R relief for drivers and when there is a conflict between the use of “individual” and “employee” if there is no intended difference).

Two comments received on Subpart C involve a recommendation to conduct further evaluation. They are:

- Examine issues with allowing sensitive and non-sensitive information to be stored on tablets or smartphones.
- Examine the practices for licensees to carry security documents to field sites in vehicles.

3.9.1.4 Subpart D – Physical Protection in Transit

As a result of this analysis, the staff determined that several comments received on Subpart D should be considered in rulemaking. The recommended changes to the rule include:

- Clarify constant control and/or surveillance requirements for Category 1 shipments under 10 CFR 37.79. For Category 1 shipments by road, 10 CFR 37.79(a) does not state, as is done for road shipments of Category 2 radioactive material, that “...each license that transports Category 1 quantities of radioactive material shall maintain constant control and/or surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance.”
- Align requirements in 10 CFR 37.79(c) for an investigation and reporting of an event for lost or missing Category 1 shipment; 10 CFR 37.79(a)(1)(iii) for implementation of procedures during theft, loss, or diversion of a shipment; and 10 CFR 37.79(b)(1)(i) for implementation of procedures in response to actual, attempted, or suspicious activities related to the theft or diversion of a shipment.
- Clarify requirements for a written report for lost or missing and actual or attempted theft or diversion, to provide consistency between 10 CFR 37.81(c)-(d) and 10 CFR 37.81(g)(2).
- Clarify who is responsible for developing and implementing the security plan for the transportation of Category 1 and Category 2 radioactive material. Licensees responsible for implementing the security plan are required to establish a security zone for Category 1 and 2 quantities of radioactive material. The definition of “security zones” does not clearly reflect that these zones are established by the licensee for the physical protection of Category 1 or 2 quantities of radioactive material during use or storage (10 CFR 37.47(a)) and are not implemented or required in regard to Category 1 or 2 shipments via a common carrier.

Several comments received on Subpart D involve revising guidance documents related to 10 CFR Part 37. The recommended revisions include:

- Make language concerning telemetric monitoring consistent and clear. Positive confirmation for the shipment can be understood in this context as telemetric monitoring of either the transport vehicle or the package.
- Clarify the activities of movement control center and railroad communication center to ensure consistency and explain differences. Align guidance regarding activities of movement control center and railroad communication center and clarify the description of monitoring expectations, to ensure licensees understand the guidance.
- Clarify proper implementation of notifications under 10 CFR 37.77 for NRC licensees and Agreement State regulatory bodies and their licensees.
- Clarify the requirements in 10 CFR 37.79(c) for an investigation and reporting of an

event for a lost or missing shipment; 10 CFR 37.79(a)(1)(iii) for implementation of procedures during theft, loss, or diversion; 10 CFR 37.79(b)(1)(i) for implementation of procedures in response to actual, attempted, or suspicious activities related to the theft or diversion of a shipment; and 10 CFR 37.79(a)(1)(iii) for theft, loss, or diversion of a shipment.

- Clarify who is responsible for developing and implementing the security plan for the transportation of Category 1 and Category 2 radioactive material (guidance will support the effectiveness of rule changes identified above).

3.9.1.5 NUREG-2155

One comment received on NUREG-2155 is recommended by the PRT to be addressed with rulemaking. The recommendation was to clarify the terms “activated material” and “contaminated material.” NUREG-2155 provides clarification concerning what is considered “activated material.” However, these terms are not clearly defined in the rule.

Several comments received on NUREG-2155 involve revising guidance documents related to 10 CFR Part 37. They include:

- Provide direction on the evaluation of routes of incursion and adequacy and continuity of barriers.
- Clarify when notification to the LLEA shouldn’t constitute an event requiring notification to the NRC.
- Clarify licensee coordination with LLEA, including developing a MOU with their LLEA.
- Include greater detail on requirements for when the 7-day period for removal of access begins.
- Provide examples of two independent physical controls. The current paragraph reads as if the requirements are for three rather than two independent physical controls used for Category 1 or Category 2 quantities of radioactive material in a mobile device at a licensed facility.

3.9.1.6 NUREG-2166

Two comments received on NUREG-2166 involve revising guidance documents related to 10 CFR Part 37. They include:

- Augment guidance regarding operating nuclear power plants and those undergoing decommissioning to incorporate the Q&A’s that were provided to the nuclear power industry concerning the application of 10 CFR Part 37 requirements to licensees with 10 CFR Part 73 security plans.
- Revise guidance to describe the role of the RO in making T&R determinations in a bifurcated T&R process. For example some licensees utilize their Human Resources (HR) department to review background investigation information and then inform the RO that the information does/does not support approving the individual for unescorted access to Category 1 or 2 quantities of radioactive material. Based on the HR department’s recommendation and the results of the FBI criminal history records check, the RO makes the determination as to whether the individual may have, or continue to have, unescorted access.

3.9.1.7 General Comments

Two comments received during public outreach were general in nature.

One recommendation will be considered for rulemaking consistent with the disposition of NEI's petition for rulemaking:

- The NRC should promptly initiate rulemaking to implement the proposed changes in NEI PRM 37-1.

One comment will involve pursuing another course of action:

- Coordinate with licensees to ensure generic information and guidance regarding 10 CFR Part 37 issued by the NRC is getting to the individual who is implementing the security program.

4.0 Conclusion

This program review considered the security infrastructure created through the regulatory requirements and interagency liaison following the events of September 11, 2001. These efforts culminated in the issuance of 10 CFR Part 37 in 2013. The rule, which was implemented by NRC licensees in 2014 and subsequently implemented by Agreement States through the promulgation of compatible requirements or license conditions, provides an enhanced level of protection for risk-significant radioactive materials.

Section 403 of Public Law 113-235 tasked the NRC with assessing the effectiveness of 10 CFR Part 37 after 2 years of implementation by NRC licensees. In response to this direction, the NRC conducted a comprehensive analysis of events and inspection findings related to the security of risk-significant radioactive material as a means to assess the adequacy of rule provisions in protecting against the theft or diversion of Category 1 and 2 quantities of radioactive material. 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 IACs. Extensive stakeholder feedback was also obtained through multifaceted outreach efforts. In totality, these activities formed the basis for assessing the adequacy of the regulatory infrastructure for security of Category 1 and 2 quantities of radioactive material. The scope of the program review reached beyond the two areas directed by Public Law 113-235 in the interest of conducting a thorough review of the rule after gaining experience in its implementation.

As described in the body of this report, the analysis of events and inspection results, combined with the additional assessment activities performed during the program review, demonstrate that 10 CFR Part 37 provides a strong regulatory framework to ensure the security of Category 1 and 2 quantities of radioactive material, and is effective at doing so. Although the NRC intends to pursue specific outreach actions to communicate relevant information to stakeholders, enhance the clarity of implementing guidance, and consider rulemaking in specific areas where the regulations could be strengthened or administratively clarified, the overall assessment of 10 CFR Part 37 determined that the regulation itself is effective in achieving the 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

10 CFR	Title 10 of the <i>Code of Federal Regulations</i>
ADAMS	Agencywide Documents Access and Management System
FBI	Federal Bureau of Investigation
GAO	Government Accountability Office
IAC	Independent Assessment Consultants
IAEA	International Atomic Energy Agency
IMP	Insider Mitigation Program
IT	Information Technology
ITDB	IAEA's Incident and Trafficking Database
LLEA	Local Law Enforcement Agency
LVS	License Verification System
M&D	Manufacturing and Distribution
MOU	Memorandum of Understanding
NEI	Nuclear Energy Institute
NMED	Nuclear Material Events Database
NMSS	Office of Nuclear Material Safety and Safeguards
NNSA	National Nuclear Security Administration
NRC	U.S. Nuclear Regulatory Commission
NSIR	Office of Nuclear Security and Incident Response
NSTS	National Source Tracking System
PRM	Petition for Rulemaking
PRT	Program Review Team
Q&A	Question and Answer
RIN	Regulation Identifier Number
RIS	Regulatory Issue Summary
RO	Reviewing Official
RSO	Radiation Safety Officer
SECY	Office of the Secretary
SL	Severity Level
SRM	Staff Requirements Memorandum
TI	Temporary Instruction
T&R	Trustworthiness and Reliability
TTC	Technical Training Center
WBL	Web-Based Licensing