Independent Assessment Contractor's Review of Title 10, Code of Federal Regulations (CFR) Part 37 Requirements To Protect High-Risk Radioactive Material

Judith A. Joustra

EXECUTIVE SUMMARY

This independent external assessment of the rollout of Title 10 of the Code of Federal Regulations (10 CFR) Part 37 requirements to protect high-risk radioactive material was conducted from October 1, 2015, through March 25, 2016. The main focus of this independent assessment was to determine the effectiveness of the 10 CFR Part 37 rollout to internal and external stakeholders. The review also includes an evaluation of inspection results and event reports from the first 2 years of implementation of the requirements in 10 CFR Part 37 for Nuclear Regulatory Commission (NRC) licensees. Specifically, this assessment addressed the following: 1) NRC staff's communication to stakeholders on new regulatory requirements in 10 CFR Part 37; 2) NRC staff's outreach to stakeholders to gather feedback when developing and updating regulatory requirements and guidance; 3) NRC staff's activities related to providing NRC and Agreement State inspectors adequate training on 10 CFR Part 37 requirements related to background investigations and access control programs, including review of trustworthiness and reliability investigations, physical protection during use of materials, including aggregation of sources, and physical protection during transit; 4) NRC's use of on-line tools to communicate with stakeholders in a timely and secure manner; 5) Agreement State rollout of compatible requirements and identification of best practices for NRC to implement in the future; and 6) inspection and event reports from the first 2 years of implementation of 10 CFR Part 37 for NRC licensees.

In support of this assessment, numerous documents were reviewed. The documents are listed at the conclusion of the report. In addition, questionnaires were developed and issued, and/or several interviews were conducted with the following:

- Seven individuals from the NRC's offices of Nuclear Material Safety and Safeguards (NMSS), the Division of Materials Safety, State, Tribal, and Rulemaking Programs (MSTR);
- Four individuals from the NRC's Office of Nuclear Security and Incident Response (NSIR);
- Two individuals from the NRC's Technical Training Center (TTC);
- Eleven NRC materials health physics inspectors from three NRC Regional offices; and
- Representatives from seven Agreement State Programs (Ohio, Iowa, Washington, Minnesota, Georgia, Oklahoma, and Texas).

In addition, a total of nine non-Federal NRC licensees who possess or did possess at one time Category 1 and/or Category 2 radioactive materials were provided a questionnaire and/or participated in an interview. Included in the nine were some licensees whose facilities are located in NRC and Agreement State jurisdictions. A total of eight Federal licensees were also issued questionnaires and/or participated in interviews. Also one Federal Agency, the National Nuclear Security Administration (NNSA) responded to a questionnaire and participated in an interview. Interviews were conducted, when needed, to follow-up on questionnaires in order to gather additional information or when time prohibited issuing a questionnaire to a particular individual. The questionnaires and interviews were necessary in order to address some of the information provided in several reports issued by the Government Accounting Office (GAO).

During this assessment, nine non-Federal Government licensees and nine Agreement State Programs were authorized to be contacted in order to gather information in support this assessment. An attorney from the NRC's Office of the General Counsel (OGC) provided the following regarding the process for contacting licensees and Agreement States during this assessment process:

> The Paperwork Reduction Act (PRA) requires Federal Agencies, including independent regulatory agencies such as the NRC, to follow various procedures, including providing comment periods, developing supporting statements, and obtaining Office of Management and Budget (OMB) review and approval, before undertaking a collection of information addressed to ten or more "persons" (with corporate or other non-Federal Government entities counting as "persons" for this purpose). Collections of information covered by the PRA include, among other things, situations in which an agency requires ten or more "persons" to respond to government requests for information, including government surveys. The PRA, however, specifically avoids requiring agencies to follow its procedures for collection of information addressed to fewer than ten "persons" thus allowing agencies to undertake smaller-scale information collection activities in a simpler and more expedited manner.

For a number of reasons, including scheduling and the time authorized to complete the assessment, OMB review and approval was not obtained by the NRC. Therefore, the nine non-Federal licensees selected for this assessment were supplemented by including eight Federal licensees. Licensee participation in this assessment was strictly voluntary.

Based on the results of this assessment, I have concluded the following: 1) The NRC made considerable effort to communicate with stakeholders on the new regulatory requirements in 10 CFR Part 37; 2) The NRC conducted a considerable amount of outreach activities to stakeholders to gather feedback when developing and updating regulatory requirements and guidance, with one exception, the development of NUREG-2166. I recommend the NRC completes its assessment process of the effectiveness of NUREG-2166, determines whether revisions to NUREG-2166 are needed, and provides the required response to the GAO; 3) The NRC's S-201 training provided to NRC and Agreement State material health physics inspectors, appears to be thorough and comprehensive and provides adequate training on 10 CFR Part 37 requirements. I do, however, recommend that the NRC requires refresher training in security at a frequency of at least every 2 to 3 years. I also recommend that the NRC's Integrated Materials Performance Evaluation Program include a determination of the equivalency of Agreement State Program training in security; 4) The NRC has developed a number of effective on-line tools to communicate with stakeholders in a timely and secure manner. I recommend that the NRC completes its development of training videos regarding the Web-based Licensing System and informs its staff and Agreement State Programs of the availability of these training videos; 5) It seems to be too early to make any real meaningful assessment of Agreement State Program roll-out of 10 CFR Part 37 compatible requirements to identify best practices for the NRC to implement in the future. I recommend that the NRC performs another review of this area again at a later date; and 6) There was a limited amount of information available regarding

inspection results and event reports due to the fact that most of the information is security-sensitive and is not publically available.

However, based on the information that was available, I recommend that the NRC analyzes and trends 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. This may result in modifications to 10 CFR Part 37 in the future.

BACKGROUND INFORMATION

After September 11, 2001, the NRC issued a number of Security Advisories to licensees recommending specific action be taken in order to enhance security of high-risk radioactive material. These recommendations were voluntary and not legally binding. Subsequent to the NRC issuing the Security Advisories, the NRC during 2003, 2004, 2005, and 2007 issued a number of Security Orders to licensees who were authorized to possess risk significant radioactive material (high-risk radioactive material). These Orders imposed legally binding requirements to licensees. One March 16, 2012, the Commission affirmed its vote on the final rule, 10 CFR Part 37 (SECY-11-1070); voted to approve publication of the final rule, placing security measures, fingerprinting, and portions of the previously issued Security Orders into NRC regulations; and the approval of 10 CFR Part 37 was announced in an NRC memorandum. On March 19, 2013, 10 CFR Part 37 was published in Federal Register Notice (78 FR 16922). NRC staff recommended that the final rule be effective one year after publication in the Federal Register, and that Agreement States would be required to issue compatible regulations within 3 years of publication. Title 10 of the Federal Regulations Part 37, "Physical Protection of Category 1 and 2 Quantities of Radioactive Materials," became effective on May 20, 2013. NRC licensees were required to comply with 10 CFR Part 37 by March 19, 2014. Agreement States had until March 19, 2016, to issue compatible requirements. Key elements of 10 CFR Part 37 include the following: background investigations and access control; physical protection requirements during use; and physical protection during transit.

On December 16, 2014, Public Law 113-235, "Consolidated and Further Continuing Appropriations Act, 2015," was signed by the President of the United States. The statute provides annual funding for Federal Agencies, including the NRC. Section 403 of the legislation requires "… the NRC to provide a report to Committees on Appropriation of the House of Representative 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 radioactive materials and that such an evaluation consider inspection results and event reports from the first two years of implementation of the requirements in 10 CFR Part 37 for NRC licensees."

The NRC determined that in addition to establishing an internal review team to address the effectiveness of 10 CFR Part 37, external independent consultants would be beneficial and provide additional perspectives. On October 1, 2015, the Independent Assessment Consultants (IACs) initiated their independent review process. The NRC requested that each individual consultant address and meet several specific goals, including participation in stakeholder outreach activities related to 10 CFR Part 37 assessment activities with the NRC's internal review team; and communication with Agreement States, specifically with those states that have implemented 10 CFR Part 37 or compatible requirements. Individual final reports containing conclusions and recommendations were to be due to the NRC within 180 days of initiating work.

REPORT DETAILS

1. Review of NRC Staff's Communication to Stakeholders on New Regulatory Requirements in 10 CFR Part 37

a. Scope

A review of the NRC staff's communication to stakeholders on new regulatory requirements in 10 CFR Part 37 was conducted. A review of the following documents was performed: SECY-09-0181; Federal Register Notice (FRN) 73 FR 826; Staff Requirements Memorandum (SRM) dated May 13, 2010; Implementation Guidance for 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Materials," (NUREG-2155); FRN 75 FR 40756; FRN 75 FR 33902; FRN 78 FR 53; International Atomic Energy Association (IAEA), Nuclear Security Series No. 11; Radiation Source Protection and Security Task Force Report for 2014; "Physical Security Best Practices for the Protection of Risk-Significant Radioactive Material," (NUREG-2166); NRC Regulatory History Index; Summer and Fall 2013 FSME Newsletters; Regulatory Issue Summary (RIS) - 2014-03; Chairman Jaczko's letter dated September 14, 2010. Responses to questionnaires were evaluated, and information received during interviews was also evaluated. In addition, a review of the following GAO reports was conducted: "Additional Actions Needed to Improve Security of Radiological Sources at U.S. Medical Facilities," dated September 2012; and "Additional Actions Needed to Increase the Security of U.S. Industrial Radiological Sources," dated June 2014.

b. Observations

Prior to the development of 10 CFR Part 37 the NRC had a vulnerability assessment performed by Sandia National Laboratories. The vulnerability assessment was performed in order to identify vulnerabilities in security, and the effectiveness and costs of certain physical protection enhancements at various types of NRC-licensed facilities. The results of the vulnerability assessments were used in the development of the original Security Orders. According to information provided by two staff members from the NRC's Office of Nuclear Security and Incident Response (NSIR), information obtained from the vulnerability assessment along with lessons learned during the implementation of the original Security Orders, recommendations from an Independent External Review Panel and the Materials Program Working Group, stakeholder comments received on the original Security Orders, and comments received on the preliminary rule language that the NRC had posted on Regulations.gov on November 19, 2008, were some of the things considered by the NRC while developing 10 CFR Part 37.

In SECY-09-0181 dated December 14, 2009, (ML092820195), the NRC's then Executive Director for Operations (EDO) requested that the Commission approve publishing the proposed rule, 10 CFR Part 37, in the Federal Register. The EDO informed the Commission that rulemaking for this rule would be conducted in an open process allowing for public comment. An NRC Rulemaking Working Group and Steering Committee were formed for the proposed 10 CFR Part 37 rulemaking. The Working Group and the Steering Committee consisted of representatives from both NRC and Agreement States. The Commission approved publication of the proposed rule in a Staff Requirements Memorandum (SRM) dated May 13, 2010.

On June 1, 2010, the NRC's Office of Public Affairs issued a press release indicating that the NRC was seeking public comment on the proposed rule on the security of radioactive materials. Public meetings were held during development of the original Materials Security Orders, as well as during the associated guidance development process. Based on information obtained during this assessment, it appears the same approach was taken by the NRC for the 10 CFR Part 37 roll-out.

Methods used by the NRC to communicate with stakeholders prior to the issuance of 10 CFR Part 37 included the following outreach activities: conducting and/or participating in several stakeholder meetings; issuing press releases; and issuing FRNs. Some additional meetings the NRC attended during the roll-out of 10 CFR Part 37 include the following: Nondestructive Testing Management Association on February 15, 2012; the Baltimore-Washington Chapter of the Health Physics Society meeting on May 3, 2013; the Master Material Licensees (MMLs) during an annual counterpart meeting conducted in 2013; and the American Society for Nondestructive Testing on November 6, 2013. The NRC also provided two opportunities for stakeholders to provide input, once during the preliminary draft language process for Subparts, B, C, and D of 10 CFR Part 37, and once during the proposed draft rulemaking process. Additional outreach activities by the NRC included interaction with the MMLs, specifically the Navy, Air Force, and Veterans Affairs.

While 10 CFR Part 37 was being developed, the associated implementing guidance was also being developed. NUREG-2155 was developed in a question and answer format, the questions obtained from various sources including the following: questions asked during implementation of the original Security Orders; questions submitted to the NRC Increased Controls (IC) Toolbox; questions developed as a result of violations that had been identified during previous inspections of licensees implementing the original Security Orders; questions developed by members of the Implementation Working Group; and questions that were asked during multiple public meetings held from 2008 through 2011. The Implementation Working Group discussed all questions received in order to determine the appropriate answers to each question. In addition, several outreach activities had been conducted by the NRC, which included: public meetings held by the NRC during rulemaking activities; three meetings also held during January 2008, as part of rulemaking activities specific to transportation of radioactive materials; and four meetings held during 2013

and 2014 concerning the integration of security plans for licensees who have active 10 CFR Part 73 security plans in place. In addition, a presentation had been conducted with Campus Radiation Safety Officers during a Health Physics Society annual meeting held in 2012, in which discussions focused on the differences between the proposed 10 CFR Part 37 and the original Security Orders, which were in affect at the time of the presentation.

The NRC maintains the following document, "Regulatory History Index," which contains data regarding the proposed rule, "Physical Protection of Byproduct Material." The document contains a list of various documents pertaining to the development of 10 CFR Part 37. The "Regulatory History Index" lists documents from April 30, 2008, through July 7, 2010. The documents are referenced by an ADAMS accession number, title, date, and availability (either non-public or public). Those documents that are publically available are, for the most part, accessible on the NRC Public Website by searching the accession number. The following are examples of documents contained in the "Regulatory History Index:" Technical Basis Package for Radioactive Material Quantities of Concern; Federal Register Notice on Availability of Preliminary Draft Rule; Language for 10 CFR Part 37, Physical Protection of Byproduct Material; Comments from interested Stakeholders; SECY-09-0181, Proposed Rule: Physical Protection of Byproduct Material; Press Release 10-096, dated June 1, 2010, "NRC Seeks Public Comment on Proposed Rule on Security of Radioactive Materials;" and copies of multiple letters sent to stakeholders who expressed interest in the proposed rule, thanking them for their interest and informing them that two public meetings would be conducted in September of 2010. A review was performed of several of the documents contained in the history index. This document demonstrates that the NRC frequently communicated with stakeholders throughout the 10 CFR Part 37 roll-out process.

The proposed rule was published in a FRN on June 15, 2010 (75 FR 33902). On page 33908 of the FRN, the NRC provided tips for stakeholders for preparing and submitting comments. There was a 120-day public comment period ending on October 13, 2010, associated with the proposed rule. The NRC extended the public comment period to January 18, 2011, due to the number of requests to extend the comment period. The NRC received 110 comment letters. The comments came from licensees, Agreement States, industry organizations, individuals, and a Federal agency. The NRC provided the Agreement States with a copy of the draft Federal Register containing the final rule prior to it being published. The final rule was published on March 19, 2013.

Implementation Guidance for 10 CFR Part 37 (NUREG-2155) was published in February 2013; (Revision 1 to NUREG-2155 was published in January 2015). On July 14, 2010, the draft guidance document was noticed in the FRN, 75 FR 40756. The 120-day comment period was also extended from November 12, 2010, to January 18, 2011. The NRC also conducted two public meetings during the comment period, one in Austin, Texas, and one in Rockville, Maryland. The

10 CFR Part 37 Implementation Working Group was tasked with addressing questions and/or concerns raised by licensees during the 10 CFR Part 37 implementation period. In addition, according to the 10 CFR Part 37 Implementation Working Group Draft Charter; the working group would update guidance in the form of frequently asked questions and answers on the NRC's public website. At the time of this assessment, the NRC's public website contained several sets of questions and answers (Q&A's) pertaining to radioactive material security.

Other examples of methods used by the NRC to communicate to its stakeholder regarding 10 CFR Part 37 include the following: an article titled, "A New Regulation" was published in its summer 2013 FSME Programs Newsletter (NUREG/BR-0177, No. 13-02), and another article titled, "Update on Implementation Activities" in its fall 2013 FSME newsletter (NUREG/BR-0117 No. 13-03). The NRC also issued Regulatory Issue Summary, RIS-14-03, "Notice of Part 37 Implementation Deadline for NRC Licensees," which was distributed to NRC licensees on March 14, 2014, as a reminder to NRC licensees who were required to comply with 10 CFR Part 37.

Eleven NRC materials health physics inspectors were contacted during this assessment in order to determine what actions they took in order to roll-out 10 CFR Part 37 with respect to preparing to inspect licensees for compliance with 10 CFR Part 37. The following actions were provided by the inspectors: obtaining training and conducting inspection preparation.

Regarding training, according to the NRC materials health physics inspectors (inspectors), the NRC requires that they complete a qualification process that includes successful completion of the NRC's S-201 training (NRC required training is discussed further in Section 3 of this report). The inspectors also stated that the NRC regional offices conduct presentations during seminars and Division Meetings. The NRC also provided what is known as "GAP Training" to its inspectors (GAP Training is discussed in Section 3 of this report).

Regarding inspection preparation, the inspectors indicated that they complete additional training assignments, such as individual study activities and extensive on-the-job training activities under the tutelage of a senior inspector. Furthermore, the NRC inspectors typically perform reviews of the Nation Source Tracking System (NSTS) for licensee entries, applicable licenses, and the pre-licensing visit checklist. In addition, inspectors indicated that they review applicable regulations and previous inspection documentation.

Some NRC inspectors indicated that while performing inspections prior to the implementation of 10 CFR Part 37, they typically reminded licensees of the impending 10 CFR Part 37 rule and reviewed the new requirements with the licensees and provided available guidance documents.

In addition, as part of the NRC qualification process, the inspectors are required to lead an inspection, while being observed, before going out independently to conduct an inspection of a licensee who is implementing 10 CFR Part 37. In one NRC Regional Office (Region), each inspector must complete the 10 CFR Part 37 Inspector Preparation Tracking Form. Once completed, the inspector is issued a memorandum titled, "Authorization to Independently Perform 10 CFR Part 37 Security Inspections," which is signed by the appropriate branch chief.

According to one NRC inspector, there are several documents that contextualized and reinforced the application of the requirements, including NUREG-2155, Inspection Procedure (IP) 87137, and NUREG-2166, which were available to inspectors. These documents provide a technical basis for much of the material to assist with evaluating licensee compliance.

One NRC Region took the following additional actions in order to develop and roll-out 10 CFR Part 37. The actions included the following: 1) designated a 10 CFR Part 37 Team consisting of three members, including a Team Leader; 2) assigned inspectors to participate on the 10 CFR Part 37 Implementation Working Group, NUREG-2166, and Inspection Procedure (IP) 87137 development; 3) established an inspector preparation form to ensure that inspectors were knowledgeable prior to conducting inspections; 4) developed and delivered inspector GAP Training to materials health physics inspection staff; and 5) developed an inspection checklist to be used as inspection notes by NRC materials health physics inspectors. Other NRC regional offices also participated by sending inspectors to serve as representatives on the 10 CFR Part 37 Implementation Working Group.

As part of this assessment, 17 licensees were contacted in order to determine if they were given an opportunity to provide input/comments or feedback to the NRC regarding 10 CFR Part 37 or Agreement State compatible regulations during its development. The licensees contacted included the following: representatives from two NRC Master Material Licensees that possess shelf shielded irradiators; other licensees that possess shelf shielded irradiators, including two academic licensees; a manufacturing and distribution licensee that possesses Category 1 and Category 2 radioactive materials; a well logging licensee; two radiography licensees; a medical licensee that possesses a gamma knife; and one licensee that possesses several large panoramic pool irradiators. A total of 13 licensees indicated that they were given an opportunity and either did or did not provide input/comments. Two licensees indicated that they were not provided an opportunity to provide input/comments, and two licensees did not indicate either way.

Also as part of this assessment, a number of GAO reports were reviewed and an assessment was conducted in order to address some of the comments raised in the GAO reports.

The GAO states in its report "Additional Actions Needed to Improve Security of Radiological Sources at U.S. Medical Facilities," dated September 2012, that one

reason NRC's requirements did not consistently ensure the security of high-risk radioactive sources was that the requirements are written too broadly and do not prescribe specific measures that licensees must take to secure their equipment containing high-risk radioactive sources. In addition, the GAO states in its report, "Additional Actions Needed to Increase the Security of U.S. Industrial Radiological Sources," dated June 2014, on page 20, that licensees face challenges as a result of broadly written security controls in that they may select from a menu of security measures that allow them to meet NRC's controls but not necessarily address all potential security vulnerabilities.

The same 17 licensees were contacted in order to determine if they believe 10 CFR Part 37 (or compatible regulation) needs to be prescriptive, and if so which section(s), and whether they have any suggestions for modifying 10 CFR Part 37. A total of 11 licensees indicated that 10 CFR Part 37 should be performance-based and not prescriptive. Of the licensees that answered the question regarding whether they have any suggestions to modify 10 CFR Part 37, three did provide suggestions and five indicated that they do not have any suggestions for modifying 10 CFR Part 37. It should be noted that three licensees did suggest that 10 CFR Part 37 could be a combination of both prescriptive and performance-based. Specifically, the licensees indicated that it would be helpful if the requirement to perform trustworthiness and reliability (T&R) determinations was prescriptive rather than performance-based. Several of the licensees that were in support of the performance-based regulation stated that it allows licensees to meet the requirements in ways that best fit their particular set of circumstances and their facility. In addition, one licensee stated that it disagrees with the GAO report, in that, it does not believe that a performance-based rule makes radioactive material more vulnerable.

The GAO states in its report "Additional Actions Needed to Improve Security of Radiological Sources at U.S. Medical Facilities," dated September 2012, on page 11, that an NRC official had informed the GAO that the NRC's risk-based approach aligns with Executive Order 12866, which directs Executive Branch agencies to tailor their regulations to impose the least burden on society, including individuals, businesses of differing sizes, and other entities. They also stated that the Executive Order requirements do not apply to the NRC, but the NRC follows many of the provisions voluntarily. The GAO further stated in its report that an NRC official told the GAO that "due to diverse economic conditions, facility type, layout, and operations of hospital and medical facilities, a "one size fits all" approach to radioactive source security is neither practical nor desirable." An NRC representative indicated to the GAO that some licensees would not be able to afford the cost of instituting prescriptive measures.

A review of the GAO Report "Additional Actions Needed to Increase the Security of U.S. Industrial Radiological Sources," dated June 2014, states that the NRC had informed the GAO that "the intent of the security controls is to develop a combination

of people, procedures, and equipment that will delay and detect an intruder and initiate a response to the intrusion and not to provide absolute certainty that theft or unauthorized access will not be attempted but to recognize and address such efforts should they occur." It should be noted that 10 CFR Part 37 evolved from the original Security Orders issued by the NRC.

Regarding NRC's collaboration with other Federal agencies with respect to security of radioactive material, the following information was evaluated as part of this assessment. The GAO Report "Additional Actions Needed to Increase the Security of U.S. Industrial Radiological Sources," dated June 2014; states on page 36 that although DHS, NNSA, and NRC have an interagency mechanism for collaborating on, among other things, radiological security, they were not always doing so effectively. On page 50 of the GAO report, the NRC responds by saying that it agrees and will continue to conduct periodic meetings with senior management of these agencies to enhance coordination and collaboration on overarching technical and policy issues related to source security.

Five employees from NRC's Offices of NMSS and NSIR were contacted in order to determine what specifically has been accomplished to improve collaboration between the NRC, the Department of Homeland Security (DHS), and the Department of Energy (DOE)/NNSA).

A staff member of the NRC's Office of NSIR and a Branch Chief from NRC's Office of NMSS stated that the NRC has been actively involved in a number of initiatives to improve collaboration between NRC, DOE/NNSA, and DHS. The initiatives foster enhanced communication and working relationships between the agencies. The NRC has and continues to participate in the following forums:

- The Radiation Source Protection and Security Task Force, which was established by the Energy Policy Act of 2005. The Task Force evaluates and provides recommendations related to the security of radioactive sources within the U.S. There are twelve member agencies, and three additional agencies are invited to attend the meetings, which are held approximately every 5 to 6 months;

- Senior managers from the NRC, DHS, and DOE/NNSA with additional support and participation from the Federal Bureau of investigation (FBI) conduct periodic meetings to enhance coordination on technical and policy issues;

- DHS, Government Coordinating Council (GCC) on Radioisotopes and Infrastructure Partnership Advisory Council (CIPAC) groups; and

NRC management (Division Directors and Branch Chiefs within NMSS, and NSIR) meet quarterly with DHS and DOE/NNSA to discuss technical and policy issues associated with radioactive source security.

Another example of collaboration between the NRC and other Federal agencies includes the sharing of the NRC's National Source Tracking System (NSTS) data, which is routinely provided to partner agencies, including the FBI, DHS, and DOE. The FBI's Weapons of Mass Destruction Directorate Special Projects Unit combines NSTS data with data sets from across the FBI, interagency partners, and the private sector. DHS's Transportation Security Administration (TSA) Operation Center uses NSTS data for situational awareness in incident response. DOE/NNSA uses the NSTS data for its Voluntary Security Upgrade Program. Furthermore, the NRC's Web-Based Licensing System (WBL) is available to DHS's Customs and Border Protection (CBP), National Targeting Center. CBP can access WBL in order to evaluate shipments entering the United States (U.S.). A staff member from the NRC's Office of NSIR also stated the NRC also provides daily Category 1 Advance and Active Shipment information to the FBI, Department of Transportation (DOT), DHS (CBP, DNDO, and TSA), DOE, and U.S. Northern Command (Northcom).

Based on a review performed during this assessment of the Radiation Source Protection and Security Task Force Report for 2014, the Task Force Report describes examples of the accomplishments as a result of the collaborative efforts between the Federal Agencies. The Chairman of the NRC serves as Chair of the Task Force, and the other Federal Agencies are represented by the following members: Secretary of Homeland Security; Secretary of Defense; Secretary of Energy; Secretary of Transportation; Attorney General; Secretary of State; Director of National Intelligence; Director of the Central Intelligence Agency; Administrator of the Federal Emergency Management Agency; Director of the Federal Bureau of Investigation; and the Administrator of the U.S. Environmental Protection Agency.

The Task Force report includes a section titled, "Key Accomplishments Between 2010 - 2014." The following are some of the accomplishments described in the report: 1) Expanded disposal capacity; 2) Increased physical protection; 3) Enhanced tracking and accounting; 4) Increased preparedness and communication; and 5) Improved transportation security coordination.

The following provides a brief summary of each accomplishment as described in the Task Force Report:

- Expanded disposal capacity - In 2012 the Waste Control Specialists commercial low-level radioactive waste disposal facility licensed by the State of Texas initiated operations. The disposal facility has "provided commercial disposal access to sealed source waste generators in 36 States that had been without commercial disposal pathway since 2008. Disposal options for many commercial Class A, B, and C sealed sources are now available to low-level waste generators in all 50 states." In

addition, progress has been made regarding ongoing challenges with transportation of sealed sources that exceed current commercial disposal activity limits. Furthermore, according to the report, revision of NRC guidance regarding commercial disposal of sealed sources, development of new transportation containers to facilitate the recovery of high-activity sources and devices, and progress toward a final Environmental Impact Statement for the disposal of greater-than-Class C low-level radioactive waste included public and private sector engagement.

- Increased physical protection - The NRC published a final rule in the Federal Register specifying the requirements of 10 CFR Part 37. The DOE/NNSA continues to provide voluntary security enhancements and specialized training.

- Enhanced tracking and accounting - The NRC deployed two key software systems, Web-Based Licensing and License Verification System in August 2012 and May 2013, respectively.

- Improved transportation security coordination - A final draft of the Transport Security Memorandum of Understanding (MOU) between the NRC, DHS, and DOT was issued during 2014. This MOU serves "as a foundation for cooperation in the establishment of a comprehensive and consistent transport security program for risk-significant sources." According to the report, the MOU is aimed at ensuring that the transportation of radioactive sources in the U.S. and across U.S. borders is carried out in a manner that protects the public health and safety and does not impact the common defense and security of the U.S.

Chapter 1 of the report addresses Coordination and Communication Improvements. As an example of the Task Force's accomplishments in the area of communication, the report states, on page 4, that "the Task Force continues to support progress and maintains awareness of developments in the area of public education, outreach, and communication initiatives related to radiation and other hazards." On page 5 of the report, it states that senior managers of the "trilateral agencies" (NRC, DHS, and DOE/NNSA with support from the FBI) continue to meet periodically "with the goal of enhancing coordination on overarching technical and policy issues related to source security." Also on page 5 of the report, it states that the agencies have conducted public meetings and outreach efforts since 2006 on major topics addressed in the report. The outreach activities included 10 CFR Part 37 rulemaking and the Integrated Source Management Portfolio (ISMP).

The Task Force Report also includes recommendations and status from 2010 and 2014 to "facilitate progress in the research, development, and implementation of alternative technologies." The recommendations are as follows: "U.S. Government enhance support to short-term and long-term research and development for

alternative technologies; U.S. Government, contingent upon the availability of alternative technologies and taking into consideration the availability of disposal pathways for disused sources, investigate options such as a voluntary prioritized, Government-incentivized program for the replacement of Category 1 and Category 2 sources with effective alternatives, with an initial focus on sources containing Cesium Chloride (CsCl); and contingent upon the availability of viable alternative technology, the Task Force recommends that the NRC and Agreement States review whether the licensing for new Category 1 and 2 CsCl sources should be discontinued, taking the threat environment into consideration." The Report also contains a "Summary Table of 2006 and 2010 Recommendations and Actions and New 2014 Recommendation."

During this assessment, an attempt was made to evaluate collaboration between the NRC and NNSA. Also information was obtained regarding NNSA's approach to securing radioactive material. According to an NRC employee who has been a staff member of the NRC's Offices of NMSS and NSIR, the NNSA does not share its criteria for enhancing security with other entities. The NNSA has developed a document titled, "Protection and Sustainability Criteria," which has been designated Official-Use-Only (OUO) and, therefore, not publically available. She elaborated by stating that it appears the NNSA has a suite of upgrades, which consists of the "one size fits all" approach. Furthermore, she stated that the NNSA has not performed a vulnerability assessment in order to arrive at its security enhancements, and that the NNSA uses a checklist while evaluating facilities. Additionally, she indicated that the NNSA's primary focus is on Category 1 sources.

A member of the NRC's Working Group for NUREG-2166 and former staff member from the NRC's Office of NMSS stated that representatives from NNSA participated in the NUREG-2166 working group. This individual also served as a co-lead for the NRC-sponsored Training Subgroup and indicated that the subgroup felt it was important for S-201 training to include a discussion regarding NNSA Global Threat Reduction Initiative (GTRI) security "upgrades." Also according to this individual, the Training Subgroup noticed that inspectors seemed to know little about technologies employed, and that some inspectors seemed to have a tendency to assume that a licensee was in compliance if he had employed the NNSA GTRI upgrades and, therefore, did not, in some cases, perform a thorough inspection. So based on these observations, the Training Subgroup decided it would be beneficial to include a presentation by the NNSA GTRI during the S-201 training classes. Representatives from the NNSA have presented training during the S-201 class regarding their security upgrade program. Apparently this training has been well received, based on class feedback.

Representatives from the NNSA were contacted in order to determine if they were aware that the NRC was conducting rulemaking to establish regulations for the physical security of radioactive materials prior to the final publishing of 10 CFR Part 37, and if yes, did the NNSA participate by providing any input or feedback on the

proposed rule? Specifically, does the NNSA think the regulation should have been more prescriptive and/or included specific disqualifying criteria for personnel access? The NNSA was also asked to summarize any comments or input provided and any response received from the NRC.

A representative from the NNSA stated in her response to the questionnaire that they were aware that the NRC was conducting rulemaking to establish regulations for the physical security of radioactive materials and that the NNSA neither provided official comments to the proposed rule nor took a position on the regulatory approach of the proposed rule. The NNSA representative also stated that the NNSA understands that regulations can take several forms to include prescriptive, performance-based, or a combination of both approaches. Also in her response to the questionnaire, the NNSA representative indicated that the NRC is in the best position to determine the appropriate regulatory approach and to determine the specific disqualifying criteria for licensees and personnel access. Since the NNSA's representative's comment seemed to be contrary to the NRC's position regarding disqualifying criteria, during a subsequent interview with the NNSA representative, an attempt was made to obtain clarification concerning the representative's earlier response. During the interview, the NNSA representative stated that the NNSA is in agreement with the NRC regarding disqualifying criteria. It should be noted that on page 29 of the GAO report, "Additional Actions Needed to Increase the Security of U.S. Industrial Radiological Sources," dated June 2014, it states that NRC's controls place the responsibility on the licensee to evaluate all the information and determine whether an employee is trustworthy and reliable. It further states that, in response to the NRC's proposal of 10 CFR Part 37, it received comments stating that it should provide specific criteria such as disqualifying convictions for use by licensees with respect to the T&R determination. The NRC declined to provide specific criteria, stating that it is the licensee's responsibility to consider all information and make a determination. Based on this information, it may be beneficial for an NRC representative to continue a dialog with the NNSA representative to ensure that each agency clearly understands the other's position regarding disqualifying criteria for T&R determinations.

In addition, the NNSA representative indicated in her response to the questionnaire that she thinks that comments received by the NRC on the proposed regulation were adequately addressed by the NRC. She also stated the NNSA believes that the NRC provided adequate communication to its stakeholders during the rulemaking process.

The GAO stated in its report, "Additional Actions Needed to Improve Security of Radiological Sources at U.S. Medical Facilities," dated September 2012, that one reason NRC's requirements did not consistently ensure the security of high-risk radioactive sources was that the requirements are written too broadly and do not prescribe specific measures that licensees must take to secure their equipment containing high-risk radioactive sources.

The NNSA representative was asked to provide her professional opinion regarding whether, upon her review of 10 CFR Part 37, the requirement appeared to be too broadly written and, if so, was this communicated to the NRC? Additionally, the NNSA representative was asked if she did communicate her opinion, what actions, if any, were taken by the NRC to address the concern. The NNSA representative was also asked if there were any areas of 10 CFR Part 37 that the NNSA currently believes should be modified to be more prescriptive. The NNSA representative stated that the NNSA believes that 10 CFR Part 37 is a comprehensive regulation that is consistent with International Atomic Energy Agency (IAEA) recommendations and the NNSA Global Material Security Guidance for Category 1 and Category 2 radioactive material. The NNSA representative further stated that the IAEA recognizes three regulatory approaches: prescriptive, performance-based, or a combination of both approaches. The NNSA understands that 10 CFR Part 37 is primarily performance-based due to the varied types of facilities and users that must implement the regulation. The NNSA representative also stated that, in general, NNSA understands why NRC prefers a performance-based system over a prescriptive system. However, the NNSA representative further stated that this requires specialized expertise and analysis and can be time consuming and costly. Furthermore, the NNSA representative stated that the challenge to effective security is not necessarily the adequacy of the regulatory requirements; it is the field implementation of the requirements. The NNSA representative went on to say that a performance-based approach requires well-trained and knowledgeable licensees to implement the desired goals of the regulation, and experienced and well-trained NRC inspectors to conduct security inspections that review the effectiveness of a site's implementation of 10 CFR Part 37. According to the representative, the NNSA believes that robust protection against the risk of an insider is critical, and while 10 CFR Part 37 does address the insider threat primarily through the background check requirement, "best practices" such as those identified in NUREG-2166 and promoted by the NNSA, could offer further protection. The NNSA representative recommends that 10 CFR Part 37 clearly requires engineering checks on the insider at Category 1 facilities at a minimum. According to the NNSA representative, these checks could be technical countermeasures, such as zoned alarms that cannot be deactivated and redundant alarm monitoring locations. In addition, the representative stated that the NNSA was aware that the NRC had developed a number of guidance documents for 10 CFR Part 37 and indicated that the NNSA had provided input to NUREG-2166.

GAO's report "Additional Actions Needed to Increase the Security of U.S. Industrial Radiological Sources," dated June 2014, recommends on page 40, that the Administrator of NNSA, the Chairman of the NRC, and the Secretary of the DHS should review their existing collaboration mechanism for opportunities to enhance collaboration, especially in the development and implementation of new technologies.

A representative with the NNSA stated that the NNSA appreciates the cooperation and assistance provided by the NRC, to date, on the NNSA's domestic security enhancements program for radioactive sources and looks forward to working with NRC on enhancing this cooperation going forward. In addition, both the NRC and NNSA play a key role in preventing radiological terrorism and that continued partnership and communication is essential. The representative also stated that the NNSA and NRC hold periodic meetings to inform each other of areas of mutual interest concerning source security and participate in various Federal task forces and working groups on the security of radioactive materials. According to the representative, the NNSA and NRC also, on an as-needed basis, communicate on an informal level, keeping one another informed. The NNSA representative noted that the NNSA would like to continue this cooperation and mutual sharing of relevant information. The representative indicated that the NNSA has gone through a re-organization within the past year, and since that time, has conducted formal and informal monthly bilateral meetings (i.e., meeting between the NRC and NNSA staff) as well as participated in trilateral meetings with the NRC and DHS staff. The FBI was also in attendance at these meetings. The NNSA representative believes that communication is vital. In addition, according to the NNSA representative, the NNSA is reviewing its strategic review process internally, and this review will look at its prioritization methodology, implementing goals, and mission, and will be reaching out to other agencies regarding the results of its review.

In the GAO report, "Additional Actions Needed to Improve Security of Radiological Sources at U.S. Medical Facilities," dated September 2012, on page 23, the GAO states that NNSA's Domestic Material Protection program is designed to raise the security at U.S. facilities with high-risk radioactive material, including hospitals and medical facilities, to a level that is above NRC and Agreement State's regulatory requirements. Page 23 also states that according to the NNSA officials, the agency does not share the assessments because of its concern that hospitals and medical facilities, which are voluntarily cooperating with the NNSA, would not provide complete and candid information to NNSA, if it shared the assessments with NRC and Agreement States' regulatory inspection agencies. After completing the assessments, NNSA installs security upgrades, such as remote monitoring systems, biometric access controls, and security cameras, to secure devices and facilities that contain high-risk radioactive sources. According to the report, which contains NRC's response to the report, NRC and Agreement States use a multilayered, risk-informed performance-based approach for security. As stated on page 11 of the report, the key elements of NRC's requirements include: 1) limiting access to only approved individuals through the use of background checks that include fingerprinting; 2) enhancing physical barriers and intrusion detection systems; 3) coordination with local law enforcement to respond to an actual or attempted theft, sabotage, or diversion of radioactive material; 4) promptly notifying authorities of incidents; and 5) monitoring shipments of radioactive materials during transit.

The NNSA representative stated in her response to the questionnaire that the NNSA may share generalized observations with the NRC but does not make any assessments or determinations on whether a cooperating site meets the NRC's requirements. The NNSA does assume, as a condition of a site participating in the voluntary security enhancements program, that the site meets the NRC's requirements as evidenced by the NRC license.

It became clear during this assessment, based on discussions with licensees who have participated in the NNSA's volunteer security enhancement program and discussions with the NNSA's representatives, that the NNSA security enhancement program is designed to enhance security to a level that is above the NRC's and Agreement States' regulatory requirements. During an interview with representatives from NNSA, they stated that the NRC is aware of the types of upgrades the NNSA recommends to licensees. The licensees who have participated in the NNSA volunteer security enhancement program indicated that the NNSA makes it very clear that the enhancements do not ensure or guarantee compliance with the NRC's requirements.

In the GAO report, "Additional Actions Needed to Increase the Security of U.S. Industrial Radiological Sources," dated June 2014, on page 29, the GAO states that NNSA officials told GAO that they consider an insider threat to be the primary threat to facilities with radioactive sources. According to an NNSA fact sheet, almost all known cases of theft of nuclear and radioactive material involved an insider.

A review of the NNSA Fact Sheet was conducted during this assessment. The fact sheet is titled, "Insider Threat to Nuclear and Radiological Materials: Fact Sheet" and dated March 23, 2012. It states that a multilayered approach can mitigate the insider threat. It further states that each nuclear facility applies layers of security measures to protect material to include administrative controls and policies and technical systems that are integrated to minimize the insider threat. The NNSA Fact Sheet specifies the following measures as examples of administrative controls: materials accounting; procedures; human reliability program; and nuclear security culture. The Fact Sheet also specifies the following measures as examples of technical systems: access controls; materials controls; detection; and delay features. The Fact Sheet concludes by stating that combined with legal penalties for theft, unauthorized possession, and smuggling of material, these security measures are aimed at deterring a potential insider and making their task more difficult. According to a representative from the NNSA, the Fact Sheet had been previously provided to the NRC.

Based on the review of the NNSA Fact Sheet during this assessment, it appears the Fact Sheet parallels the NRC's key elements to security of radioactive material.

The NNSA representative provided the following description of the NNSA's approach to security. The NNSA uses a graded security approach to ensure that radioactive material with the potential to cause the most harm if used maliciously receives the

highest level of security enhancements. Further, the categories used for sources are a measure of risk based on the relative consequences if that material type and quantity were used for a radioactive dispersion device or a radioactive exposure device. There are common potential consequences that drive the need for common security enhancements on material of similar categories in the NNSA's security enhancement program. In addition, the NNSA implements a consistent and streamlined approach to enhancing protection on similar materials against a defined threat level. Furthermore, NNSA uses the term "Potential Adversary Capabilities" (PAC) to describe the method of documenting a realistic threat level that the NNSA voluntary security enhancements address. Also in establishing its default PAC, NNSA attempts to be as consistent as possible with current U.S. interagency threat assessments on global nuclear and radiological facilities and recent international efforts to address adversarial capabilities. The NNSA PAC is sensitive and, therefore, specific information contained in the PAC was not provided. The NNSA has proposed a briefing for NRC to review the NNSA PAC. The PAC is also being updated as part of the NNSA's Office of Radiological Security's Program review.

During an interview with representatives of the NNSA, they elaborated on their "consistent approach". Specifically, the NNSA uses a suite of upgrades; basically, a compilation of pre-approved "tools" (guidance) created by experts in area of physical protection systems. The guidance includes such things as options for intrusion detection, assessment, detection, and response. This information is maintained in a guidance document (toolbox). They indicated that the NNSA would like to use a performance-based approach when assessing facilities for security upgrades however, it would be cost prohibitive to take this approach for every facility. Further, they indicated that the NNSA upgrades are based on risk, specifically theft of radioactive material. In the future, the NNSA would like to open a dialogue with the NRC concerning the risk of sabotage. The NNSA also stated during the interview that the Protection and Sustainability document developed by the NNSA contains its internal guidance program, types of radioactive material, assigned priorities for the radioactive material and sites, the toolbox, and activities to promote sustainability. They also indicated that the NNSA's approach to security is a blend of prescriptive and performance-based. Specifically, in order to determine a baseline for its approach to security upgrades and to reach its performance objective consistently, the NNSA starts out with a prescriptive approach and then tailors that to each specific site and available response.

Although the NNSA representatives indicated that their approach to security is a blend of both prescriptive and performance-based, it seems, based on information provided by some NRC staff, the NNSA approach could be considered prescriptive compared to the NRC's approach. Representatives from the NRC's Office of NSIR indicated that the NRC chose not to establish prescriptive requirements in 10 CFR Part 37 because there are many different types of licensees and licensee facilities that are required to comply with 10 CFR Part 37, and prescriptive requirements may not be appropriate for every licensee's security program. Performance-based

regulations allow licensees to tailor their security program to meet their specific needs.

A representative from the NRC stressed that the NNSA does not have regulatory requirements or standards where the NRC does. According to the NRC representative, the NNSA performs an assessment of a licensee's current security and then provides additional security equipment installed by a contractor. The NRC's approach to performance-based regulations and performance-based inspections has been discussed in many documents. Many different types of licensees must comply with 10 CFR Part 37. Additionally, there are many differences between licensees of the same type. Therefore, the "one size fits all" approach may not be successful.

According to a Branch Chief in the NRC's Office of NMSS, it is important to make a determination as to what it is one is trying to protect against when establishing security requirements. The NRC has conducted several discussions with NNSA, and it should be noted that the NNSA has voiced its agreement that the NRC requirements are adequate for protection of Category 1 and Category 2 high-risk radioactive material. The Branch Chief confirmed that the NNSA raises security at facilities with high-risk radioactive material to a level that is above NRC and Agreement States' requirements.

A copy of a letter and its enclosure from the former Chairman of the NRC, Gregory B. Jaczko, to the Honorable Byron Dorgan, Chairman, Subcommittee on Energy and Water Development, Committee on Appropriations of the United States Senate, dated September 14, 2010, was reviewed during this assessment. The enclosure contains a joint report by the NRC and the NNSA. Chairman Jaczko states in his letter that the NRC has the authority to regulate the safety, security, and nonproliferation aspects in the civilian use of byproduct, source, and special nuclear material. He also states that the NNSA's authority relates to the management and security of the Nation's nuclear weapons. Additionally, in his letter, Chairman Jaczko states that the enclosed report describes the distinct roles of the NRC and NNSA regarding safety and security of radioactive sources. He further states that the roles and authorities are complementary, and while different, both the NRC and NNSA have a common goal of preventing the malicious use of radioactive material. The Joint Report states that ultimate responsibility for securing nuclear and radioactive materials in the U.S. rests with the licensees that are authorized to possess the materials. The joint report further describes the activities that the NRC and NNSA have worked together on since September 11, 2001. The activities include, but are not limited to, the following: a meeting between the NNSA Administrator and the NRC Chairman to align on common goals and objectives; updating the GTRI Protection and Sustainability Criteria Document (published February 2010); NRC inviting GTRI to observe NRC Increased Controls inspections at radiological site and GTRI inviting NRC to a voluntary security assessment visit at a research test reactor;

and GTRI inviting NRC, DHS, FBI, and others to observe GTRI Alarm Response Training at Y-12.

Although the NNSA has a different mission than the NRC, some NRC staff members believe that there should be one standard across the board for all Federal Agencies, and there is a need for a national threat assessment that governs all Federal agencies. One NRC staff member indicated, during this assessment that the NNSA comes to the NRC for its threat assessment. As mentioned above, the NNSA uses a suite of upgrades; basically a compilation of pre-approved "tools" (guidance) created by experts in the area of physical protection systems. According to one NRC staff member, the NRC provided comments to the NNSA during the development of the NNSA's "Protection and Sustainability Criteria" document, which is OUO, however, the comments were not incorporated into the document during the last revision in February 2010. This document does contain discussions on material attractiveness as well as rationale and thresholds. Since the NNSA's document, "Protection and Sustainability Criteria," is designated as OUO, a review of the document could not be performed during this assessment. In addition, one NRC staff member indicated a difference between the NNSA's approach to security and the NRC's approach. Specifically, the NNSA has not conducted a vulnerability assessment, where-as the NRC conducted a vulnerability assessment prior to issuing the original Security Orders to licensees.

An NRC staff member who has been employed by NRC's Offices of NMSS and NSIR stated that the NRC's security requirements are "transparent, and stable, that provides a graded approach to security of radioactive materials across a wide variety of licensee types and uses, and NNSA's international and domestic security enhancements for specific sources and facilities are very different." The NRC requires licensees to develop formal, documented security programs, which include hardware, people, software, infrastructure, and practices to work together to provide necessary protection for specified radioactive materials.

c. Conclusions and Recommendations

The NRC made considerable efforts to communicate with stakeholders on the new regulatory requirements in 10 CFR Part 37.

Based upon a review of the information available during this assessment, it is apparent that the NRC made considerable efforts to communicate with stakeholders throughout all phases of the 10 CFR Part 37 roll-out process. I have concluded that NRC did an admirable job communicating with stakeholders during the development phase in order to ensure stakeholders were involved and informed of the new requirements in 10 CFR Part 37.

Based on a review of the Radiation Source Protection and Security Task Force Report as well as information provided by several NRC employees interviewed, collaboration between several Federal Agencies appears to have improved.

However, with this said, the U.S. Federal Government must continue to pursue all available avenues of communication and must continue to actively pursue improvements/enhancements for securing risk-significant radioactive sources.

The NNSA representative mentioned in one of her responses to the questionnaire, that the NNSA assumes, as a condition of a site's participation in the voluntary security enhancements program, that the site meets NRC's requirements as evidenced by the NRC license. This seems to be a misconception by the NNSA. If the NNSA assumes that the mere possession of an NRC license means the licensee is in compliance with the NRC's requirements, then the NRC and NNSA should discuss how the NRC determines licensee compliance by conducting inspections of licensees at a determined frequency.

The NNSA Fact Sheet titled, "Insider Threat to Nuclear and Radiological Materials: Fact Sheet" and dated March 23, 2012, appears to be in close agreement with the key elements of the NRC's requirements in 10 CFR Part 37 specifically, 1) limiting access to only approved individuals through the use of background checks that include fingerprinting; 2) enhancing physical barriers and intrusion detection systems; 3) coordination with local law enforcement to respond to an actual or attempted theft, sabotage, or diversion of radioactive material; 4) promptly notifying authorities of incidents; and 5) monitoring shipments of radioactive materials during transit. The issue then becomes whose standard is used to determine what constitutes an appropriate level of security, and what specifically one is trying to protect against. I believe a discussion needs to continue between the NNSA, NRC, and DHS on this subject, and a common, agreed-upon standard should be obtained. This effort should include additional discussion regarding the basis for not utilizing a Design Basis Threat (DBT) when developing 10 CFR Part 37.

2. Review of NRC Staff's Outreach to Stakeholders to Gather Feedback When Developing and Updating Regulatory Requirements and Guidance

a. Scope

An independent assessment of the NRC staff's outreach to stakeholders to gather feedback when developing and updating regulatory requirements and guidance was conducted. As part of this assessment, a review of the following documents was performed: SECY-11-0170; FRN 78 No. 53; 10 CFR Parts 37 and 73; 10 CFR Part 37 Implementation Working Group Draft Charter; Enforcement Guidance Memorandum, Enforcement Discretion for Part 37 for Large Components; Inspection Procedure (IP) 87137; Temporary Instruction (TI) 2800/042; NUREG-2155; NUREG-2166; and IAEA Nuclear Security Series No. 11. Responses to questionnaires were evaluated, and information received during interviews was also evaluated. In addition, a review of the following GAO reports was conducted: "Additional Actions Needed to Improve Security of Radiological Sources at U.S. Medical Facilities."

dated September 2012; and "Additional Actions Needed to Increase the Security of U.S. Industrial Radiological Sources," dated June 2014.

b. Observations

After 10 CFR Part 37 was issued, the NRC conducted additional outreach activities with stakeholders. For example, the NRC conducted stakeholder meetings with the following: MML Annual Counterpart Meeting in 2014 and 2015; International Source Suppliers and Producers Association on February 26, 2014 (occurred just prior to 10 CFR Part 37 being issued); Nuclear Materials Management and Safeguards System Annual Training on May 13, 2014; the Organization of Agreement States Annual Meeting on August 26, 2014; the Texas Regulator Conference on September 11, 2014; the Campus Safety, Health, and Environmental Management Association Conference on July 29, 2015; the Nondestructive Testing Management Association on February 12, 2915; the Rocky Mountain Chapter of the HPS in May 2015; the Steel Manufacturers Annual Meeting on May 15, 2015; and the Conference of Radiation Control Program Directors Annual Meeting on May 20, 2015.

A review of SECY-11-0170, Final Rule: Physical Protection of Byproduct Material, Regulatory Information Notice (RIN 3150-A112), dated July 24, 2002, and revised August 22, 2007, determined that the SECY includes an Implementation Plan Summary as an attachment. The summary states the following: "the NRC will form an implementation working group in accordance with Management Directive 5.3, Agreement State Participation in Working Groups." "The working group will resolve licensee questions and issues that emerge during the implementation period, track development of inspection guidance and training programs, and update implementation guidance as needed." In addition, the summary states that "Communication with the Agreement States, the NRC Office of General Counsel, the NRC staff and others is necessary to provide information to stakeholders regarding the status of implementation milestones, training, updated guidance and best practices and to resolve questions or problems that will arise during the implementation period."

It was determined during this assessment that the NRC formed the10 CFR Part 37 Implementation Working Group to develop the implementation guidance for 10 CFR Part 37. Based on interviews conducted with several NRC staff members who serve on the10 CFR Part 37 Implementation Working Group, they confirmed that the 10 CFR Part 37 Implementation Working Group had been formed in November 2012, and has been meeting biweekly since then.

According to the Implementation Working Group Draft Charter, which was distributed to working group members in August 2013, the Implementation Working Group consisted of representatives from the NRC, Organization of Agreement States (OAS), and the Conference of Radiation Control Program Directors (CRCPD). This particular working group was divided into 12 subgroups. Each subgroup was assigned a focus area. The focus areas included the following: rescission of original

NRC Security Orders, tracking Agreement State Regulations, Information Protection, Stakeholder Outreach, enforcement guidance, inspection procedures, best security practices guidance, implementation guidance, inspection activities, training, and removal of NRC license conditions. The 10 CFR Part 37 Implementation Working Group Draft Charter states that the working group would develop a communication plan in order to determine the needs for interaction with the public. The communication plan was developed but is designated as OUO and not part of this assessment. In FRN Vo. 75, No. 151, dated August 6, 2010, "Implementation Guidance for Physical Protection of Byproduct Materials; Category 1 and Category 2 Quantities of Radioactive Material; Meeting," the NRC announced that two meetings were going to be conducted, one in Austin, Texas, on September 1, 2010, and one in Rockville, Maryland, on September 20, 2010. The purpose of these meeting was to solicit comments on the draft implementation guidance.

Based on information provided by two members of the 10 CFR Part 37 Implementation Working Group, one of the subgroups of the 10 CFR Part 37 Implementation Working Group was tasked with leading the development of NUREG-2166, "Physical Security Best Practices for Protection of Risk-Significant Radioactive Material," which was subsequently published in May 2014. Other activities the 10 CFR Part 37 Implementation Working Group has been involved with include development of the following: IP 87137 issued April 3, 2014; TI on Trustworthiness and Reliability (TI 2800/042 issued November 25, 2015); and several Regulatory Issue Summaries. In addition, members of the 10 CFR Part 37 Implementation Working Group also communicated with stakeholders about the new security requirements by participating in public meetings and updated the NRC public website with information pertaining to the new requirements.

IAEA Nuclear Security Series No. 11 Guide states, on page 26, that a performance based approach is one in which the regulatory body allows flexibility for the operator (licensee) to propose the particular combination of security measures that will be used to achieve the security objective in Table 2. Additionally, it states that that the proposed security measures should be based on a vulnerability assessment, taking into account information provided by the regulatory body, based on a national threat assessment and, where applicable, a DBT. Table 2 "Security Levels and Security Objectives" contains a list of security functions, such as detect, delay, response, and corresponding security objectives, such as security level (as defined in the Guide and an associated goal. The goals are as follows: prevent, minimize likelihood of unauthorized removal, and reduce likelihood of unauthorized removal. The NRC has chosen the performance-based approach. A vulnerability assessment was performed by a contractor for the NRC. The NRC's proposed security measures specified in 10 CFR Part 37 were based, in part, on a national threat assessment. The NRC determined that a DBT was not applicable due to the fact that several different types of licensees (i.e., well loggers, medical, irradiators and radiography) with individual types of facilities would be required to comply with10 CFR Part 37. Furthermore, a performance-based approach would allow each licensee to be able to

select which security system would be the most effective for its unique circumstances. One apparent difference in NRC's approach and that as specified in the IAEA Guide No.11 is that the IAEA indicates that for Level A radioactive material which corresponds to Category 1 radioactive material, that the goal is to prevent unauthorized removal of the radioactive materials. On the other hand, the NRC has indicated that the intent of its security controls for Category 1 and Category 2 radioactive material is to develop a combination of people, procedures, and equipment that will delay and detect an intruder and initiate a response to the intrusion and not to provide absolute certainty that the theft or unauthorized access will not be attempted, but to recognize and address such efforts should they occur.

During this assessment, representatives from the NRC stated that the IAEA Guide No.11 was used as the basis for developing the original Security Orders issued by the NRC prior to 10 CFR Part 37 and was reviewed by the10 CFR Part 37 Rulemaking Working Group. In addition, two measures from the IAEA Guide No. 11 were added to 10 CFR Part 37. Specifically, 37.49(a)(3)(i) and 37.49(a)(3)(ii), which address the following: monitoring and detection with respect to unauthorized access; means to detect unauthorized removal of radioactive material; immediate detection of any attempted removal of Category 1 quantities of radioactive material; and weekly verification through physical checks of Category 2 quantities of radioactive material. The IAEA Guide No. 11 was also considered when developing NUREG-2166, "Physical Security Best Practices for the Protection of Risk-Significant Radioactive Material" and is referenced in Section 6 of NUREG-2166.

In addition, according to NRC representatives, the NRC continually evaluates new licensees and facilities against the current and new threats as well as performing an evaluation against the current vulnerability assessment. They indicated that the NRC worked with the intelligence community while developing 10 CFR Part 37, in that, NRC communicated every other week with members of the intelligence community during this process. Also, the NRC conducted a threat assessment in coordination with other National entities annually.

During this assessment, an evaluation was performed of the GAO's conclusion regarding training of licensee officials. Specifically, the GAO report, "Additional Actions Needed to Improve Security of Radiological Sources at U.S. Medical Facilities," dated September 2012, states, in part, on page 19, that hospital and medical facility personnel they interviewed said that the NRC training has not prepared them to adequately enforce the NRC's requirements. GAO recommended that the NRC trains facility officials, including RSOs who may be responsible for implementing NRC's security controls. Furthermore, on page 38, it states that NRC neither agreed nor disagreed with the GAO's recommendation to train facility officials who may be responsible for implementing NRC security controls in how to adequately secure equipment and conduct trustworthiness and reliability determinations. Also on Page 40 of the report, it states that according to NRC, as a regulator, it must maintain independent, objective oversight of licensees and may not

operate in a consultative role. Therefore, NRC does not provide training to licensees but provides regulatory guidance documents to aid facility officials… The NRC did state that it does provide regulatory guidance documents that aid licensees as they establish programs and specific controls to meet requirements. In addition, the NRC also stated that its public website contains implementing guidance and over 200 questions and answers for existing security requirements.

As part of this assessment, the same 17 licensees mentioned earlier in this report were contacted in order to determine if they received and were satisfied with the training/guidance supplied by the NRC to prepare them to comply with 10 CFR Part 37 (or compatible regulation). The licensees were also asked to describe the guidance documents they found helpful/useful in aiding them in establishing a security program and meeting requirements. Twelve licensees indicated that although they may not have received formal training from the NRC, they were satisfied with the guidance provided by the NRC; specifically, they found NUREG-2155 and NUREG-2166 to be helpful. Two licensees indicated that they found the NNSA security upgrade program to be very helpful. In addition, one licensee stated that having a professional security expert as an employee was very helpful. This particular licensee also stated that he found NUREG-2166 too long and difficult to get through, but he does use it as a reference. He also stated that the NRC did try to be helpful by developing the guidance document.

According to a Branch Chief from the NRC's Office of NMSS, the NRC encourages licensees to attend the NNSA training course on response to radiologic events. The NRC does not provide training to licensees but did, however, develop NUREG-2166, "Best Practices," to provide guidance to licensees who were required to comply with 10 CFR Part 37. The NRC conducted several outreach activities when the original Security Orders were issued, but no formal training had been provided to licensees by the NRC regarding basic security principles or controls, or on how to conduct trustworthiness and reliability determinations. This representative also confirmed that the NRC posted questions pertaining to 10 CFR Part 37 on its public website, and that the NRC promotes the security training provided by NNSA on the topic of response to radiological events.

An effort was made during this assessment to determine, based on the NRC's approach to rolling-out 10 CFR Part 37, if there would be a number of challenges encountered by the NRC and licensees.

A number of challenges have been identified by members of the NRC staff. A former Branch Chief from the NRC's Office of NSIR, stated, though not unique to the roll-out of 10 CFR Part 37, was the actual process of rolling out the regulation to a variety of licensee types and ensuring that they have a clear understanding of the requirements. According to one staff member from the NRC's Office of NSIR, the biggest challenge has been informing all licensees about 10 CFR Part 37 requirements. Although the NRC communicated to licensees by using several

different methods, the NRC is still identifying, during inspections, that many licensees are still not aware of the requirements specified in 10 CFR Part 37. The staff member believes that one main reason for this problem is that communications sent by the NRC regarding security requirements are either not being read, or the appropriate individuals are not receiving the communications. According to the staff member, this has resulted in the NRC's issuance of violations to some NRC licensees for failing to comply with 10 CFR Part 37 requirements. Also, according to the staff member, violations that have been identified during inspections have also created challenges within the NRC, in that, all findings were being discussed during the Security Issues Forums (SIF's) (SIF's are discussed further in this Section and Section 6 of this report). Since the NRC's Enforcement Policy had not been revised to incorporate changes to address the requirements of 10 CFR Part 37, a precedent needed to be established for violations being cited against 10 CFR Part 37. In addition, 10 CFR Part 37 inspection findings were not only discussed at the SIF but also during enforcement panels and during discussions held at Implementation Working Group meetings, creating additional burden on NRC staff in that additional time. Also, resources are needed in order to determine the appropriate enforcement action to be taken.

Eleven NRC materials health physics inspectors from the NRC's Regional Offices were contacted in order to ascertain if they had identified any challenges with the implementation of 10 CFR Part 37, specifically in the area of inspections, training of staff, interactions with licensees, and enforcement.

A total of nine NRC materials health physics inspectors, who responded, described challenges concerning the NRC's enforcement process, specifically, the SIF. According to the inspectors, there was little to no pre-established guidelines regarding the Severity Level classification of violations or example violations. The NRC established the SIF to develop guidance/precedent for violations identified during inspections of licensees implementing 10 CFR Part 37. Several inspectors have indicated that the SIF process is burdensome and time consuming. Another challenge occurred while dispositioning unique cases. For example, how to disposition a case involving service provider licensees since they are authorized to provide the service but are not licensed to possess Category 1 or Category 2 sources and therefore, not required to comply with Subpart B of 10 CFR Part 37.

According to one NRC inspector, some individuals within the NRC believe that current examples in the Enforcement Policy were sufficient and that no further enforcement guidance was needed. According to the inspector, individuals with no materials experience, who have never been to a materials licensee facility, are weighing in on materials matters of which they have no understanding, and they would try to "re-inspect" after the fact. The NRC inspector stated that the SIF default position is to take the findings to a traditional enforcement panel, which is the forum for discussing escalated enforcement actions. This frequently results in the same outcome, had it been treated as a Severity Level IV violation initially. Several NRC

inspectors believe that, had the NRC developed Enforcement Guidance and Enforcement Policy examples for violations of 10 CFR Part 37, the SIF process would no longer be necessary and efficiencies could be gained. One inspector indicated that it would have been more efficient if a working group made up mostly of inspectors had been established, who can review the regulations and anticipate the violations that would most likely be identified. The working group could have coordinated with OE and OGC in advance to establish an enforcement table, consisting of violations and the associated Severity Level for use by all the NRC regions. The SIF could then be used as a sounding board for all unusual inspection findings. Another inspector stated that one reason the SIF process slowed things down was due to equipment issues. The SIF is conducted on a secure video. The system was not always reliable, and it would delay discussions and result in delays in completing inspection documentation.

Challenges were also identified in the area of staff training. Specifically, according to one NRC inspector, the training provided to the staff was marginal, considering the amount of effort the NRC Program Office expected from the NRC regional inspectors. According to the inspector, expectations on enforcement had not been provided in a timely manner. According to another NRC inspector, the inspection procedure was not released for use until the implementation date of 10 CFR Part 37, which did not allow for procedure training prior to conducting the first inspections performed of 10 CFR Part 37, compliance. In addition, the GAP Training was not developed by the NRC's Technical Training Center (TTC). As a result, it was developed by an NRC regional inspector and was offered late in the process.

Additional challenges were identified in the area of outreach to licensees. One inspector indicated that the RIS 2014-003 to notify licensees of the implementation date of 10 CFR Part 37 was not available until after the March 19, 2014, implementation date, so many licensees were not fully aware of the new 10 CFR Part 37 requirements and had not updated their existing security programs. Also according to another inspector, outreach could have been improved by the NRC by instituting a checklist similar to one issued by one particular Agreement State Program. It was acknowledged that the NRC did conduct outreach activities with stakeholders, however, it is believed by one inspector that it would have been helpful if the NRC had developed and issued additional tools/guidance prior to the implementation date for 10 CFR Part 37, such as the checklist developed by the State of Ohio.

A review of the checklist developed by the State of Ohio was conducted during this assessment. The State of Ohio divided the checklist into four subject areas as follows: 1) Unescorted Access Authorization Program; 2) Implementing the Security Plan and Maintenance Testing of System Components; 3) Transportation and Logistics; and 4) Training. It should be noted that the inspector believes that the effort taken by the State of Ohio improved the rate of compliance among Ohio licensees. Based on the review performed during this assessment, the checklist

appears to contain guidance that may be helpful to licensees, however, it is difficult to make a determination regarding compliance by Ohio licensees by simply reviewing the contents of the checklist. Additional factors would need to be evaluated in order to obtain a well-supported conclusion regarding the effects of the Ohio checklist on licensee compliance.

Another inspector described a concern that has been identified while conducting inspections. Specifically, licensees are having challenges complying with 37.49(a)(3)(ii), which states that licensees are required to perform weekly verification through physical checks, tamper indicating devices, use, or other means to ensure that the radioactive material is present. The inspector stated that some licensees assume that if they have an alarm in place and it never alarms, then that was sufficient for complying with this requirement. According to the inspector, the NRC Office of NSIR has stated that it is not sufficient, in that, it is a separate requirement, and there must also be additional methods in place to verify that radioactive material is present. The inspector indicated that this is a challenge for smaller licensees, in that, if they decide to close down operations for an extended period of time (two weeks or more), the licensee is not able to comply with the requirement easily. Furthermore, the inspector stated that the regulation requires the licensee to perform the weekly verification, however, there is no requirement to document that the verification had been performed. The inspector also stated that this concern has been brought to the SIF as well as the 10 CFR Part 37 Implementation Working Group and is being discussed. Based on additional discussions with the NRC regarding the challenges some licensees are having complying with 37.49(a)(3)(ii), during this assessment, it seems that it would be appropriate that the issue be discussed with the NRC's OGC to obtain an official interpretation of this particular requirement. In addition, the NRC should ensure that licensees are made aware of the OGC's determination regarding this requirement.

Additionally, one inspector stated that there is one area where he is "profoundly disappointed." He continued by stating that he developed a 10 CFR Part 37 Inspection Checklist that can be used as inspection notes. He indicated that the checklist helps inspectors document the inspection and helps the inspector keep track of what needs to be inspected. He continued by stating that the majority of the inspectors in his Region have used it and said they like it and believe it is a useful tool. The inspector stated that the checklist is not an official record and can be customized by the inspection staff. He has received many requests by Agreement State staff to send them the 10 CFR Part 37 Inspection Checklist and has freely provided this to the Agreement State staff. However, some have raised concerns that a checklist could prevent an inspector from performing a performance-based inspection and have convinced the NRC Headquarters staff that it should not be placed on the inspector toolbox. According to this inspector, he does not agree with NRC's position, and he is willing to discuss this issue with anyone who would like to have a discussion on how to better prepare inspectors for performing a 10 CFR Part 37 inspection.

As part of this assessment, a review of the "checklist" was performed. It seems to closely follow IP 87137 in content and is similar to the NRC's "Field Notes," which the NRC had used for many years when performing materials safety inspections. Field notes had been used by materials health physics inspectors to document notes taken by inspectors while performing inspections. Field notes were not required to be used by inspectors. However, what the field notes did do was to help an inspector prepare for an inspection and provide a reasonably consistent method to document inspections for later use by the inspector. When an inspection was completed, the inspector could review the field notes to verify that all pertinent areas had been reviewed by the inspector. Simply, the field notes captured the who, what, where, when, why, and how of the inspection. They were a useful tool when the inspector briefed his/her supervisor after the completion of the inspection. Additionally, the field notes could be referred to when developing and documenting the formal findings of an inspection. It should be noted that most, if not all, inspectors do take notes while inspecting.

IP 87137 states that "where appropriate, licensee may choose the implementation methods they determine are best, provided those methods meet the intent of the rule. Therefore, inspectors will see different methods of complying with some of the Part 37 requirements. The IP further states that a determination regarding compliance with the NRC's requirements should be based on direct observation of work activities, testing of communications, monitoring, and detection systems, interviews with licensee workers, demonstrations by appropriate workers performing tasks regulated by the NRC, and where appropriate, a review of selected records within the scope of the program requirements." Basically, this supports NRC's policy of conducting performance-based inspections, and inspectors are expected to follow this inspection procedure.

As part of this assessment, an attempt was made to determine if licensees had experienced the same challenges as mentioned in the GAO report. Specifically, in the GAO report, "Additional Actions Needed to Increase the Security of U.S. Industrial Radiological Sources," dated June 2014, on page 28, the GAO indicates that licensees of mobile and stationary radiological sources also face challenges in determining which of their employees are suitable for trustworthiness and reliability certification, as required by NRC's security controls. Some licensee's GAO spoke to indicated they faced challenges making T&R determinations. The licensees stated that the challenges included limited security experience, training, and incomplete information to determine an employee's suitability for unescorted access.

The same 17 NRC licensees were contacted in order to determine if they have identified the same challenges as mentioned by the GAO in determining which employees are suitable for Trustworthiness and Reliability (T&R) certification, as required by NRC's security controls.

Of the 17 licensees that responded to this question, a slight majority had stated they have not identified the same challenges as mentioned by the GAO. Of those licensees that indicated they have experienced the same challenges as mentioned in the GAO report, one licensee representative indicated that he agrees with some of the challenges identified in the GAO report. Specifically, he indicated the "lack of expertise in conducting background checks and evaluating criminal history reports." The licensee representative stated that the NRC should consider a program similar to the TSA's Transportation Workers Identification Credential (TWIC) process in which the NRC would complete the T&R determination and provide conclusion of the evaluation back to the licensee. Another licensee representative believes the T&R determination is very subjective and, therefore, likely to be evaluated differently by individual licensee Reviewing Officials (RO's), resulting in inconsistencies across the industry. One licensee representative indicated that he is concerned that the NRC will second guess T&R decisions, so he tends to error on the conservative side and not approve someone if he has any doubt.

One licensee representative stated that it is difficult to obtain verification of education and work history for foreign nationals who need to be T&R certified. The representative also stated that they have mixed emotions regarding establishing disqualifying criteria.

GAO Report "Additional Actions Needed to Increase the Security of U.S. Industrial Radiological Sources," dated June 2014, page 29, states that NRC declined to provide specific criteria, stating that it is the licensee's responsibility to consider all information and make a T&R determination. An NRC official told GAO that this was a policy choice by the Commission.

According to a staff member from the NRC's Office of NMSS, the NRC did reach out to stakeholders during the development of the technical bases for 10 CFR Part 37. The draft language was published on the NRC's public website. A total of four NRC working groups were formed. The fourth working group compiled the language together, and it went to Draft Rule Language. Additionally, the NRC had received a lot of comments stating that the NRC should provide specific criteria such as disqualifying convictions for use by licensees with respect to the T&R determinations.

During the rulemaking process, NRC received comments and provided answers, which were published in the Federal Register (https://www.gpo.gov/fdsys/pkg/FR-2013-03-19/pdf/2013-05895.pdf. The NRC determined that a performance-based rule provides licensees the flexibility to develop programs and criteria with which they are comfortable. This approach is consistent with the access authorization requirements for power reactors (https://www.gpo.gov/fdsys/pkg/FR-2009-03-27/pdf/E9-6102.pdf).

NUREG-2155 clearly states the criteria that can be used to determine trustworthiness and reliability. NRC has determined that it will not develop a set of criteria for determining T&R. According to a Q&A listed in NUREG-2155, specifically

Q&A No. 4, the NRC has concluded that there is no single list that would likely cover all licensees, and that the licensee is in the best position to weigh the many considerations that must support such determinations. Ultimately, the licensee is responsible for making the T&R determination for all employees granted unescorted access. NUREG-2155 also lists in Annex A, some indicators that the licensee should consider and are provided for convenience. The indicators, according to NUREG-2155, in Annex A, are not meant to be all inclusive nor intended to be disqualifying factors. It has been emphasized by the NRC that the T&R determination requirement in 10 CFR Part 37 is intended to provide reasonable assurance that those individuals are trustworthy and reliable and do not constitute an unreasonable risk to the public health and safety, including the potential to commit or aid theft or radiological sabotage.

It should be noted that 10 CFR 73.56, "Personnel access authorization requirement for nuclear power plants," describes the general performance objective in Section 73.56(c) as follows: the licensee's or applicant's access authorization program must provide high assurance that the individuals who are specified in paragraph (b)(1), and, if applicable, paragraph (b)(2) of this section are trustworthy and reliable, such that they do not constitute an unreasonable risk to public health and safety or the common defense and security, including the potential to commit radiological sabotage. On the other hand, 10 CFR Part 37.21, "Personnel access authorization requirements for Category 1 or Category 2 quantities of radioactive material," describes the general performance objective as follows: the licensee's access authorization program must ensure that the individuals specified in paragraph (c)(1) of this section are trustworthy and reliable. For Category 1 and Category 2 quantities of radioactive material, the NRC has responded to the GAO report dated June 2014, stating that the NRC's implementation guidance is designed to provide reasonable assurance that individuals with unescorted access to radioactive sources are trustworthy and reliable and that facilities have a reliable means to monitor events that are potentially malevolent and have a process for prompt response. The NRC's response to the GAO is very similar to the wording in Annex A of NUREG-2155, which states that the purpose of the T&R determination requirement is to provide reasonable assurance that those individuals are trustworthy and reliable and do not constitute an unreasonable risk to the public health and safety, including the potential to commit or aid theft or radiological sabotage. The words "common defense and security" and "high assurance" do not appear anywhere when addressing Category 1 or Category 2 radioactive sources. These words may have been left out intentionally when the NRC decided to issue 10 CFR Part 37 under health and safety rather than common defense and security. According to information provided by an NRC Project Manager from the NRC'S Office of NMSS, the NRC's Office of General Counsel (OGC) stated that the NRC may not have legal authority to assume T&R functions and adjudicate for unescorted access to risk-significant material unless the basis of the authority from issuing requirements for the regulation is changed from public health and safety to common defense and security for all affected licensees. The

Project Manager stated that under common defense and security, Agreement States would not be allowed to have a role in implementing, inspecting, or enforcing the 10 CFR Part 37 regulations.

The NRC did provide extensive guidance to licensees in its Implementation Guidance NUREG-2155 and additional guidance in NUREG-2166 “Best Practices.” The NRC is firm in its belief that the licensee knows the person the best, and the licensee needs to look at all information available when determining the person’s trustworthiness and reliability.

However, according to the NRC, it has initiated a review of inspector findings in the areas of licensee T&R determinations. The NRC has issued a TI 2800/0442, “Evaluation of Trustworthiness and Reliability Determinations,” dated November 25, 2015, to inspectors to enable the NRC to determine that inspectors are being consistent in their approach, review, and action when inspecting licensee compliance of this requirement.

In addition, 11 NRC materials health physics inspectors from the NRC’s regional offices were asked if, while conducting inspection of licensees implementing 10 CFR Part 37, have they identified the same challenges as mentioned by the GAO, that licensees of mobile and stationary radioactive sources also face in determining which of their employees are suitable for T&R certification, as required by the NRC’s security controls? If so, they were asked to please provide examples. Of the NRC inspectors who responded to this question, seven indicated that they have not identified the same challenges as mentioned by the GAO.

Of the NRC inspectors who indicated they had identified the same challenges as mentioned in the GAO report, one NRC inspector indicated that, based on the inspections he has conducted so far, licensees wish that guidance for the T&R determination process was more specific (step-by-step), so they could either approve or deny an individual. Another NRC inspector stated that licensees with foreign-born students/researchers have complained that it is difficult to verify work experience and education for these students. The inspector further indicated that licensees are not fully comfortable with 10 CFR 37.25(a)(7) that allows information to be obtained from an alternate source, and they feel that they would be penalized for using alternate information.

The same 17 NRC licensees were asked if there are other areas of 10 CFR Part 37 (or compatible regulation) with which they find difficult to comply. If so, they were asked to describe which areas and to discuss whether additional training in basic security concepts/principles would be helpful. In addition, they were asked if they considered alternative methods of obtaining training in security concepts/principles, such as other Federal agencies well versed in basic security concepts or an independent third-party expert in basic security concepts/principles. If so, they were asked if they obtained the additional security training prior to being required to implement 10 CFR Part 37 (or compatible regulation).

Of the 17 licensees that responded, ten indicated that there were no other areas of 10 CFR Part 37 with which they found difficult to comply. Of those licensees that did identify other areas of 10 CFR Part 37 with which they found difficult to comply, one licensee representative indicated that he found it a challenge to comply with37.25 and 37.29(a)(1). This representative also specifically stated a concern regarding reinvestigations and whether they are required for individuals who meet the criteria in 37.29. Another licensee representative expressed concern regarding whether there will be varying levels of what is considered acceptable by inspectors for meeting the intent of the 10 CFR Part 37. One licensee representative indicated that he believes that Subpart D of 10 CFR Part 37 is challenging. This representative stated that this section of the regulation should be broken down for each category of radioactive material (i.e., Category 1, 2, and 3), and by type of authorization/use (i.e., medical, radiography, irradiator, well logging, etc.). Another licensee representative felt that the frequency for retraining individuals can be an issue, if they do not get ahead of it. Based on a review of the responses, it appears that alternative methods of obtaining training were not considered by most licensees. Only one licensee indicated that he had obtained additional training through an alternative method. In addition, a few licensees did mention that they did obtain the NNSA security upgrades.

In addition, 11 NRC inspectors from the NRC's regional offices were asked if during inspections any licensees described to them challenges they had encountered while implementing any section of 10 CFR Part 37. If so, the inspectors were asked to describe which specific section(s) of 10 CFR Part 37 the licensees considered challenging. For example, did licensees describe challenges with respect to T&R determinations, due to their limited security experience and training, and if so, please describe.

Of the inspectors who responded, seven indicated that, during inspections, licensees did identify challenges they were encountering while implementing 10 CFR Part 37. Four inspectors stated that licensees did not describe challenges they were encountering while implementing the rule. Of those inspectors who indicated that licensees did describe challenges to them, the majority of concern seems to be in the areas of developing and documenting required policies and procedures, and the T&R determination process.

As a follow up to the questions above, 11 NRC inspectors from the NRC's regional offices were asked if they believe that additional outreach would have been helpful to licensees prior to implementation of 10 CFR Part 37.

Of the 11 inspectors who responded, six felt that additional outreach would have been helpful to licensees prior to implementing 10 CFR Part 37. Two inspectors believe that additional outreach would not have been helpful to licensees, and three inspectors believe that it would depend on a number of factors. Of those inspectors that believe that additional outreach would have been helpful, most indicated that more information regarding the specific differences and changes between 10 CFR

Part 37 and the original Security Orders would have helped licensees, as well as additional public meetings. One NRC inspector believes that better outreach would have reduced the number of enforcement issues. Two NRC inspectors stated that some of the Agreement State Programs were successful in conducting classroom training and providing step-by-step instructional guidance on how to implement programs to comply with the requirements. In addition, according to these inspectors, these Agreement State Programs also conducted site visits. These inspectors also referred to the State of Ohio specifically, that the State sent out a "Licensee Preparation Checklist" to assist licensees. There was one NRC inspector who stated that he did not believe that additional outreach would have been helpful to licensees prior to implementation of 10 CFR Part 37. This inspector believes that ample time, training, assimilation materials, and opportunities for training were provided for licensees to be successful, had they made an honest effort. The inspector also believes that additional outreach would have had minimal effect for those already deferring proper preparation and implementation of the additional security requirements.

GAO Report "Additional Actions Needed to Increase the Security of U.S. Industrial Radiological Sources," dated June 2014, on pages 33 and 34, and the NRC's response on page 49 address the NRC's development of the Best Practices Guide (NUREG- 2166). On page 33, the GAO states that an NRC official told GAO that NRC is relying on a working group, which includes, among others, representatives from NNSA, four inspectors from NRC's regional offices, one Agreement State inspector, and one Agreement State manager to provide insight into the challenges licensees face in complying with NRC's security controls. The NRC official also told the GAO that they had not directly reached out to the licensees during the development of the Best Practices Guide. On page 34, the GAO states that NRC cannot be certain that the Guide will be as useful as it could for those who will be directly affected by the process without including the views of the licensees. On page 49, the NRC states in its response to the GAO, that NRC and Agreement State inspectors interact with licensees during inspections to discuss questions and issues that the licensees have regarding the NRC's security requirements and that the Best Practices Guide is being written to focus on areas of concern that licensees indicated to the inspectors during the inspections. Also, on page 49, the NRC states that during the first 2 years of post-implementation of 10 CFR Part 37, the NRC will assess the effectiveness of this guidance document (Best Practices Guide, NUREG-2166) to determine if any revisions to this document are needed and will make revisions accordingly, using its public participation process.

According to the NRC Project Manager for NUREG-2166, "Physical Protection Best Practices for the Protection of Risk-Significant Radioactive Material," the reason input was not sought from all stakeholders when developing the NUREG was because the working group members included representatives from two Agreement States as well as several NRC staff members and because years of data resulting from inspections performed could provide adequate information to determine licensee problem areas

to be addressed in the NUREG. This data was used to determine compliance with the previously issued Security Orders. In addition, six members of the DOE/NNSA's GTRI provided physical security advice and information for inclusion in the NUREG. The Project Manager indicated that the working group and the Steering Committee concluded that they would not be able to effectively use licensee input. They felt that licensee input would be site specific, and the NRC previously concluded that prescriptive guidance would not necessarily help all licensees who were required to comply with 10 CFR Part 37. The NRC wanted this guidance to assist most, if not all, affected licensees.

Based on NRC's response to the GAO as stated on page 49 of the GAO report, an attempt was made during this assessment to determine if the NRC had established a formal process to collect and assess information in order to determine if NUREG-2166 has been effective and whether revisions were needed. Based on information initially collected during this assessment, it did not seem as though the NRC had established a formal process to collect and assess information to determine if NUREG-2166 has been effective and whether revisions are needed.

Eleven inspectors from the NRC's Regional Offices were contacted to determine if, while performing inspections of licensees implementing 10 CFR Part 37, they had identified any best practices that could be helpful to other licensees. Also, they were asked what the NRC does with this information and whether the NRC provided any training to inspection staff regarding best practices.

Eight of the NRC inspectors indicated that they have not identified any best practices while performing inspections that would be helpful to other licensees. However, two NRC inspectors indicated that they consider the NNSA GTRI upgrades as a best practice. One NRC inspector indicated that he did identify some best practices during inspections. This inspector went on to say that best practices are exhibited by those licensees who have placed engineering over administrative controls, incorporated redundancies to avoid single point failure conditions, trained personnel in the "why" and not just the "what", and have promoted safety culture tenants specifically, questioning vulnerabilities that may exist in their programs. The inspector also stated that inspection experiences, including best practices, are routinely informally shared among inspectors at his NRC Region, with the NRC Program Offices, and the other Regions through weekly meetings during the SIF. In addition, regional, divisional, and branch training sessions are also held during the year, and best practices can be shared with other NRC regions. According to one inspector, he is not aware of a formal mechanism to share additional insights/best practices with other regions and, more importantly, to accumulate this knowledge in some sort of living document. One NRC inspector indicated that a review of the NUREG-2166 is the extent of NRC training on the subject of best practices.

On March 24, 2016, a project manager from the NRC's Office of NMSS stated that "the NRC will gather feedback from stakeholders during webinars and public meetings conducted by the NRC."

Based on information reviewed during this part of the assessment, the following additional information is being presented for your consideration, although it is not directly tied to the specific goals assigned to be reviewed during this assessment, specifically, training of licensee officials. Since it is not part of the goals assigned, I will also make recommendations here rather than including them in the Conclusions and Recommendation section of this report.

IAEA Nuclear Security Series No.11 "Security of Radioactive Sources" states on page 26, that a prerequisite for choosing a performance based regulatory approach is that it requires both the operator (licensee) and the regulatory body to have relatively high levels of security expertise (In Section 3 of this report I discuss training of members of the regulatory body, specifically NRC and Agreement State materials health physics inspectors).

The GAO report, "Additional Actions Needed to Improve Security of Radiological Sources at U.S. Medical Facilities," dated September 2012, states, in part, on page 19, that hospital and medical facility personnel they interviewed said that the NRC training has not prepared them to adequately enforce NRC requirements. NRC responded to this statement and the GAO's recommendation to provide training to facility officials, by stating that it does not provide training to licensees but does, however, provide guidance. NRC further responded by stating that, as a regulator, the NRC must maintain independent, objective oversight of licensees and may not operate in a consultative role with the licensees. Page 37 of the report states that the GAO recommends the NRC "Supplement existing guidance for facility officials, including RSOs who may be responsible for implementing NRC's security controls, in how to adequately secure equipment containing high-risk radioactive sources and conduct trustworthiness and reliability determinations." This is a modification from the GAO's original recommendation. The GAO explains the need for the modification on page 40 of their report. The modification was due to the NRC's role as an independent regulator. The GAO encouraged the NRC to supplement existing guidance and ensure that it is widely disseminated.

Title 10 of the Code of Federal Regulations Part 37, requires, in part, that the licensee conduct training to ensure that those individuals implementing the security program possess and maintain the knowledge, skills, and abilities to carry out their assigned duties and responsibilities effectively. The training must include, among other things, instruction in the licensee's security program and procedures to secure Category 1 or Category 2 quantities of radioactive material and in the purpose and functions of the security measures employed. However, there does not appear to be a clear requirement in 10 CFR Part 37 that the person responsible for conducting the

training have any formal training in the areas for which they are required to provide training.

NUREG-2166 states on page 1-1 under the section titled, "Purpose of the Report," "the NRC recognizes that some licensee personnel with responsibilities related to the implementation of the requirements in 10 CFR Part 37 lack expertise in physical security and the development of physical protection programs, which may result in inconsistent application of security measures and in the potential vulnerability of licensed materials. It further states that the NUREG provides practical guidance to applicants and licensees…" On page 2-1 of the NUREG, it also states in Section 2.1 that licensees are encouraged to talk to stakeholders (e.g., other licensees, organizations, or businesses) with knowledge, experience, and expertise in developing a physical protection program. However, it should be noted that licensees may not talk to other stakeholders due to the requirement to protect security-related information and only discuss with those that have been T&R-certified and have a need to know.

A review of NUREG-2166 during this assessment determined that the NUREG does provide very helpful guidance/information in general terms, using a performance-based approach, and provides attributes that certain key elements of a physical protection program should possess. The NUREG provides an extensive discussion on background investigations and trustworthiness and reliability determinations. In addition, the NUREG contains a section on Security Training. This section states that personnel with particular security responsibilities or functions require additional specific knowledge, skills, and abilities training, including the use of security equipment, to enable them to effectively perform these security functions. As helpful as this NUREG appears to be, it does not take the place of formal training in the basic concepts/principles of physical security.

The NRC developed and issued NUREG-2166, "Physical Security Best Practices for the Protection of Risk-Significant Radioactive Material" in May 2014, after the GAO report issued in September 2012. Based on information provided by NRC employees, NRC licensees, and Agreement State Program staff, NUREG-2166 appears to have been widely disseminated. NUREG-2166 provides detailed guidance, which directly addresses the recommendations made by the GAO in its report. NUREG-2166 provides guidance to licensees on developing and implementing a physical protection program for the protection of risk-significant materials. It provides options and methods the NRC considers acceptable for complying with the requirements on 10 CFR Part 37. However, licensees are not required to implement the guidance contained in NUREG-2166.

One option the NRC may want to consider is modifying 10 CFR Part 37 to include a requirement that the responsible person obtain some type of formal training in basic security concepts/principles. This could be achieved by obtaining training from either another Federal agency or an independent third-party security expert. The NRC

could modify the guidance in NUREG-2166 to specifically direct the licensee's representative, who is responsible for providing the required training in 10 CFR Part 37, on how to obtain additional formal basic security training. Contact information could be provided for other capable Federal agencies that could/would provide this type of training. This could be worked out during the collaboration process between Federal agencies. This approach would assist licensees in establishing a security program specific to their facility needs as well as aiding them in making informed decisions when or if they decide to volunteer for the NNSA program. However, this approach may place additional burden on licensees to train additional individuals.

It should also be noted that the NRC does endorse the NNSA's response training and does recommend that licensees attend the Y-12 training. This training, according to an NNSA GTRI Fact Sheet, teaches site security and LLEA how to protect themselves and their communities when responding to alarms indicating possible theft of civilian nuclear and radioactive materials, and it includes realistic scenarios using radioactive sources, irradiators, and security equipment. The course includes both classroom instruction and hands-on exercises. However, the focus of this training is on response and may not incorporate basic concepts and principles of security.

Another option the NRC could consider would be to modify 10 CFR Part 37 to be more aligned with the IAEA Nuclear Security Series No.11 and revise 10 CFR Part 37 to be more prescriptive. The decision to modify 10 CFR Part 37 could also be based on an evaluation of inspection findings and observation made by inspectors in the field.

In addition, it became apparent during this assessment that the NRC has periodically provided what could be considered, by some individuals, as training to licensees regarding 10 CFR Part 37. Specifically, on July 16, 2015, an NRC inspector provided a presentation on 10 CFR Part 37 to representatives from the Arkansas Department of Health and some of their licensees. The individual who conducted the "workshop" was interviewed during this assessment. He summarized the contents of his presentation, which included a discussion on 10 CFR Part 37 requirements and a discussion on the comparisons between 10 CFR Part 37 and the original Security Orders. In addition, a similar presentation was given by the NRC to licensees located in the city of New York on December 3, 2015. Although presentations (forms of training) were provided at these sessions, it must be emphasized that the NRC did not provide specific training <u>on exactly how to</u> adequately secure high-risk radioactive sources to specific licensees. There is a subtle difference between the two. The type of presentation provided by representatives from the NRC appear to support the NRC's position regarding training, as expressed in its response to the GAO September 2012 report. The presentations appear to focus on providing guidance rather than actual training on what specific licensees must do in order to comply with 10 CFR Part 37 (i.e., specific type of monitoring system to use).

c. Conclusions and Recommendations

The NRC conducted a considerable amount of outreach activities to stakeholders to gather feedback when developing and updating regulatory requirements and guidance, although there may have been a few occasions in which documents sent to some licensees may not have been received.

With respect to the "checklist" document developed by the regional materials health physics inspector, it is this independent assessor's belief that the availability of a standardized document for use by the inspection staff should be instituted by the NRC. The NRC may want to consider forming a working group assigned to review the current "checklist" created by the NRC Region I materials health physics inspector, and determine if it needs to be modified prior to distribution to the Regions. The working group would also develop a brief training session for materials health physics inspectors, to be provided at the time of distribution of the document. The training would emphasize that the document is not to be used to drive the inspection but rather as a tool to aid in preparing for an inspection as well as to consistently document inspections. The working group would also emphasize that inspections are to be performance-based, since it is NRC's policy, that performance-based inspections be conducted. Performance-based inspections are to be performed regardless of whether the inspector uses a "checklist" or field notes. It should be recognized that most, if not all, inspectors take notes while performing inspections. The use of a standardized format would help to ensure that documentation is consistent, and it can aid some inspectors when documenting formal inspection results. With proper training in its use, inspector performance with regard to efficiency and effectiveness may improve. The use of this type of tool may improve productivity and the quality of the inspector's final written product. NRC should reconsider the use of this or a similar tool for use by inspectors. Since the document will contain security sensitive information, it would be categorized as a non-public document.

It appears, based on information obtained during this assessment, the document has already been distributed to some NRC staff and to individuals outside of the NRC. It is not clear that those individuals outside the NRC understand that the current document has not been endorsed by the NRC. I believe it is better for the NRC to take a proactive approach and develop a document the Agency finds acceptable, is willing to endorse, and makes available to the materials health physics inspection staff. Additionally, I believe, the NRC should provide information on this document to the Organization of Agreement States.

Regarding NUREG-2166, it is this assessor's opinion that it would have been beneficial to obtain input from stakeholders when developing NUREG-2166. The licensees' perspective could have been helpful when the NRC was developing NUREG-2166. Licensees can provide insight that may not be apparent to the regulator. Even if licensee input is site specific, if evaluated by the "Best Practices"

working group, it would have the option of developing the input further, revising if necessary, and possibly determining a broader application for specific licensee input. Gathering information during an inspection may be beneficial but interacting with licensees outside of the inspection process, such as during stakeholder meetings, may also be beneficial. During inspections, the licensee's primary focus is on the progress of the inspection, demonstrating various aspects of its licensed program, answering questions, and providing reasonable assurance that it is conducting its licensed program in compliance with NRC regulations. The licensee may not be completely focused on peripheral issues. Additionally, based on the NRC's response to the GAO, as stated on page 49 of the GAO's June 2014 report, the NRC, during the first 2 years of post-implementation of 10 CFR Part 37, will assess the effectiveness of the Best Practices Guide to determine if any revisions are needed and will make revisions accordingly using its public participation process. During this assessment, an attempt was made to identify if the NRC had established a formal process to instruct inspectors to look for best practices during inspections and whether there was some mechanism in place to provide the information identified during inspections to the NRC program office and, subsequently, to the 10 CFR Part 37 Implementation Working Group. Based on the information obtained during this assessment, it was not clear whether the NRC, over the past 2 years, has effectively addressed this issue. Some information was obtained during this assessment that seems to indicate that during the NRC's SIF process, some best practices may have been discussed. However, if this is accurate, it seems to be only one part of the process. Additional information provided by the NRC on March 24, 2016, indicates that the NRC does intend to gather feedback from stakeholders in order to respond to the GAO.

The Best Practices, NUREG-2166, was published in May 2014, and as of March 19, 2016, it will have been 2 years since 10 CFR Part 37 was implemented. Based on the NRC's response to the GAO, it is recommended that the NRC completes its assessment process of the effectiveness of NUREG-2166 and determines whether revisions to NUREG-2166 are needed.

3. Review of NRC Staff's Activities Related to Providing NRC and Agreement State Inspectors' Adequate Training on 10 CFR Part 37 Requirements Related to: Background Investigations and Access Control Programs, Including Review of Trustworthiness and Reliability Investigations; Physical Protection During Use of Materials, Including Aggregation of Sources; and Physical Protection During Transit.

a. Scope

A review of NRC staff's activities related to providing NRC and Agreement State inspectors' adequate training on 10 CFR Part 37 requirements was conducted. A review of the following documents was also conducted: S-201 Training Modules; Summary of S-201 Course Evaluations January 2014 - December 2015; Inspection

Manual Chapter (MC) 1248; 10 CFR Part 37 Lessons Learned and Inspector Experience presentation slides; GAP training slides; NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program" (IMPEP); TN: DT-04-03 and its associated Handbook dated November 5, 1999, (Revised February 26, 2004); FSME Procedure "Reviewing the Common Performance Indicator, Technical Quality of Inspections-SA-102," dated July 23, 2007; and NRC Human Resources Training and Development (HRTD) Operating Procedure 0410, Revision 2, dated October 1, 2009. Responses to questionnaires were evaluated, and information received during interviews was also evaluated. In addition, a review of the following GAO reports was conducted: "Additional Actions Needed to Improve Security of Radiological Sources at U.S. Medical Facilities," dated September 2012; "Nuclear Security Actions Taken by the NRC to Strengthen its Licensing Process for Sealed Sources are not Effective," dated July 12, 2007; and "Industrial Radiological Sources, Additional Actions Needed to Increase the Security of U.S. Industrial Radiological Sources," dated June 2014.

b. Observations

The HRTD Operating Procedure defines the process for evaluating training conducted by the NRC's Office of Human Resources. According to the HRTD Operating Procedure, the HRTD's mission, in part, is to provide training to meet the integrated needs of the NRC and Agreement States and to provide assistance to the agency in the areas of its expertise. To accomplish this mission, HRTD manages the Technical Training Center (TTC) in Chattanooga, Tennessee.

Based on a review of documents provided by the NRC, the NRC has provided initial security training to both NRC and Agreement State material health physics inspectors since February 2004. As a result of NRC's actions to develop and issue Security Orders to licensees, the NRC contracted with Sandia Laboratories to conduct a 2-week training course at Sandia Laboratories. This course provided initial required security training to NRC and Agreement State inspectors. The course included thorough and in-depth training on the requirements contained in the original Security Orders. The course also included, among other things, the following: background investigations and access control programs; including review of trustworthiness and reliability determinations; physical protection during use of materials; aggregation of sources; physical protection during transit; components of physical protection systems; review of applicable guidance documents; and exercises involving on-site tours of licensee facilities in which students evaluated the adequacy of specific licensee security programs.

A representative from the NRC's TTC stated that required training for NRC inspectors is S-201, in accordance with Appendix B of Inspection Manual Chapter 1248. S-201 is also on the NRC's Sponsored Training List for Agreement State staff. Agreement State staff may attend, but it is not a requirement for Agreement State

inspectors. Agreement States can either send their staff or create their own equivalent training programs.

According to the TTC, the NRC established training for 10 CFR Part 37 by first forming a 10 CFR Part 37 Training Review Committee, consisting of a senior health physicist, and two senior security training specialists. The committee revised the existing Materials Security course curriculum, developed a new curriculum, and created draft modules, which were approved by the 10 CFR Part 37 Steering Committee. In 2013, a week-long course was conducted at the NRC's TTC. The course, S-201, provided similar course instruction as the original Sandia course. However, it has been condensed into a week-long course from the original 2-week course offered by Sandia Laboratories.

Appendix B on MC 1248 states that inspectors must take S-201 or be able to demonstrate that they have the equivalent training or experience. The S-201 course has also been attended by some Agreement State inspectors and NRC Master Material Licensee personnel. According to the NRC, S-201 training also provides instruction on a performance-based methodology to evaluate and assess the adequacy of physical protection systems. A review of the S-201 training modules was performed during this assessment. The following is an example of some of the modules in the S-201 training course: Module 3 includes a discussion on aggregation of material; the estimated amount of time designated for this module is 45 minutes. Module 4 includes a discussion on background investigations, including trustworthiness and reliability determinations, and access control; the estimated amount of time designated for this module is 60 minutes. Modules 5 and 6 include a discussion on physical protection requirements during use; the estimated total amount of time designated for these modules is 225 minutes. Module 13 includes a discussion on physical protection in transit; the estimated amount of time designated for this module is 75 minutes. The S-201 course also includes an exercise, designated as Subgroup Exercise 4, which contains three scenarios. Each of the three scenarios tests the students' level of knowledge regarding the sum of fractions method (unity rule), and their level of understanding regarding aggregation of sources, as it applies to 10 CFR Part 37 requirements.

Based on a review of the course syllabus and modules used during the S-201,"Materials Control, Security Systems and Principles" training, the course seems to provide a thorough overview that includes, but is not limited to, 10 CFR Part 37 requirements, potential threats, background investigations and access control, physical protection requirements during use of risk significant radioactive material, aggregation, critical components of physical protection systems, intrusion detection systems, physical protection in transit, security zones, access delay, and inspection procedures. Upon completion of the S-201 course, a 25-question exam is given, and students must pass the test with a minimum score of 70%.

In addition to successfully completing S-201, the NRC requires that its material health physics inspectors obtain on-the-job training (OJT). Specifically, MC-1248, starting on page B-96, outlines the OJT required to be a qualified inspector and to be authorized to perform independent inspections of licensees implementing 10 CFR Part 37. This module provides a number of references as well as evaluation criteria and tasks to be performed by the inspector. The references include but are not limited to the following: Security Orders; 10 CFR Part 37; Inspection Procedures (IP) 87135 "Panoramic and Underwater Irradiator Security Program," IP 87136 "Manufacturing and Distribution Security Program," and IP 81120 "Inspection Requirement and Guidance for Additional Security Measures for the Physical Protection in Transit for Radioactive Material Quantities of Concern;" Transportation of Radioactive Materials of Quantities of Concern Order; TI 2800/038 "Inspection of the Implementation of the Increased Controls for Licensees Authorized to Possess Risk Significant Radioactive Materials." In order to satisfy the evaluation criteria in this module, the inspectors must be able to, among other things, successfully describe the procedures for conducting security inspections, describe how the reference documents listed in this module are used by qualified inspectors, demonstrate competency in performing security inspections, and describe what actions would be taken by the inspector when provided a specific security scenario. The individual must also accompany a qualified inspector on security inspections of licensees possessing Category 1 or Category 2 radioactive material. In addition, the individual must be observed by a qualified inspector prior to performing security inspections on his own.

MC-1248 also includes OJT for pre-licensing visits. This training is provided to help ensure that inspectors are familiar with the NRC's Pre-Licensing process. References listed in the module include NRC's Pre-Licensing Guidance and the GAO Report, "Nuclear Security Actions Taken by the NRC to Strengthen Its Licensing Process for Sealed Sources Are Not Effective," dated July 12, 2007. In order to satisfy the evaluation criteria in this module, the inspectors must be able to, among other things, explain how to use the screening criteria, explain how to use the additional screening criteria, discuss the purpose of the pre-licensing visit, and discuss the GAO report on nuclear security. The individual must review and be familiar with the NRC's Pre-Licensing Guidance as well as learn where to obtain the necessary information needed for the additional screening criteria, among other things.

As of December 22, 2015, a total of 33 NRC inspectors successfully completed the S-201 training course. I requested whether the NRC retained a list of all Agreement State inspectors that have attended the S-201 training. The NRC provided a list, which was reviewed during this assessment. As of November 18, 2015, a total of approximately 76 Agreement State inspectors successfully completed the S-201 training course.

The review of the list also identified eight Agreement States whose inspectors, as of November 18, 2015, had not attended the S-201 training. The NRC has determined that all Agreement State inspectors may not be provided with an opportunity to attend the S-201 training because of course availability and limited class capacity. The NRC recognizes that there is a backlog of Agreement State personnel requesting attendance in the S-201 course. Based on a review of documentation provided by the NRC, it seems that in order to accommodate additional students, the TTC has decided to possibly move at least two of its three scheduled courses back to the Sandia Laboratories site. The Sandia facility allows for a larger class size. NRC anticipates this to occur in 2016.

According to the NRC's IMPEP Program Coordinator, the NRC's IMPEP program uses a performance-based approach when conducting reviews of Agreement State Programs. Members of the IMPEP team accompany Agreement State inspectors while they conduct on-site inspections of licensees. If the IMPEP team member identifies a weakness in the inspector's performance, then the IMPEP team member will look into that inspector's training. The IMPEP team does not evaluate the quality of the Agreement State's security training course in order to determine whether it is, in fact, equivalent to NRC's S-201 course. Since S-201 is a "core" course, each Agreement State must also specify its equivalent security training course as "core" training. Core training was once defined by the NRC as the minimum formal classroom and OJT required for a specific inspector, license reviewer, or project manager/technical reviewer discipline. The term "core" has been replaced by the term "Required" Training.

In addition to the formal training, there are many guidance/reference documents available to both NRC and Agreement State inspectors detailing 10 CFR Part 37 requirements, implementation guidance, and inspector responsibilities, which can be located on the NRC's Website.

Based on information provided by a representative from the NRC's Office of NMSS, on December 3, 2015, representatives from NRC's Office of NMSS and NRC Region I gave a presentation to the Organization of Agreement States (OAS) on "10 CFR Part 37 Lessons Learned and Inspection Experience." The presentation reinforced the need to communicate with licensees regarding implementation dates and major changes. The presentation stressed the need to be familiar with the requirements of 10 CFR Part 37 and various NRC reference documents such as NUREG-2155, REV.1, NUREG-2166, Regulations Cross Walk (comparison document), NRC RIS 2014-003, and GAP Training slides, as well as the need for formal security training. The presentation also summarized the most frequently identified licensee violations. At the conclusion of the presentation, the NRC staff's contact information was provided.

Based on additional information provided by a representative of the NRC's Office of NMSS, some members of the NRC's internal 10 CFR Part 37 Assessment Team

believe that materials security training should not have specific required refresher training because experience is obtained by completing inspections that present a variety of approaches for meeting the 10 CFR Part 37 requirements. They also believe that requiring specific security refresher training would be contrary to NRC's current policy (i.e., no specific safety or security training course is identified for refresher training). Other members believe there should be required security refresher training, and that possibly an online version "could assist inspectors in reviewing certain security principles that are consistently applied during security inspections." NRC's MC-1248 Appendix B "Materials Health Physics Inspector Qualification Journal," dated April 19, 2013, states, on page B-5, that qualified inspectors must maintain their qualification by completing 24 hours of refresher training in the established requalification cycle of 24 months. This refresher training can consist of either health and safety or security topics. MC-1248 does not specifically state that security refresher training must be obtained. It does identify a number of training options that can be considered for refresher training, which include, but are not limited to, the following: NRC technical training courses; external training courses; and developing presentations on subjects related to health and safety or security. The NRC's internal assessment team determined that the issue of required security refresher training has been identified as an "Observation" by the team. According to a staff member from the NRC's Office of NMSS, an Observation means that the NRC's internal assessment team will present the Observation to the 10 CFR Part 37 Program Review Steering Committee to determine if the staff should conduct further reviews of the issue.

According to information provided by the NRC, the S-201 course is typically at maximum capacity, making it very difficult to support refresher training. At the time of this independent assessment, there appears to be no requirement for recurrent training in security other than what appears in MC-1248. S-201 was only intended to serve as initial qualification training for NRC and Agreement State inspectors as well as NRC Master Material licensees. However, GAP Training was created in 2014, by a materials health physics inspector from NRC Region I and approved by the NRC's 10 CFR Part 37 Steering Committee. The 10 CFR Part 37 Implementation Working Group and the Steering Committee agreed that the GAP Training would be suitable for inspectors who have obtained initial security training and experience in order to transition from the original Security Orders to 10 CFR Part 37. The GAP Training would also be suitable for security refresher training. The GAP Training currently provides instruction to material health physics inspectors on new 10 CFR Part 37 requirements. The GAP Training also includes an overview of the differences between the original Security Orders and new requirements in 10 CFR Part 37. This training was provided to all applicable NRC regions by webinar in March 2014.

As part of this assessment, a limited review of the NRC's IMPEP was conducted. MD 5.6 states that it is the policy of the NRC to evaluate the NRC regional materials programs and Agreement State radiation control programs in an integrated manner, using common and non-common performance indicators to ensure that the public

health and safety is being adequately protected. The objectives include, but are not limited to the following: to establish the process by which the NRC's Office of NMSS, Division of Material Safety, State, Tribal, and Rulemaking Programs, conducts its periodic assessments to determine the adequacy of its programs in the NRC regions and Agreement States; to provide NRC and Agreement State management with a systematic and integrated approach to evaluate the strengths and weaknesses of their nuclear materials licensing and inspection programs; to provide significant input to the management of the regulatory decision making process; and to indicate areas in which the NRC and Agreement States should dedicate more resources or management attention. It states, in part, in Common Performance Indicator 1- Technical Staffing and Training, that training requirements for NRC license reviewers and inspectors are specific in NRC Inspection Manual Chapter 1246, and that the requirements include a combination of classroom requirements and practical on-the-job training. It also states that the qualification process for NRC materials program inspectors includes demonstration of knowledge of relevant sections of the Code of Federal Regulations, completion of a qualification journal, and appearance before a qualification board. Common Indicator 3 - Technical Quality of Inspections states, in part, that the IMPEP review team members will accompany a sample of inspectors at different types of licensed facilities to evaluate the knowledge and capabilities of regional and Agreement State inspectors. Furthermore, these reviews focus on the scope, completeness, and technical accuracy of completed inspections and related documentation. Common Performance Indicator 4 - Technical Quality of Licensing Actions states, in part, that an acceptable program for licensing radioactive material includes preparation and use of internal licensing guides and policy memoranda… (when appropriate, NRC guides may be used); pre-licensing inspection of complex facilities; and supervisory review, when appropriate. Furthermore, it states that this performance indicator evaluates the technical quality of the licensing program on the basis of an in-depth, onsite review of a representative cross-section of licensing actions. Upon conclusion of an IMPEP review, a management review board (MRB) will make the overall assessment of each NRC region or Agreement State program. The MRB will consist of a group of senior managers, or their designees, and the Organization of Agreement States also will be invited to designate a representative to serve as a member of each MRB, as a nonvoting Agreement State liaison. It should be noted that with respect to Handbook 5.6, MC 1246 was superseded by MC 1248 for materials health physics inspectors in August 2012. In addition, the criteria for conducting pre-licensing visits was modified in July 2007, as a result of a weakness in the NRC's licensing process identified by the GAO.

The NRC document titled, "Reviewing the Common Performance Indicators, Technical Quality of Inspections - SA-102," dated July 23, 2007, describes the procedure for conducting reviews of NRC and Agreement State radioactive materials programs using the common performance indicators. This document outlines a number of objectives. One objective is to ensure that inspections of licensed activities focus on health and safety issues in accordance with NRC Inspection

Manual Chapter 2800, Materials Inspection Program. The document also describes the roles and responsibilities for the Team Leader and the Principal Reviewer and associated guidance. On page 4 of the document, it states under Review Guidance, that for NRC Regions, tallies of completed inspections can be obtained from the Licensing Tracking System. In addition, the document states that IMPEP accompaniments are performance-based evaluations of inspector effectiveness. Appendix B is an attachment to this document, which provides a Summary of the Evaluation performed during an IMPEP. The summary includes such things as security verified, records verified against oral statements, and inspectors knowledge of health physics and regulations. It should be noted that the Licensing Tracking System is no longer in operation and was replaced by the WBL System.

It should also be noted that separate training had been conducted for power reactor safety/security inspectors on implementation of 10 CFR Part 37 at power reactor facilities. Power reactor security training was not included within the scope of this review.

As part of this assessment, an attempt was made to confirm the GAO's conclusion on page 19 of the GAO Report, "Additional Actions Needed to Improve Security of Radiological Sources at U.S. Medical Facilities," dated September 2012, that the NRC and Agreement State inspectors felt that the training they received from the NRC did not adequately prepare them to perform security inspections.

It should be noted that, in most cases, the inspectors performing these inspections would possess extensive experience and training in a specific field of science, such as health physics with a strong focus on safety.

It states on page 38 of the same GAO report, that NRC neither agreed nor disagreed with the GAO's recommendation that it ensures that NRC and Agreement State inspectors receive more comprehensive training to improve their awareness and ability to conduct related security inspections. Page 40 of the GAO report does state that the NRC will evaluate whether any additional training enhancements are needed to its inspector qualification program based on the GAO recommendation, and that NRC plans to review and revise the training associated with the inspector's qualification program in conjunction with pending security regulations.

Three staff members from the NRC's Office of NMSS provided a response to the following: Describe all required security training for the NRC and Agreement State inspectors, and describe any additional training that has been given to inspectors since 10 CFR Part 37 was issued. They were also asked to describe what actions the NRC has taken with respect to training of NRC and Agreement State inspectors since this GAO report was issued.

One NRC staff member from the NRC's Office of NSIR stated that the NRC has developed a very comprehensive training course, S-201 for NRC and Agreement State inspectors. This individual has taken the course and found it to be "very

effective in providing inspectors with the necessary information to effectively inspect the new requirements." In addition, this individual stated that GAP Training has been developed for inspectors who had prior experience performing security inspections under the original Security Orders. This individual indicated that the GAP Training does a "good job in bridging the gap" so that inspectors will understand the differences between the original Security Orders and 10 CFR Part 37. This individual also believes that no additional training is needed. However, he does believe that since there is a high turnover of Agreement State inspectors, additional funding should be provided to ensure that the Agreement State inspectors obtain the necessary training.

A staff member from the NRC's Office of NMSS stated that the GAO report dated September 2012, and its draft versions, were issued while the NRC was in the process of revising S-201 training to reflect the issuance of 10 CFR Part 37 and that this specific GAO report was included as a reference in Module 3 and Module 16 of the S-201 training. Extensive revisions have been made to the S-201 training course, since it was originally developed, that made it more comprehensive than the previous course. Specifically, the exercises were revised, and new exercises were added. Additionally, class demonstrations and laboratory exercises have also been enhanced. Also according to this NRC representative, the Agreement State Radiation Control Programs were engaged by the NRC when S-201 training was being revised. This individual stated that MC 1248 identifies S-201 as required training for NRC materials inspectors. MC 1248 also allows for "equivalent" training. This is also applicable to Agreement State inspectors and license reviewers. Furthermore, this equivalent training can be provided by either an independent third party of other government agencies.

In addition to the training specified above, NRC inspectors also attend counterpart meetings every year (twice a year), and a determination is made prior to these meetings as to whether some form of additional security training is necessary.

Eleven NRC regional health physics materials inspectors were asked if additional, or changes to, training have been helpful to inspectors; if so describe. Also, they were asked to describe the required training they received in order to perform inspections of licensees who are implementing 10 CFR Part 37 and whether they believe the training they received was adequate. The inspectors were also asked if they believe there should be a requirement for periodic refresher training specific to security and, if so, to describe.

Of the NRC inspectors who responded, eight NRC inspectors felt the training they received was adequate. The training included the original Sandia security training course, S-201, and GAP Training. Of the inspectors that responded, four did not believe that refresher training should be required, and three believe refresher training should be required. One NRC inspector indicated that he felt additional, or changes to the training received would have been helpful to inspectors. Specifically, this

inspector feels that NRC Program Office "positions" change often, making it difficult for inspectors to provide thorough assessments. Additional information regarding this NRC inspector's response should be obtained by the NRC Program Office in order to ascertain the exact root cause of his concern and whether any additional action is needed by the Program Office.

Representatives from seven Agreement State Programs were asked to describe the required training they received in order to perform inspections of licensees who are implementing 10 CFR Part 37 compatible regulations, and whether they believe the training was adequate. They were also asked to describe any changes they believe would improve the training. In addition, they were asked if there is a requirement for periodic refresher training, and if so, to describe. Six Agreement State Programs representatives indicated that members of their inspection staff had attended the NRC's S-201 training. Of the six representatives, two indicated that they feel the S-201 training was adequate; three did not provide a response; and one indicated it was too soon to make a determination, since training is on-going.

One representative from an Agreement State Program stated that he does not agree with reducing the S-201 training to a one-week course. He feels it should remain a 2-week course and continue to be conducted at Sandia National Laboratory. Additionally, two Agreement State Programs representatives indicated that they have provided in-house training to their inspectors, and they also feel that the training was adequate. Two Agreement State Programs representatives indicated that there is no requirement for periodic refresher training, and two Agreement State Programs representatives indicated that periodic refresher training would be or has been provided. One Agreement State Program representative indicated that NRC-sponsored webinars should be periodically conducted.

A representative from one Agreement State Program stated that the NRC security class was available, and one inspector had been sent to the class. The information obtained from that class was utilized to provide internal training. This representative also stated that prior to the February 2016, 10 CFR Part 37 Webinar training, additional training would have been desirable. During an interview, the representative confirmed that one inspector attended the NRC course S-201 and that the State has used and will continue to use the S-210 course material to provide training to its other inspectors. Their final training class was to be conducted in early March 2016. He indicated that training will be provided during inspections, in that, the inspections will serve as scenarios similar to the practical hands-on scenarios included in the NRC's S-201 course. He further indicated that a test is not administered at the conclusion of their training. The representative also mentioned that their inspectors have also received NRC's GAP Training and have reviewed the NRC Inspection Procedure.

Representatives from the NRC's TTC were asked to describe specifically what actions NRC has taken based on the NRC's response to GAO report, "Additional

Actions Needed to Improve Security of Radiological Sources at U.S. Medical Facilities," dated September 2012. Specifically, it states, in part, on page 19 that NRC and Agreement State inspectors they interviewed said that the NRC training has not prepared them to adequately enforce the NRC's requirements. Pages 47 through 50 of the report provide a copy of the NRC's response. NRC's response includes, among other things, the following: the NRC Materials Control, Security Systems and Principles course provides instructions on a performance-based methodology to evaluate and assess the adequacy of a physical protection system to protect against theft or sabotage of materials identified in the Increased Controls. This combined with on the job training and other requirements prepare NRC and Agreement State inspectors to complete their required duties. Further, NRC stated that it will evaluate whether any additional enhancements are needed to its inspector qualification program based on GAO's recommendation. The NRC also stated that it currently plans to review and revise the inspector qualification program for radioactive materials security inspections to include the associated training, to support the implementation of 10 CFR Part 37 rule.

According to a representative from the TTC, the NRC, S-201 course was completely revised to coincide with the implementation of 10 CFR Part 37. The revised course was initially conducted in February 2014. The course includes a module on the NRC-NNSA's GTRI Partnership. The GTRI provides training in the area of response for radiological events. GTRI attended the May 2013 S-201 training course held at the TTC and gave a presentation on its program to the class. According to information provided by the NRC, representatives from GTRI provided insight into security upgrades that had already been installed in facilities across the U.S. Additionally, according to a representative from the NRC's TTC, they have not provided nor do they plan any additional training regarding S-201. It is possible that the GAO report published in June 2014 did not capture or consider the three S-201 classes conducted by the NRC from February 2014 through June 2014.

Members of the TTC believe that the S-201 training is adequate and that the overwhelming majority of the students would say the same thing based on the feedback provided by students who have attended the S-201 training. Members of the TTC stated that they review the feedback provided by students and have made some course revisions based on the comments received. The instructors have taken all written and verbal feedback seriously and have discussed what, if any, changes should be made based on the feedback.

According to documentation provided by the NRC, they have performed an internal assessment of S-201 student feedback. Specifically, the NRC reviewed feedback from students who attended S-201 classes during the period of February 3, 2014, through August 14, 2015. There were seven classes held during this period. The NRC reviewed a total of 130 course evaluations. The assessment included not only evaluations completed at the conclusion of each class, but the NRC also has an electronic evaluation/online process that was evaluated. The online process is

located in “iLearn,” which is a Learning Management System that the NRC has deployed. The course evaluation consists of 14 questions and three additional questions. Students rate the responses using a numeric response of 1 to 5, 5 indicating that the student strongly agrees and 1 indicating that the student strongly disagrees. The overall rating for the classes attended during this period was 4.7 out of 5, meaning that the majority of the students were satisfied with the course. The 14 questions asked of the students include, but were not limited to the following: I feel that I expect what I learned to improve my current or future job performance; I feel that I am overall satisfied with the course; and the instructor helped participants relate the material to their job. One of the three additional questions was - Do you have any recommendation to improve any aspects of the course? According to the NRC’s assessment, the majority of the students did not identify any significant improvements for the course.

c. Conclusions and Recommendations

The NRC security training course, S-201 “NRC Materials Control, Security Systems and Principles,” appears to provide students with a basic understanding of physical security concepts and principles as well as 10 CFR Part 37 requirements. It seems that based on this independent review; S-201 should have addressed the concerns expressed by the inspectors questioned by GAO from April 2011 to September 2012. I agree with the NRC’s position, as stated in GAO Report “Additional Actions Needed to Improve Security of Radiological Sources at U.S. Medical Facilities,” dated September 2012. On Page 40 of the report, the NRC states that inspector’s completing a five-day training course in combination with on-the-job training and other requirements prepares NRC and Agreement State inspectors to complete their required duties. However, with this said, this training may not necessarily qualify the inspectors as security experts. NRC may want to consider polling its material health physics inspection staff further in order to determine if any of the inspectors feel they could benefit from additional specific security training. If possible provide a resource/point-of-contact to the inspectors to whom they can reach out to obtain clarification and/or guidance regarding specific security issues. This could be someone internal to the organization or external, such as another government organization with expertise in security. If the issue or area of concern is specific to a particular licensee or inspection finding, the discussion could be conducted in a manner that would protect the identity of the licensee and not disclose specific licensee vulnerabilities.

It seems, based on student feedback, that the week-long course is sufficient. It is my conclusion that, short of hiring security experts to perform inspections of licensees implementing 10 CFR Part 37 requirements, the NRC’s initial training (S-201) appears to be thorough and complete.

Based on information provided by the NRC’s IMPEP Program Manager and one Agreement State Program representative, during this assessment, the NRC may

want to re-evaluate its performance-based approach to evaluating training provided by Agreement State Programs. Specifically, during this assessment, it was determined that IMPEP teams do not evaluate the quality of Agreement State Programs security training courses in order to determine whether the training is equivalent to NRC's S-201 training course. It was also determined that one Agreement State Program's security training will be conducted during inspections specifically, the practical hands-on training as included in the NRC's S-201 course; and that they do not administer a test at the completion of the training as included in the S-210 course. This information also raised the following questions: 1) how are the Agreement States providing equivalent GTRI training? and 2) What other Agreement State Programs have decided to provide equivalent training?

Since it is not a requirement for Agreement State Programs to send their staff to the NRC security course as long as they create their own equivalent training, I believe, based on information provided during an interview with one Agreement State Program representative, it may be beneficial to perform an evaluation of the training provided by Agreement State Programs, specifically, those states that have decided to provide "equivalent" security training to their staff. Agreement State Programs should initially demonstrate that their security training is, in fact, equivalent to S-201 training, and then IMPEP teams can use the performance-based approach to determine if the security training obtained by inspectors has been effective.

With respect to the apparent need to train additional Agreement State inspectors, the NRC should move forward as quickly as possible to offer S-201 training to additional Agreement State inspectors so that each state is staffed with the necessary number of qualified inspectors. Action should be taken by the NRC to make any needed changes in course location that will provide for an increased number of students per class.

Regarding security refresher training, although many inspectors and some Agreement State Program representatives indicated that they do not believe required periodic refresher training is needed, it is the belief of this independent assessor that security refresher training should be conducted at some frequency, possibly every 2 to 3 years. I also believe that since security, in many cases, is not the inspector's primary area of expertise, it is important to periodically re-enforce an individual's level of knowledge in this area by providing refresher training. Relying solely on experience gained while completing inspections may be beneficial, however, it is equally important for inspectors to periodically review the basic principles and fundamental concepts as well as other topics such as physical protection systems, improvements in technology, inspection findings, enforcement, lessons learned, and best practices. The GAP Training could be used as refresher training if modified, and expanded to include a review of the topics just mentioned. Material health physics inspectors typically acquire refresher training in safety and/or health physics topics either from their employer or through either the local or National Health Physics Society Chapter. The concern is that they may not obtain additional security

training in the topics listed above, if not provided by the NRC or an Agreement State Program. In addition, it is this assessor's opinion that this type of refresher training should be provided to Agreement State Program inspectors by either attending NRC training or by each Agreement State developing an equivalent refresher training course. The NRC's IMPEP process should determine if Agreement State Programs have implemented equivalent refresher training for their inspectors.

Regarding the FSME document "Reviewing the Common Performance Indicator, Technical Quality of Inspections," it appears that this document, in my opinion, needs to be updated by the NRC. Specifically, the document refers to the Licensing Tracking system, which is no longer in operation, and that Appendix B should be updated to include increased focus on security although security inspections (10 CFR Part 37) have been included under health and safety. Specifically, the following focus areas could include additional specific details directly related to 10 CFR Part 37: security verified; records verified against oral statements; and knowledge of health physics and regulations.

4. Review of NRC's Use of On-Line Tools to Communicate with Stakeholders in a Timely and Secure Manner.

a. Scope

A review of NRC's use of on-line tools to communicate with stakeholders in a timely and secure manner was conducted. The following document was reviewed "GAO Testimony Presented to Permanent Subcommittee on Investigation, Committee on Homeland Security and Governmental Affairs U.S. Senate," dated July 12, 2007. Responses to questionnaires were evaluated, and information received during interviews was also evaluated. In addition, a review of the following GAO report was conducted, "Actions Taken by the NRC to Strengthen Its Licensing Process for Sealed Radioactive Sources are Not Effective," dated July 12, 2007.

b. Observations

There is an abundance of information on the NRC's Public website that can be accessed by any and all stakeholders. The site includes, for example, the following public information: Regulatory Guides (NUREG's); Code of Federal Regulations (CFR); Temporary Instructions (TI); Information Notices (IN), Commission Papers (SECY Papers); Regulatory Issue Summaries (RIS); and Federal Register Notices (FRN). In addition to the public website, the NRC also established a number of tools accessible to those who have requested access, been approved by the NRC, and have obtained a required password.

The GAO released the following document on July 12, 2007, which contains testimony presented before the Permanent Subcommittee on Investigation, Committee on Homeland Security and Governmental Affairs U.S. Senate titled,

"Actions Taken by the NRC to Strengthen its Licensing Process for Sealed Radioactive Sources are Not Effective." Included in this document is a statement by the GAO indicating that in 2003, the GAO reported weaknesses in the NRC's licensing program that could allow terrorists to obtain radioactive materials. The NRC, in response to this statement by the GAO, issued guidance to its license reviewers. As a follow-up to the NRC's action to issue guidance to its license reviewers, the Subcommittee requested that the GAO determine whether the NRC's actions were sufficient. In 2006, the GAO initiated an investigation that included creation of a bogus company and obtaining an NRC license. The investigation was conducted from October 2006, through June 2007. After obtaining the license, the GAO modified the license and proceeded to contact suppliers of radioactive material. The suppliers contacted by the GAO approved their request for radioactive material. The GAO also stated in its testimony that the amount of radioactive material it could have acquired from the suppliers was "sufficient to reach the International Atomic Energy Agency's definition of Category 3 and that with proper financial resources they could have accumulated substantially more radioactive material."

The GAO testimony indicates that, as a result of its investigation, the NRC suspended its licensing program until it could determine what corrective actions were necessary to resolve the weaknesses identified by the GAO. On June 1, 2007, the GAO contacted the NRC and discussed the results of its investigation. On June 12, 2007, the NRC issued supplemental interim guidance with additional screening criteria. The NRC would make a determination as to whether a site visit or face-to-face meeting is required of license applicants.

Since the GAO investigation regarding NRC's actions to strengthen its licensing process for sealed sources, the NRC established additional tools. Specifically, according to the NRC's current website, the NRC established a set of "information technology tools" that support the Radioactive Material Security Program and related radioactive materials licensing and tracking activities of the NRC. The set of information technology tools is known as the Integrated Source Management Portfolio (ISMP).

The ISMP is essentially comprised of three key systems, including the National Source Tracking System (NSTS), the Web-Based Licensing (WBL), and License Verification System (LVS). According to the NRC, together these systems help to ensure the security of all licensed radioactive material possessed by NRC and Agreement State licensees.

The NSTS was deployed in January 2009, and according to the NRC's website, it is a highly secure web-based database that is designed to enhance the accountability of certain radioactive sources, specifically, nationally tracked sources that are equal to or greater than Category 2. The data in the NSTS is designated for "Official Use Only," therefore, access to information will vary and be limited to those with a "need to know." The approval process for granting access to the system involves the

"credentialing" of individuals. Credentialing includes issuance of a one-time password. NRC's web-site provides information to individuals regarding available options for the one-time passwords issued by the NRC and the requirement for protecting the one-time password. The password is good for five years. The NRC also makes it clear that any personal information entered into the system by individuals is protected.

The NSTS database was designed to provide authorized/approved stakeholders a reliable method of tracking certain radioactive materials essentially from "cradle to grave." Title 10 of the Code of Federal Regulations 20.2207 clearly specifies what information is required to be entered in the NSTS system by licensees possessing Category 1 and Category 2 sources. There are a number of ways licensees can enter the required data into the system. The NRC has also established a Help Desk to assist licensees. According to the NRC, the data in the NSTS system can be used by the NRC to determine which licensees will receive certain security advisories, thereby, providing timely notification to licensees regarding security-related issues.

Also according to the NRC, an individual who has been credentialed for the NSTS system and wants to gain access to the other two systems will not need to go through the credentialing process again but only needs to contact the NSTS Help Desk for assistance and access.

The NRC's website states that the WBL System was deployed in August 2012, and according to the NRC, the system combined previously established tracking systems employed by the NRC, such as the former License Tracking System (LTS), Inspection Planning System (IPS), Reciprocity Tracking System (RTS), and the Transportation Approval Package Information System (TAPIS). The NRC website further states that the WBL enables the NRC and Agreement States to manage the life cycle of a license from initial application through license issuance, amendment, reporting, and termination.

The NRC's website also states that the LVS was deployed in May 2013, and will aid in ensuring that only authorized licensees obtain radioactive materials in authorized amounts. The system will be more actively used once manufacturers, which are mostly located in Agreement States, start to access the system. The NRC clearly describes on its website that the LVS was designed to provide access to license information maintained by the NRC and Agreement States. The system enables authorized licensees to verify certain information about licensees who are authorized to possess, use, or ship radioactive materials. Specifically, licensees will be able to confirm that a license is valid and accurate, and if a licensee is authorized to acquire quantities and types of licensed radioactive material being requested. The NRC website indicates that the LVS, when accessed, will display an official license image and will notify suppliers or licensees to contact the regulator if there are any discrepancies. According to an NRC representative, licensees would only contact the NRC for verification if the receiving licensee is an NRC licensee, and if the

receiving licensee is an Agreement State licensee, the Agreement State would be contacted for verification. The same NRC representative indicated that the NRC LVS Help Desk has recorded 11 manual verifications performed by NRC in 2014, and 10 in 2015, and that the majority of contacts made to the LVS help desk involved requests regarding access to the LVS. In 2014, the Help Desk received 173 requests for assistance regarding access, and in 2015, there were 94 requests regarding access.

Another site available is the NRC's State and Tribal Programs Increased Controls (IC) Toolbox, which was deployed on June 20, 2006. The IC Toolbox was converted to the Materials Security Toolbox in January 2015, due to the implementation of 10 CFR Part 37. It should be noted that access to the Toolbox is protected and was not accessed by this independent assessor. The NRC did, however, provide an outline of topics contained in the Toolbox. Based on discussions with members of NRC's staff, it was determined that in June 2015, a new contractor was selected to oversee the implementation of the Toolbox. The new contractor basically deployed a new Toolbox replacing the original Toolbox created by the previous contractor.

Currently, the Toolbox contains helpful and informative references for 10 CFR Part 37 such as, GAP Training slides; 10 CFR Part 37; NRC Inspection Manual, Inspection Procedure 87137; 10 CFR Part 37, Materials Security Program; Best Practices for Protection of Risk-Significant Radioactive Material; NRC Regulatory Issue Summary 2014-03, Notice of 10 CFR Part 37 Implementation Deadline for NRC Licensees; 10 CFR Part 37 Implementation Plan; Implementation Guidance for 10 CFR Part 37; and NRC Regulatory Issue Summary 2005-31, Control of Security-Related Sensitive Unclassified Non-safeguards Information Handled by Individuals, Firms, and Entities Subject to NRC Regulation of the Use of Source, Byproduct, and Special Nuclear Material. Another important feature of the toolbox is the Materials Security Mailing List, which provides a method for stakeholders such as licensees and Agreement States to receive notification when new reports are added to the Materials Security Toolbox. The Toolbox also contains the Materials Security Toolbox Message Board. At the time of this assessment, the message board was under construction and, according to an NRC representative, the NRC hopes to have the message board operational in early 2016. Once operational, the message board will provide a mechanism for authorized Agreement States to communicate with each other. According to another NRC representative, no training was provided to Agreement State staff on how to navigate the Toolbox. However, the Toolbox does contain NRC contact information, so that if an authorized individual has a question or needs help, he or she can contact the NRC for assistance. As of the date of this report the NRC has not received any questions or requests regarding how to navigate the Toolbox. Also, according to information provided by the NRC, the Toolbox has been accessed numerous times by both NRC and Agreement State staff. The contractor overseeing the Toolbox at the time of this assessment indicated that, as of December 3, 2015, a total of 394 individuals have accessed the Toolbox.

As part of this assessment, 11 NRC materials health physics inspectors and a total of seven Agreement States Programs were asked if they had received training on the use of the NRC Inspector's Toolbox (Materials Security Toolbox) associated with security of radioactive materials. They were asked if they have used the Toolbox and if so, if they found it to be user friendly and a useful tool. Specifically, they were asked if they were able to locate needed information and if they had experienced any problems associated with its use. In addition, they were asked if they had used the following NRC systems: National Source Tracking System or Web-Based Licensing System and if so, if they found them helpful.

A total of five NRC inspectors that responded stated that they did not receive training from the NRC on the use of the Toolbox; the remaining NRC inspectors did not provide a response. A total of five NRC inspectors stated that they do not use the toolbox. A total of seven NRC inspectors indicated that they use the NSTS, and a total of nine NRC inspectors stated that they use WBL. Of the NRC inspectors that have used the NSTS, four indicated that they found NSTS to be helpful. In addition, six of the NRC inspectors indicated that they found WBL to be helpful.

With respect to the NSTS, one NRC inspector indicated that the NSTS cannot change the number of viewable sources per-page, nor does it offer any way to print information. However, according to a staff member of the NRC's Office of NMSS by using the "Inventory Report" link in NSTS, there is a way to print the inventory report as well as export the report into an Excel or PDF file. Based on the information obtained during this assessment, the NRC should ensure that its materials health physics inspectors are made aware of how to print the inventory report and export the report into an Excel or PDF file.

With respect to the WBL system, two NRC inspectors indicated that the WBL system is useful for tracking licensing actions, but it currently cannot be used to track inspection findings. One of the two inspectors added that it should be a priority to further develop the system, so that violations can be trended. According to a staff member from the NRC's Office of NMSS, there are two areas in which inspection findings are tracked. On the inspection tab, there is a "summary of findings" at which the inspector will use checkboxes to indicate the type of findings in the inspection. Multiple types of inspection findings can be selected. Then, there is a "findings" tab at which the inspector will list specific findings. They note the type of finding (Severity Level) and reference the specific regulation being cited or the license condition that the finding is against. There is also a section at which inspectors can enter text in order to summarize the findings. The information on how to enter inspection findings is detailed in the WBL Users Guide. Based on information provided by the NRC, the process for entering inspection findings seems clear, but there may be some uncertainty among some NRC inspectors regarding how to perform a search of previously entered inspection findings in WBL. In addition, according to another NRC staff member from the NRC's Office of NMSS, training on WBL was last offered during the summer of 2012. If someone was hired after that

date, training in the WBL system would have been provided by the respective NRC regional office. According to this NRC staff member, the NRC is in the process of developing training videos for all the modules in the WBL system primarily to assist Agreement State personnel who are or will be implementing the WBL system, however, these training videos can also be used by NRC staff.

Four Agreement State Program representatives that responded stated that they did not receive training from the NRC on the use of the toolbox, and do use the toolbox. Seven Agreement State Programs representatives indicated that they use NSTS. Of the Agreement State Program representatives who indicated that they have used the NSTS, six stated that they have found it to be helpful. A total of three Agreement States representatives indicated that they do not use WBL.

With respect to the WBL, one Agreement State Program representative indicated that the State has not used it nor will it be utilized by the State, as it was found to be less than intuitive. Consequently, the State opted to revamp and build its own licensing and inspection computer program. During an interview, the representative stated that WBL did not come across as user friendly, and noted that WBL will require a strong IT support system in the future in order to be maintained, so they decided to adopt another system developed by another State. He noted that it may take a minimum of a year to have their system functional.

As part of this assessment, the same 17 NRC licensees mentioned earlier in the report were asked if they have used the following NRC sites: National Source Tracking System or License Verification system. In addition, they were asked if they had used the systems, if they found them user friendly and useful/helpful. Based on a review of the responses, it appears that 13 of the licensees have used the NSTS, and six licensees use the LVS.

Of the licensees that have used the NSTS, 11 of the licensees indicated that they found the system to be useful and helpful. Four Federal licensees indicated initial credentialing and/or logging-on issues. Specifically, their computer systems were not compatible with the original card readers used to activate the NSTS. However, according to a staff member from the NRC's Office of NMSS, the NRC has since discontinued the use of cards and readers for accessing NSTS; there should not be any ongoing issues. With the new one-time password "tokens," licensees who are Federal entities do not have to download any drivers and should now be able to log onto the NSTS with ease. Another licensee stated that the NSTS does not identify the location of a specific source, and only the actual licensee has this information. This licensee also described another issue regarding the NSTS system. Specifically, they have sources located very close to the manufacturer and distributer of the sources they possess. When the licensee needed to replace a source, the source is driven to the manufacturer's facility, and the licensee waits for the exchange to be completed and leaves with the new source. The manufacturer sends the source exchange documentation to its corporate office to be entered into the NSTS system.

According to the licensee, sometimes this process takes two to three days to complete. In the meantime the licensee has taken possession of the new source; however, the license is unable to enter the new source information into NSTS until the manufacturer completes its entries into the NSTS. As a result, the NSTS is not accurate at this particular point in time. The NRC was present when this information was provided by the licensee and indicated that the licensee should provide the specifics to the NRC for further discussion. According to a staff member of the NRC's Office of NMSS, the receiving licensee should be able to meet its regulatory requirement. According to a representative from the NRC, if the licensee has online access, they can enter the information as an "unrecorded transfer." If the receiving licensee does not have online access, they can submit an NRC Form 748, National Source Tracking Transaction Report for the receipt of the radioactive material, which will then be entered into NSTS by the NRC's contractor. Based on the information obtained during this assessment, an NRC representative should discuss this directly with the licensee who raised the concern in order to answer any additional questions or concerns the licensee may have regarding this issue.

One licensee mentioned that he had experienced issues regarding the LVS system, in that, he would receive error messages and believes it would be helpful if the error messages would identify the specific error. The licensee also described another issue involving the LVS system. Specifically, he indicated that it is not clear how often the LVS system needs to be checked for routine standing orders from customers in order to verify the customer's license.

It should be noted that several licensees that provided responses to these questions, indicated that, when they had experienced difficulties with either the NSTS or the LVS system, they contacted the respective NRC Help Desk and the Help Desk had been very helpful.

c. Conclusions and Suggestions

Based on the information reviewed during this assessment, I have concluded that the NRC's use of on-line tools to communicate with stakeholders has been accomplished in a timely and secure manner. Some areas for NRC consideration are as follows: 1) once revisions to the Materials Security Toolbox are complete, the NRC should conduct additional outreach to NRC and Agreement State inspectors in order to discuss the contents and functions of the toolbox; and 2) the NRC should determine the level of knowledge its inspectors have regarding the function, operation, and capabilities of the WBL system. The NRC should continue its staff and Agreement State Programs of the availability of these training videos so that inspectors are knowledgeable regarding the available functions of the WBL system, including the process for obtaining inspection findings.

5. **Review Agreement State Roll-Out of Compatible Requirements and Identification of Best Practices for NRC to Implement in the Future**

a. Scope

A review of the Agreement State roll-out of compatible requirements and identification of best practices for NRC to implement in the future was conducted. A review of the following document was also conducted: 10 CFR Part 37 Implementation Working Group Draft Charter. Responses to questionnaires received were evaluated, and information received during interviews was also evaluated. In addition, a review of the following GAO reports was conducted, "Additional Actions Needed to Increase the Security of U.S. Industrial Radiological Sources," dated June 2014. A total of seven Agreement State Programs responded to the questionnaire and/or participated in an interview.

b. Observations

The 10 CFR Part 37 Implementation Working Group Draft Charter states, that each Agreement State is responsible for promulgating legally binding requirements, after the issuance of the final 10 CFR Part 37 rule. The NRC requested that Agreement States submit proposed amendments to its regulations or other proposed generic legally binding requirements, for NRC staff review. The Draft Charter also states that the NRC Security Orders will remain in effect for Agreement State licensees until compatible regulations are promulgated and implemented by the respective Agreement States. The 10 CFR Part 37 Implementation Working Group will consider the possibility of tracking Agreement State inspection results.

For this assessment, the NRC provided information regarding the status of Agreement State adoption of 10 CFR Part 37 compatible rules or other legally binding requirements, such as license conditions. On March 23, 2016, a staff member from the NRC's Office of NMSS indicated that all Agreement States have adopted and implemented equivalent regulations or other legally binding requirements by March 19, 2016. According to the NRC, the implementation and inspection of 10 CFR Part 37 compatible regulations or other legally binding requirements by the Agreement States will be evaluated during the IMPEP review process.

As part of this assessment, seven Agreement State Programs were asked to describe actions taken by their offices prior to the roll-out of 10 CFR Part 37, and to specifically describe what actions were or will be taken in preparation for inspecting licensees who are implementing 10 CFR Part 37 compatible regulations. They were also asked if there was adequate communication between their offices and the NRC with respect to inspecting licensees who were required to implement 10 CFR Part 37 compatible regulations. There were several similar actions taken by the Agreement State Programs in order to prepare for inspecting licensees who were or will be implementing 10 CFR Part 37 compatible regulations. The actions taken include, developing their specific requirements, providing training and guidance to the inspection staff, communicating frequently with licensees throughout the process, and providing informational sessions to licensees. Two of the Agreement State Programs are using an inspection "checklist" to assist in the implementation of 10 CFR Part 37

and conducting inspections. The State of Ohio developed four "checklists" for licensees to use as guidance. Seven Agreement State Program representatives indicated that communication occurred between them and the NRC. Three Agreement State representatives specifically mentioned that the communication was adequate. The remaining 4 Agreement State representatives did not provide a response regarding whether the communication between them and the NRC was adequate. Two Agreement State Program representatives indicated that the NRC Regional State Agreements Officers have been helpful. One Agreement State Program representative stated that the NRC and other Agreement State Programs have also provided copies of NRC inspection procedures, guidance documents, and GAP Training slides.

In addition, as part of this assessment, 7 Agreement State Programs were asked to describe any challenges regarding implementation oversight, specifically in preparing to implement 10 CFR Part 37 compatible regulations, e.g., preparing inspectors to conduct inspections with licensees, and enforcement. Three Agreement State Program representatives indicated the following similar challenges specifically, the amount of time necessary to provide training to the staff, and the amount of time needed to develop inspection checklist/forms. One Agreement State Program representative mentioned the cost associated with providing training to the staff. Another Agreement State Program representative indicated the following anticipated challenge specifically, how should the State approach inspections of licensees that have facilities in multiple states, as well as NRC jurisdiction. The example he provided involved a licensee who has a location of use within its jurisdiction but also has a corporate office located within another States jurisdiction. This licensee's T&R records are maintained at that corporate office. The NRC was present during this discussion and informed the representative that the NRC is aware of this challenge and is working on guidance to address the issue.

In the GAO report, "Additional Actions Needed to Increase the Security of U.S. Industrial Radiological Sources," dated June 2014, on page 28, the GAO indicates that licensees of mobile and stationary radioactive sources also face challenges in determining which of their employees are suitable for trustworthiness and reliability certification, as required by NRC's security controls. Some licensees the GAO spoke to indicated they faced challenges making T&R determinations. The licensees stated that the challenges included limited security experience, training, and incomplete information.

Seven Agreement State Programs were asked if they were made aware of challenges licensees had encountered implementing any sections of 10 CFR Part 37 compatible regulations. If so, which specific sections of 10 CFR Part 37 compatible regulations were reported as challenging, and why? They were also asked if they believe additional outreach would have been helpful to licensees. In addition, they were asked if they believe that any section of the 10 CFR Part 37 compatible regulations will be difficult or confusing to inspect against, and if so, which sections; they were

also asked if additional training would have been helpful to inspectors, and if so, what type of training.

Four Agreement State Program representatives did indicate that they have been made aware of challenges that licensees have encountered implementing sections of 10 CFR Part 37. Specifically, one representative stated that licensees have reported challenges developing written policies and procedures, in addition to their normal duties. Another Agreement State Program representative stated that at least one of its licensees has pointed out to them that it is not clear who reviews the Reviewing Official (RO's) initial background check information. The representative stated that this is not specified in the regulation, and it is not clear in the guidance documents. This issue has been discussed with the NRC, and the NRC has indicated that there is a lack of clarity in the regulation and guidance, and it is being pursued by the NRC. Two other Agreement State Program representatives indicated that licensees have reported challenges regarding the establishment of security zones as well as the new requirements concerning fingerprinting of the RO. Although some Agreement State Program representatives have indicated that licensee challenges have been reported, only two Agreement State Program representatives indicated that additional outreach would have been helpful to licensees.

Four Agreement State Program representatives stated that they don't believe its inspectors will have any difficulty inspecting against any section of the 10 CFR Part 37 compatible regulations. However, one Agreement State Program representative did indicate that the proper establishment of a temporary security zone as required in 37.47(b) may be difficult to verify during an inspection. Specifically, the representative questioned if each established temporary security zone be documented in a revised security program. One Agreement State Program representative indicated that additional training by the NRC was requested, and two Agreement State Program representatives indicated that additional training would not have been helpful to inspectors.

As part of this assessment, seven Agreement States Programs were asked if they have observed licensees implementing 10 CFR Part 37 compatible regulations, and if so, if they have identified any best practices that could be helpful to other licensees.

All seven of the Agreement State Program representatives indicated that they have not identified any best practices that could be helpful to other licensees. This may be due to the fact that, at the time of this assessment, the majority of Agreement State licensees had not yet implemented the 10 CFR Part 37 compatible requirements. Of the 2 Agreement State Programs that have observed licensees implementing 10 CFR Part 37 compatible requirements, neither has observed any best practices that would be helpful to other licensees.

c. Conclusions and Recommendations

Based on the limited number of Agreement State Programs that could be contacted during this assessment and the fact that it may be too early to make any real meaningful assessment of Agreement State Program roll-out of 10 CFR Part 37 compatible regulations, I have concluded that the NRC should perform another review of this area again at a later date. The NRC should obtain prior OMB approval so that more than nine Agreement State Programs and be contacted. This approach will give Agreement State Programs an opportunity to; identify any challenges within their program as well as challenges identified by licensees, as well as any best practices for NRC to implement in the future. At the time of this assessment, the majority of Agreement States contacted had not performed inspections of their licensees, and those that had, except for Ohio, had performed a limited number of inspections.

6. Inspection Results and Event Reports From the First Two Years of Implementation of the Requirements of 10 CFR Part 37 for NRC Licensees.

a. Scope

A review of inspection results and event reports from the first two years of implementation of the requirements of 10 CFR Part 37 for NRC licensees was conducted. The following documents were reviewed: NRC's Annual Nuclear Materials Event Database (NMED) Report from Fiscal Year 2014, published February 2015 by Idaho National Laboratories (INL); document titled, "Lost/Abandoned/Stolen (LAS) Event Summary involving Category 1 and 2 sources FY 2006-2015," dated November 6, 2015; and documented inspection findings from March 19, 2014, through September 25, 2015.

b. Observations

The NRC developed IP 87137, "10 CFR Part 37 Materials Security Programs," which was issued April 3, 2014. It was noted that the date the IP was issued was after March 19, 2014, the date the NRC licensees were required to implement 10 CFR Part 37.

The IP is for use by material health physics inspectors, and states that the objectives of the inspection are to verify that licensees are effectively implementing the requirements promulgated by 10 CFR Part 37. There are three focus areas specified in the procedure. They are as follows: 1) background investigations and access authorization program; 2) physical protection during use; and 3) physical protection during transit. It further states that, "the focus is on security inspections of those licensed under 10 CFR Part 30, subject to Part 37 requirements while possessing certain aggregated Category 1 and 2 quantities of radioactive material." The procedure provides both general and specific inspection guidance for the three focus areas specified above.

According to a Branch Chief from NRC's Office of NMSS, the NRC Enforcement Policy was not been revised due to implementation of 10 CFR Part 37. The Branch Chief indicated that provisions of the Enforcement Policy in use during the original NRC Security Orders can still be applied to 10 CFR Part 37 inspection findings. She also noted that, when the original Security Orders were first implemented, the NRC applied what was termed "Good Faith" to some inspection findings. "Good Faith" basically meant that a violation was not assigned a Severity Level and no enforcement action would be taken by the NRC. However, if the violation was identified again, enforcement action may be taken. This was done in order to allow licensee's some time to acquaint themselves with the requirements in the Security Orders. This approach is no longer being applied by the NRC for licensees required to comply with 10 CFR Part 37. With respect to the 10 CFR Part 37 Implementation Working Group efforts concerning enforcement guidance, the Branch Chief indicated that the NRC, at the time of this assessment, was continuing a review of the NRC's Enforcement Policy. She indicated that the NRC reviews the Policy to ensure that it continues to stay up-to-date and relevant.

Based on a review of information provided by several NRC staff members and NRC inspectors, the NRC had not revised its Enforcement Policy and decided to establish the SIF. The SIF meets in order to discuss potential 10 CFR Part 37 violations that have been identified during NRC inspections. The NRC tracks the violations discussed during the SIF in order to establish a precedent for dispositioning the 10 CFR Part 37 violations. At the time of this assessment, there were no sample violations nor respective Severity Levels specified in the NRC Enforcement Policy for 10 CFR Part 37 violations. According to an NRC staff member from the NRC's Office of NMSS who serves as an Enforcement representative, the NRC plans to suspend the SIF process once the NRC has accumulated enough data and experience dispositioning 10 CFR Part 37 violations. The NRC also plans to modify its Enforcement Policy to include a representative sample of 10 CFR Part 37 violations. The NRC provided a document on January 29, 2016, titled, "Findings not Needing Discussion at the SIF." The document contains approximately 11 examples of violations for various sections of 10 CFR Part 37 that no longer need to be discussed at the SIF. The document includes a statement that violations determined to be "minor" no longer need to be discussed at the SIF, providing the supervisor is certain that the violation is minor, as described in the NRC's Enforcement Policy. According to a staff member of the NRC's Office of NMSS, this document was posted on the NRC's SharePoint site around May 2014, for NRC materials health physics inspectors to see, and was last updated on October 21, 2015. Representative from NRC regional management (Branch Chiefs) attend the SIF meetings. The posting of this document on the NRC SharePoint site was communicated at one of the SIF meetings. A subsequent email containing a link to the site was sent to the Branch Chiefs.

As stated in Section 2 of this report, the SIF process was identified by several NRC inspectors as being a challenge for the inspectors during the implementation phase

of 10 CFR Part 37 (See the observations described in Section 2 of this report for details). Some NRC inspectors believe that NRC should have been more proactive, and should have created a working group early on to create sample violations and respective severity levels to be used by the inspection staff, and only use the SIF process for unusual or unique violations that had been identified.

According to the NRC's Enforcement Manual, "the NRC's Enforcement Program uses a graded approach for violations, both in terms of addressing their significance and developing sanctions." The Manual states that violations are assigned a Severity Level ranging from Severity Level I for the most significant violations and Severity Level IV for those of more than minor concern. The Manual also states that minor violations are less significant than Severity Level IV violations and do not warrant enforcement action.

The Policy also indicates that, in some cases, it may be appropriate to group some violations as examples of a problem. Violations should not be "aggregated into a violation/problem of a higher severity level. The Policy further indicated that "grouping violations informs the licensee and public that the NRC is aware that the violations are closely related and are not separate regulatory breakdowns."

Based on information provided by the NRC on February 5, 2016, a total of approximately 179 inspections were performed by the NRC from the time NRC licensees were required to implement 10 CFR Part 37 and September 25, 2015. This assessment focused on the Severity Level of the violations issued, which section of 10 CFR Part 37 was cited, and whether there were any obvious trends. The total number of inspections performed by the NRC resulted in the following violations being issued: 1) approximately107 Severity Level IV violations (including Severity Level IV problems); 2) approximately nine Severity Level III violations (including Severity Level III problems); and 3) approximately four minor violations. In addition, it should be noted that violations of 10 CFR Part 37 that are tracked by the NRC are frequently being updated, and this assessment may not be current at the time this report is issued.

With respect to trending the violations, there were five sections of 10 CFR Part 37 that were cited most frequently. They were as follows: 37.23(f) with a total of approximately 16 violations cited; 37.43(b)(1) with a total of approximately ten violations cited; 37.43(b) with a total of approximately eight violations cited; 37.43(a)(1) with a total of approximately six violations cited; and 37.43(a) with a total of approximately five violations cited. These violations were all issued as Severity Level IV violations.

Section 37.23(f), Access authorization program requirements, Procedures, requires the licensee to develop, implement, and maintain written procedures for implementing the access authorization program. The program must include provisions for the notification of individuals who are denied unescorted access. The procedures must include provisions for the review, at the request of the affected

individual, of a denial or termination of unescorted access authorization. The procedure must contain a provision to ensure that the individual is informed of the grounds for the denial or termination of unescorted access authorization and allow the individual an opportunity to provide additional relevant information.

Section 37.43(b)(1), Implementing procedures, (1) The licensee shall develop and maintain written procedures that document how the requirements of this subpart and the security plan will be met.

Section 37.43(b), General security program requirements, implementing procedures, requires the licensee to develop and maintain written procedures that document how the requirements of this subpart and the security plan will be met.

Section 37.43(a)(1), Security plan, requires each licensee identified in 37.41(a) shall develop a written security plan specific to its facility and operations. The purpose of the security plan is to establish the licensee's overall security strategy to ensure the integrated and effective functioning of the security program required by this subpart. The security plan must, at a minimum: (i) Describe the measures and strategies used to implement the requirements of this subpart; and (ii) Identify the security resources, equipment, and technology used to satisfy the requirements of this subpart.

Section 37.43(a), General security program requirements, Security plan, requires each licensee identified in 37.41(a) to develop a written security plan specific to its facilities and operations. The purpose of the security plan is to establish the licensee's overall security strategy to ensure the integrated and effective functioning of the security program required by this subpart.

These violations appear to be administrative in nature.

There were a total of nine Severity Level III violations issued, for the following sections of 10 CFR Part 37: 1) one violation for 37.25(a); 2) four violations 37.43(d)(3)(i) and (ii); 3) one violation for 37.43(d)(1); 4) one violation for 37.49(a); 5) one for 37.49(c)(2); and 6) one violation for 37.53(a).

Section 37.25(a), Background investigations, Initial investigation. Before allowing an individual unescorted access to Category 1 or Category 2 quantities of radioactive material or to the devices that contain the material, licensees shall complete a background investigation of the individual seeking unescorted access authorization. The scope of the investigation must encompass at least seven years preceding the date of the background investigation or since the individual's eighteenth birthday, whichever is shorter. The background investigation must include at a minimum…

Section 37.43(d)(1), General security program requirements, Protection of information. Licensees authorized to possess category 1 or category 2 quantities of radioactive material shall limit access to and unauthorized disclosure of their security plan, implementing procedures, and the list of individuals that have been approved for unescorted access.

Section 37.43(d)(3)(i) and (ii), General security program requirements, Protection of information. Before granting an individual access to the security plan or implementing procedure; licensees shall: Evaluate an individual's need to know the security plan or implementing procedures; and If the individual has not been authorized for unescorted access to Category 1 or Category 2 quantities of radioactive material, safeguards information, or safeguards information-modified handling, the licensee must complete a background investigation to determine the individual's trustworthiness and reliability. A trustworthiness and reliability determination shall be conducted in 37.25(a)(2) through (a)(7).

Section 37.49(a) Monitoring, detection, and assessment, Licensees shall establish and maintain the capability to continuously monitor and detect without delay all unauthorized entries into its security zones. Licensees shall provide the means to maintain continuous monitoring and detection capability in the event of a loss of the primary power source, or provide for an alarm and response in the event of a loss of this capability to continuously monitor and detect unauthorized entries.

Section 37.49(c)(2) Personnel communications and data transmission. For personnel and automated or electronic systems supporting the licensee's monitoring, detection, and assessment systems, licensees shall: Provide an alternative communication capability for personnel, and an alternative data transmission and processing capability, in the event of a loss of primary means of communicating or data transmission and processing. Alternative communications and data transmission systems may not be subject to the same failure modes as the primary systems.

Section 37.53(a) Requirements for mobile devices, each licensee that possesses a mobile device containing Category 1 or Category 2 quantities of radioactive material must: have two independent physical controls that form tangible barriers to secure the material from unauthorized removal when the device is not under direct control and constant surveillance by the licensee.

These violations seem to be procedural in nature, and failure to implement could increase the vulnerability of the radioactive material.

Other sections of 10 CFR Part 37 were cited but they ranged from one to four violations per section of 10 CFR Part 37, and resulted in Severity Level IV or minor violations being cited. Additionally, not all sections of 10 CFR Part 37 had violations cited.

The NRC has developed a TI 2800/042, Evaluation of Trustworthiness and Reliability Determinations issued on November 25, 2015. There are three objectives specified in this TI. The first objective is "to determine and document whether licensees have chosen to establish criteria that would disqualify an individual from unescorted access to Category 1 and Category 2 quantities of radioactive material and to the extent to which the NRC or other guidance is utilized." The second objective is "to

collect and document specific information on the trustworthiness and reliability determination process for the approval of reviewing officials, individuals requiring unescorted access to Category 1 and Category 2 quantities of radioactive material, and individuals requiring access to security plans or implementing procedures, after the implementation of 10 CFR Part 37." The third objective is "to assist in the review of the effectiveness of the access authorization and background investigation requirements to determine whether any enhancements are needed through guidance, outreach or rulemaking actions." According to the TI, it provides additional direction to inspectors in collecting and documenting specific information regarding the conduct of licensee's T&R determination process, after implementing 10 CFR Part 37. The TI specifically references the GAO report dated June 2012, which recommends that the NRC conduct an assessment of the T&R process by which licensees approve employees for unescorted access to Category 1 and Category 2 quantities of radioactive material in order to determine if it provides reasonable assurance against insider threats. The NRC, in response to the GAO report, committed to conducting a review of the effectiveness of the T&R requirements in 10 CFR Part 37, over the next year or two, to determine whether any additional security measures, guidance documents, rulemaking changes or licensee outreach efforts are appropriate. It should be noted that the Background section of the TI states the following: As stated in the guidance (NUREG- 2155 and NUREG- 2166), licensees should (not a requirement) establish criteria that would disqualify an individual from unescorted access to Category 1 and Category 2 quantities of radioactive material. However, it further goes on to state that the inspector should be cognizant that 10 CFR Part 37 does not require that licensees establish such criteria.

The following is a brief review of the event reports from the first 2 years of implementation of 10 CFR Part 37.

Based on a review of information contained in the NMED, which included a comparison graph of events that covered a 10 year period (2005 -2014), and LAS Event Summary, it seems that since the implementation date of 10 CFR Part 37 for NRC licensees, there still seems to be a number of LAS radioactive material events occurring. One would expect to see a decrease in the number of events, and the number of violations identified, if licensees are complying with 10 CFR Part 37. According to INL, it does appear that the number of events for NRC licensees has decreased on the average; however, Agreement State events are on the rise. Furthermore, INL indicated that this may be due to the fact that the number of Agreement States has increased.

Based on a review of the event data provided in the LAS Events Involving Category 1 and 2 Sources FY 2006-2015, it appears that the majority of Category 2 source events involve radiography sources while either in storage or in transport. One could speculate that compliance with 10 CFR Part 37 is not preventing or reducing the number of LAS radiography events. These events, however, do appear to be a result of human error. Radiographers are still failing to secure the exposure device prior to

transport or when returning the exposure device to storage. There have been a total of 14 NRC LAS source events, excluding irretrievable well logging sources, from January 1, 2014, to November 6, 2015. Two events involved Category 1 sources and the remainder involved Category 2 sources.

According to the NMED Annual Report for fiscal year 2014, there were a total of eight significant events involving the loss of category 1 through 3 sources during 2014. They included five Category 2 lost sources and three Category 3 lost sources. All of the events mentions in the NMED report were recovered, and it appears that none had been used maliciously.

c. Conclusions and Recommendations

It should be noted that there was a limited amount of information available for this portion of the assessment. Most of the information necessary to perform a thorough review of inspection findings and some events is not publically available. This is due to the fact that the information contains licensee-specific, security-sensitive information. However, based on the information that was available during this assessment of NRC inspection findings, it would be prudent for the NRC to continue trending inspection results and attempt 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. The results of this type of analysis could be used in the future to determine if modification to 10 CFR Part 37 is necessary and/or helpful.

Based on the NRC inspector feedback regarding the SIF process and this assessor's personal opinion, I recommend that the NRC do what it can to expedite the development of 10 CFR Part 37 sample violations for use by the materials health physic inspectors. Sample violations for the original Security Order had not been developed and distributed to NRC staff prior to performing inspections against the original Security Orders, and it appears that this practice was repeated for the implementation of 10 CFR Part 37. In the future when undertaking the development and implementation of a new rule, it would be prudent to develop a strategy that would make improvements in productivity and efficiency in this area. This process could be supplemented by obtaining input from the NRC staff that will be directly impacted by the change specifically, those that perform inspections. It seems that, if the current NRC Enforcement Policy was truly adequate for dispositioning 10 CFR Part 37 violations, then the NRC would not have determined that the SIF process needed to be developed in order to establish a precedent for violations for dispositioning almost all initial 10 CFR Part 37 violations.

Based on a review of NMED data and inspection findings, I recommend reaching out to radiography licensees by conducting additional stakeholder meetings to determine and discuss the licensee's perspective regarding the root causes for these events. Hopefully, this approach will help reduce the number of LAS events. This approach can also be used to conduct additional discussions regarding best

practices. Input gathered during these meetings may result in additional guidance to be added to NUREG-2166. For example, these discussions could result in the use of new technology and clarify appropriate use of certain technology (i.e., tracking devices, kill switches, or pressure pads).

Since 10 CFR Part 37 is a performance-based regulation, the NRC may want to consider expanding the NUREG-2166 beyond what currently exists by obtaining licensee input and making any modifications the NRC feels would provide additional guidance. Another possible approach would be to work collaboratively with other Federal Agencies in order to create additional guidance documents that would provide detailed information that may further aid licensees, and subsequently help lead licensees toward making optimum decisions when determining how to enhance security, improve compliance, and hopefully reduce the number of LAS events.

Regarding the issue of establishing disqualifying criteria, the NRC may want to consider that since NUREG-2155 and NUREG-2166 state that licensees should establish disqualifying criteria, and since the first objective of this TI 2800/042 is to determine if licensees have established disqualifying criteria, it seems that it would be appropriate for 10 CFR Part 37 to include a requirement that licensees establish disqualifying criteria.

Each licensee would establish its own specific criteria. The NRC would review the criteria during inspections and confirm whether licensees were effectively using their established criteria during their T&R determination process. It should be emphasized that the NRC would not be establishing, approving, or evaluating the adequacy of the criteria, only determining that each licensee has, in fact, established disqualifying criteria and is using it effectively.

References

Secy-11-0170, Rulemaking Issue Affirmation “Final Rule: Physical Protection of Byproduct Material (RIN 3150-A112), dated December 8, 2011

GAO-12-925, Report Nuclear Nonproliferation, “Additional Actions Needed to Improve Security of Radiological Sources at U.S. Medical Facilities”, dated September 2012

GAO-14-293, Industrial Radiological Sources, “Additional Actions Needed to Increase the Security of U.S. Industrial Radiological Sources”, dated June 2014

GAO- 07-1038T, Nuclear Security, “Actions Taken by NRC to Strengthen Its Licensing Process for Sealed Radioactive Sources Are not Effective”, dated July 12, 2007

GAO-03-804 Nuclear Security, “Federal and State Action Needed to Improve Security of Sealed Radioactive Sources”, dated August 2003

Technical Paper, Safety and Security Interface Increasing Security of Category 1 and 2 Materials within the United States, Mark Satorius and Brian McDermott, dated August 5, 2013.

U.S.N.R.C., NUREG-2155, Rev.1, Implementation Guidance for 10 CFR Part 37, “Physical Protection of Category 1 and category 2 Quantities of Radioactive Material”, dated August 11, 2015

U.S.N.R.C., NUREG-2166, “Physical Security Best Practices for the Protection of Risk-Significant Radioactive Material”, dated May 2014

IAEA Nuclear Security Series No.11, Implementing Guide, Security of Radioactive Sources, dated May 2009.

IAEA Nuclear Security Series No.9, Implementing Guide, Security in the Transport of Radioactive Material, dated September 2008.

TI 2800/041, Evaluation of Trustworthiness and Reliability Determinations, November 25, 2015

Slides for 10 CFR Part 37 Materials Inspector Security “Gap” Training Introduction, overview, and Inspections, dated March 2015

Office of Federal and State Materials and Environmental Management Program (FSME) Procedure Approval, Training criteria for Agreement State Personnel, SA-600, dated March 16, 2011, Reviewed March 16, 2014

FSME Procedure Approval, Reviewing the Common Performance Indicator, Technical Quality of Inspections – SA-102, dated July 23, 2007, Reviewed July 23, 2010.

Nuclear Material Events Database, Annual Report Fiscal Year 2014, Published February 2015, Idaho National Laboratory, risk Assessment and Management Services, Idaho Falls, Idaho.

NRC status of Agreement State Adoption of 10 CFR Part 37, last updated October 14, 2015.

SECY-11-0170 Final Rule: Physical Protection of Byproduct Material (RIN 3150-A112)

NRC Enforcement Policy, dated February 4, 2015

NRC Enforcement Manual dated September 9, 2013, updated December 10, 2015

Letter to the Honorable Byron Dorgan, Chairman, Subcommittee on Energy and Water Development, Committee on Appropriations, from NRC Chairman Gregory B. Jaczko, dated September 14, 2010, and enclosure titled “Report on the Nuclear Regulatory Commission and Department of Energy/National Nuclear Security Administration Activities in Protecting Radioactive Sources”

NRC S-201 Training Modules.

NRC Inspection Manual Chapter 1248

NRC Management Directive 5.6

Integrated Materials Performance Evaluation Program TN:DT-04-03, November 5, 1999 (Revised February 26, 2004)

NRC FSME Procedure “Reviewing the Common Performance Indicators, Technical Quality of Inspections-SA-102, July 23, 2007.

NRC Human Resources Training and Development Operating Procedure 0410, Revision 2, October 1, 2009