Report on Security of Radiation Sources used by Medical Facilities as requested in the Senate Report accompanying The Energy and Water Development and Related Agencies Appropriations Act for Fiscal Year 2014

As required by Public Law 113-76, the "Consolidated Appropriations Act, 2014," the U.S. Nuclear Regulatory Commission (NRC) is submitting this report addressing NRC actions to strengthen the agency's security requirements for radiation sources used by hospitals and medical facilities. This report was requested following the findings of the U.S. Government Accountability Office (GAO) report GAO-12-925, "Nuclear Nonproliferation: Additional Actions Needed to Improve Security of Radiological Sources at U.S. Medical Facilities." This GAO report concluded that the NRC's efforts are not sufficient to secure the high-risk radiological sources that are used at hospitals and other medical facilities. The NRC's formal response to Congress on the GAO report, dated November 9, 2012, expressed the NRC's disagreement with GAO's conclusion regarding the need for prescriptive security options, described the NRC's existing program of security requirements for risk-significant radioactive materials, and outlined NRC's planned actions to address the GAO's recommendations.

As to some of the specific issues raised in the GAO Report, the NRC and the Agreement States[1] pursued the examples provided by GAO to ensure a complete understanding of the security concerns identified by the GAO following the GAO facility visits. The NRC conducted a focused review of the inspection data and determined that there were no generic insights about the oversight program that could be identified from the four potential security concerns outlined in the GAO report. Rather, the NRC concluded that the four security issues are either violations of existing requirements or represent important lessons learned from the implementation of the security orders[2], which imposed these requirements.

Subsequent to the GAO audit and report and the NRC's November 2012 response to Congress, the NRC issued a new rule, Title 10 of the *Code of Federal Regulations* (10 CFR) Part 37, "Physical Protection of Byproduct Material," that further enhanced security requirements for category 1 and 2 quantities of radioactive material. This rulemaking was conducted in an open process that allowed the general public and other stakeholders (including other Federal agencies) to comment on the proposed rule and its associated draft guidance.

Because the 10 CFR Part 37 regulations were not in effect at the time of the GAO audit, the GAO report focused on the NRC security requirements that were issued to NRC-licensees by order in accordance with the NRC's authority under the Atomic Energy Act of 1954, as amended. The rule did not simply codify the security orders, but further expanded upon the security requirements in the orders. In drafting the 10 CFR Part 37 regulations, the NRC considered, among other things, the various orders issued, lessons learned during the implementation of the orders, experience with voluntary security enhancements, and recommendations and comments from a wide variety of stakeholders. The resulting regulations are risk-informed and performance-based, and provide a framework that requires licensees to

[1] Agreement States are those States that have entered into formal agreements with the NRC, pursuant to Section 274 of the Atomic Energy Act of 1954 (AEA) (Public Law 83-703), to regulate certain quantities of AEA material at facilities located within their borders. Currently, there are 37 Agreement States.

[2] Post-September 11, 2011, security orders contained requirements for licensees to implement interim compensatory security measures beyond that which was required by NRC regulations.

develop a security program with measures specifically tailored to its facility. NRC licensees were required to be in compliance with the new regulations by March 19, 2014; and Agreement States are currently in the process of developing, and implementing compatible requirements for their licensees, which must be completed by 2016.

Although the GAO report noted a concern about the performance-based nature of the NRC's requirements in this area, performance-based regulation is a key principle of the NRC's regulatory approach that applies to virtually all NRC-regulated activities. A performance-based requirement relies upon measurable performance results being met, and provides more discretion to the regulated party as to how best to meet those outcomes. Because of the wide variety of medical facilities and businesses affected by these requirements, prescribing specific security measures without regard to the type of facility and licensee operation may create circumstances in which inappropriate levels of protection at some facilities exist.

At the time of the publication of 10 CFR Part 37, NRC also published a guidance document, which provides explanations of the rule text and acceptable means of complying with the rule's requirements. Additionally, as committed to in our November 9, 2012, response to the GAO audit, the NRC staff is currently coordinating with its State and Federal partners to develop a "best practices" document, "Physical Security Best Practices for the Protection of Risk Significant Radioactive Material," to provide guidance to NRC licensees or applicants, with specific emphasis on physical security best practices (e.g., access authorization, intrusion detection, and assessment). To address the concern that there is a need to improve the licensee's knowledge of acceptable security practices, this "best practices" document will be issued in May 2014, and will provide supplemental practical guidance to be considered by licensees in developing and implementing an effective physical protection.

Compliance with security requirements is verified during regular inspections conducted by trained NRC and Agreement State inspectors. Licensees are required to implement corrective actions when violations are identified. These corrective actions are then verified and evaluated during subsequent inspections.

As with earlier NRC security orders, agency staff will track the inspection findings as the inspections of NRC licensees are completed during the first one to two years post-implementation (2015-2016), and use that information to conduct a preliminary review of the effectiveness of 10 CFR Part 37. Based on this review, NRC and the Agreement State will ascertain any additional lessons learned and determine whether additional security measures, guidance documents, or licensee outreach activities are necessary. If additional security measures are required, staff will submit options to the Commission for its review and approval.

In August 2014, the NRC will submit its quadrennial report, "The Radiation Source Protection and Security Task Force Report," to the President and Congress. The NRC-chaired task force, which was created by the Energy Policy Act of 2005, comprises independent experts from 14 Federal agencies and two State organizations. The membership of this independent task force represents agencies with broad authority over all aspects of radioactive source control, including regulatory, security, intelligence, and international activities. This report will identify the important progress that has been made since 2010, the last issuance of the report, with regard to the security of radioactive material within the United States.