

November 9, 2012

The Honorable Joseph I. Lieberman
Chairman, Committee on Homeland Security
and Governmental Affairs
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

On behalf of the U.S. Nuclear Regulatory Commission (NRC), I am providing the NRC's response to the U.S. Government Accountability Office (GAO) report entitled, "Nuclear Nonproliferation: Additional Actions Needed to Improve Security of Radiological Sources at U.S. Medical Facilities," (GAO-12-925) dated September 10, 2012. The NRC does not agree with GAO's conclusion regarding the need for prescriptive security controls. I will describe the NRC's program of security requirements for risk-significant radioactive materials, discuss our concerns with the conclusions in the GAO report, and outline the NRC's planned actions to address the GAO's recommendations.

Security and control of radioactive sources is a priority for the NRC. The NRC has a long history of ensuring radioactive source protection and security. The NRC's regulations require licensees to secure radioactive materials from unauthorized removal and unauthorized access. The terrorist attacks of September 11, 2001, heightened concerns about the use of radioactive materials in a malevolent act. The Commission determined that certain licensed material should be subject to enhanced security requirements, and that individuals with unescorted access to risk-significant quantities of radioactive material should be subject to background investigations. (The NRC defines "risk-significant materials" as those listed in Category 1 and Category 2 of the International Atomic Energy Agency's "Code of Conduct on the Safety and Security of Radioactive Sources.") As part of the development of the enhanced security measures, the NRC performed threat and vulnerability assessments to identify gaps or vulnerabilities in security and to assess the effectiveness of certain physical protection enhancements at various licensed facilities. The results of these assessments were used in the development of security enhancement ("Increased Controls") Orders, issued to licensees, directing them to implement security enhancement.

Medical facilities have been required to secure risk-significant radioactive materials in accordance with the Increased Controls Orders issued by the NRC, or equivalent requirements issued by the Agreement States, since 2005. Implementation guidance was also made available to licensees and an implementation working group established to ensure a common understanding of the requirements. The Increased Controls represent a comprehensive, multi-layered program of security measures for radioactive materials that is focused on providing protection commensurate with the risk associated with the quantity of radioactive material possessed by the licensee. The requirements are risk-informed and performance-based, providing a framework that requires the licensee to develop a security program with measures specifically tailored to its facility. The NRC and Agreement States remains confident that the

existing performance-based program of security measures required for licensees that possess risk-significant radioactive materials, including medical facilities, is effective and appropriate. Key requirements of the program include:

- Background checks, including fingerprinting to help ensure that individuals with unescorted access to risk-significant radioactive materials are trustworthy and reliable.
- Controlling personnel access to areas in which risk-significant radioactive materials are stored and used. Access must be limited to individuals who require access to the area and are deemed trustworthy and reliable, based on a background and criminal history check.
- Documented security programs that are designed with defense in depth to detect, assess and respond to actual or attempted unauthorized access.
- Coordination and response planning between the licensee and local law enforcement agencies.
- Coordination and tracking of risk-significant radioactive materials shipments.
- Security barriers to discourage theft of portable devices that contain risk-significant radioactive materials.

During routine inspections, trained NRC and Agreement State inspectors verify licensees' adherence to security requirements. The licensees are required to implement corrective actions when violations are identified, and these corrective actions are then verified and evaluated during subsequent inspections. Additional enforcement action is considered based on the severity of the violation.

The United States was the first country in the world to mandate such enhanced security requirements for risk-significant radioactive materials used in licensed facilities including hospitals and medical facilities, and NRC and Agreement State regulators ensure that these materials remain secure. The NRC's approach is consistent with the International Atomic Energy Agency's "Code of Conduct on the Safety and Security of Radioactive Sources" and Nuclear Security Series No. 11, "Security of Radioactive Sources Implementing Guide." In addition, in accordance with the Energy Policy Act of 2005, the NRC leads the Radiation Source Protection Task Force, which includes membership from 14 Federal agencies and 2 State organizations, and is charged with evaluating and providing recommendations related to source security. The Task Force has made significant progress in ensuring that the United States continues to be a world leader in applying the Code of Conduct. Although no security program provides absolute security, domestically, we maintain a high level of safety and security of risk-significant sources. The NRC and Agreement State security requirements have greatly improved the security of risk-significant radioactive materials—including those used at medical facilities—since the terrorist attacks of September 11, 2001.

The roles and authorities of the NRC and the Department of Energy's National Nuclear Security Administration (NNSA) are closely coordinated with regard to radioactive materials. The NRC and Agreement States regulatory framework ensures adequate protection of public health and safety and the common defense and security. Through its Global Threat Reduction Initiative, the NNSA works with the NRC, the Agreement States, local and tribal governments, and other Federal agencies, as well as materials licensees, to offer voluntary security enhancements that build on the existing regulatory requirements applicable to these licensees. These voluntary security enhancements are supplementary to, and do not replace, the

licensees' obligation to meet the NRC and Agreement State regulatory requirements. The NNSA's voluntary actions provide enhanced security beyond the adequate protection of public health and safety and common defense and security provided by the NRC's requirements.

The GAO report concludes that the NRC's security controls need to be strengthened because they do not prescribe specific security measures that the licensees should take to secure their radiation sources, such as specific direction on the use of cameras, alarms, and other physical security measures. The report suggests that the NRC's performance-based approach has led to the inconsistent application of security measures by licensees, which may have left some facilities more secure than others, and recommends that the NRC adopt an approach using more prescriptive security requirements that specifically directs the industry in the use of security cameras, alarms and other security devices. The GAO bases its conclusions concerning the security requirements on four instances of potential security concerns that were identified during their field work. The NRC and the Agreement States are evaluating potential compliance concerns associated with the two issues related to security requirements for access control (a lock combination to a controlled area written on the door frame) and access authorization (failing to know and to limit who is authorized for access to a controlled room). Regarding the other two examples, insufficient information has been provided to the NRC to determine whether there are violations of regulatory requirements and the information provided did not necessarily indicate that security concerns existed.

The NRC does not agree with the GAO's conclusion that additional prescriptive security requirements are necessary. As noted in the NRC's response to the draft report, it is our view that these reported instances of a licensee's failure to properly implement security controls established under a performance-based regulatory requirement are compliance issues that are addressed through inspection and enforcement; they, do not indicate that the regulatory framework itself is inadequate. Prescriptive "one-size-fits-all" regulations may result in either excessive or non-conservative approaches to source security. The NRC and the Organization of Agreement States have expressed a shared concern regarding the GAO's characterization of the issues identified at specific facilities in the report, as well as the basis for discounting a risk-informed, performance-based approach to the security of radioactive materials.

The GAO has recently responded to the NRC's request for specific information regarding the four facilities with possible violations. In their response, the GAO declined to provide specific information, in order to protect the confidentiality of the sources interviewed during the audit, however, GAO did provide a list of all the facilities it visited. The NRC and the Agreement States are pursuing the examples provided by GAO to ensure that the security concerns were addressed appropriately following the GAO facility visits. Additionally, the NRC will conduct a focused review of inspection data to identify possible generic insights about the oversight program from the four potential security concerns identified in the GAO report. Moreover, the Commission recently approved a new final rule (10 CFR Part 37, "Physical Protection of Byproduct Material.") that provides additional source security requirements based on the NRC staff's experience in implementing the increased Controls Orders.

The GAO report provides four recommendations, one primarily directed to the Administrator of the NNSA and three that recommend specific action by the NRC. The NRC responses to the recommendations are listed below.

GAO Recommendation 1:

The GAO recommends that the Administrator of NNSA, in consultation with the Chairman of the NRC and Agreement State officials, increase outreach efforts to promote awareness of and participation in NNSA's security upgrade program. Special attention should be given to medical facilities in urban areas or in close proximity to urban areas that contain medical equipment with high-risk radiological sources.

NRC Response:

The NRC will continue to support the NNSA's outreach activities to promote licensee awareness of and participation in the NNSA's security upgrade program within the limits of our authorities and available resources. The NRC specifically discussed NNSA's activities with the Agreement States and NNSA at the Organization of Agreement States Annual meeting in August 2012.

GAO Recommendation 2:

The GAO recommends that the Chairman of the NRC strengthen NRC security requirements by providing hospitals and medical facilities with specific measures they must take to develop and sustain a more effective security program, including specific direction on the use of cameras, alarms, and other relevant physical security measures.

NRC Response

While the NRC acknowledges that GAO favors more prescriptive security regulation, the NRC does not agree that the NRC's security requirements for risk-significant radioactive material need to be strengthened, nor with GAO's conclusion regarding the need for prescriptive security controls. The NRC's existing performance-based security program for licensees who possess risk-significant radioactive materials, including those at medical facilities, is effective and provides adequate protection. 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 establishes measurable performance standards, and provides appropriate flexibility to the regulated party as to the means of achieving the mandated outcomes. The NRC and the Agreement States verify licensee performance during the inspection process. Because of the wide variety of nearly 3,000 licensed facilities affected by these security requirements, prescribing specific security measures without regard to the type of facility and licensee operations may impose excessive and unnecessary requirements and burdens on licensees. In other cases, a prescriptive approach may result in a level of protection that is too low. A "one-size-fits-all" prescriptive approach is neither practical nor desirable from a safety perspective. Two of the security concerns mentioned in the GAO report are compliance issues that are effectively addressed through established NRC and Agreement State inspection and enforcement processes.

The GAO report notes concerns that some of the licensee personnel with security responsibilities lack expertise in physical security, which may result in inconsistent application of security controls to their programs. In response to the recommendation, the NRC plans to develop and provide additional written guidance to instruct licensees on best practices, including specific guidance on the effective application of cameras, alarms, and other relevant physical security measures to consider in the implementation of their security programs. This "best practices" guidance document will be in addition to the implementing guidance document

already developed to accompany the new final rule, -10 CFR Part 37, "Physical Protection of Byproduct Material."

GAO Recommendation 3

The GAO recommends that the Chairman of the NRC ensure that NRC and Agreement State inspectors receive more comprehensive training to improve their security awareness and ability to conduct related security inspections.

NRC Response:

The current training program provides effective instruction 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, periodic refresher training, and other requirements, prepares NRC and Agreement State inspectors to complete their required duties. As part of the implementation of the final rule, 10 CFR Part 37, "Physical Protection of Byproduct Material." NRC plans to review and revise the inspector qualification program for radioactive materials security inspections. Under the implementation plan, NRC and Agreement State inspectors with responsibility for this type of inspection will receive the updated training. The rule package including implementing guidance is currently with the Office of Management and Budget for Paperwork Reduction Act review.

GAO Recommendation 4

The GAO recommends that the Chairman of the NRC supplement existing guidance for facility officials, including Radiation Safety Officers, who may be responsible for implementing the NRC's security controls, in how to adequately secure equipment containing high-risk radiological sources and conduct trustworthiness and reliability determinations.

NRC Response:

As stated in our response to the draft GAO report, the NRC must maintain independent, objective oversight of licensees and may not operate in a consultative role. However, the NRC has and will continue to provide guidance to licensees on how to comply with regulatory requirements. As discussed earlier in the NRC response to Recommendation 2, the NRC plans to develop an additional guidance document with specific emphasis on security best practices and effective application of security technology that licensees may consider in developing their security programs.

- 6 -

The NRC appreciates the opportunity to provide its perspective on the GAO report and share its planned actions to address the recommendations. Should you have any questions, please contact me Ms. Rebecca L. Schmidt, Director of the Office of Congressional Affairs, at 301-415-1776.

Sincerely,

/RA/

Allison M. Macfarlane

cc: Senator Susan M. Collins

Identical letter sent to:

The Honorable Joseph I. Lieberman
Chairman, Committee on Homeland
Security and Governmental Affairs
United States Senate
Washington, DC 20510
cc: Senator Susan M. Collins

The Honorable Darrell Issa
Chairman, Committee on Oversight
and Government Reform
United States House of Representatives
Washington, DC 20515
cc: Representative Elijah Cummings

The Honorable Eugene L. Dodaro
Comptroller General of the United States
United States Government Accountability Office
441 G Street, NW
Washington, DC 20548