

March 10, 2017

Cindy Bladey
Office of Administration
Mail Stop: OWFN-12-H08
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

RE: Request for Comment: Category 3 Source Security and Accountability (NRC-2016-0276)

Dear Ms. Bladey:

The American Association of Physicists in Medicine (AAPM)¹ is pleased to submit comments to the U.S. Nuclear Regulatory Commission (NRC) regarding Category 3 source security and accountability. The AAPM commends the NRC on its work in addressing whether it is necessary to revise NRC regulations or processes governing Category 3 source protection and accountability. The AAPM further commends the NRC for its efforts to engage stakeholders on this issue.

The AAPM, however, believes the current system appropriately manages risk and balances benefits against burdens. Accordingly, the AAPM does not support the NRC's enumerated security and accountability enhancements now under consideration, including:

- Verification of Category 3 licenses through the License Verification System (LVS) or the regulatory authority;

¹ The American Association of Physicists in Medicine (AAPM) is the premier organization in medical physics, a broadly-based scientific and professional discipline encompassing physics principles and applications in biology and medicine whose mission is to advance the science, education and professional practice of medical physics. Medical physicists contribute to the effectiveness of radiological imaging procedures by assuring radiation safety and helping to develop improved imaging techniques (e.g., mammography, CT, MR, ultrasound). They contribute to development of therapeutic techniques (e.g., prostate implants, stereotactic radiosurgery), collaborate with radiation oncologists to design treatment plans, and monitor equipment and procedures to insure that cancer patients receive the prescribed dose of radiation to the correct location. Medical physicists are responsible for ensuring that imaging and treatment facilities meet the rules and regulations of the U.S. Nuclear Regulatory Commission (NRC) and various state regulatory agencies. AAPM represents over 8,500 medical physicists.

- Inclusion of Category 3 sources in the National Source Tracking System (NSTS);
- Expanding physical security requirements for Category 3 sources.

The AAPM has the following specific comments:

Maintaining Patient Access to Care

Tens of thousands of patients each day benefit from radiation medicine procedures. Category 3 sources include sources used for high dose rate brachytherapy (HDR) treatments for cancer. Many patients' lives depend on the availability of diverse radioisotopes for diagnosis and treatment. The AAPM is concerned that vendors, if confronted with additional regulatory oversight and administrative burden, will choose to discontinue supplying certain radioisotopes, diminishing patient access to care. Accordingly, the AAPM urges the NRC to consider and heavily weight the enormous benefits of radioisotopes to patients when the Agency is assessing safety and security risk of sources.

Safety Culture Pervasive in Medical Use of Radiation Sources

There is a tradition of safety culture in the control of medical radiation sources that has informed a long record of safe and secure use. Medical facilities are well versed in accounting, control, physical security and careful disposal of medical sources. Facilities periodically evaluate workflow, human factors, quality assurance, and provide training and education by qualified experts. Moreover, on-site inspections by state regulators and accrediting bodies further assure safety and security of medical sources.

The NRC and Agreement States already have the ability to identify licensees that possess Category 3 sources, and to monitor the location and movement of the sources through the licensing and inspection program. The AAPM believes the same end result of the proposed enhancements could be achieved by implementation of more rigorous pre-licensing review and dedicating adequate resources for inspection and enforcement to ensure licensee compliance with existing requirements (e.g., 10 C.F.R. § 30.41) without increasing the regulatory burden on the licensees.

The AAPM does not believe that including Category 3 sources in the enhancements under consideration would improve safety and security of those sources. Security and accountability policy should be both risk-informed and science-based.

Robustness of System Capacity

The AAPM is concerned about the robustness of the NRC's NSTS and LVS system and its capacity to handle the significant increase in transactions if Category 3 were added to the system. We question whether the Agency has, or will have, sufficient resources to meet this challenge.

At the January 31, 2017 public meeting at NRC headquarters, stakeholders learned that there are currently approximately 1,400 licensees for Category 1 and 2 sources, which control 75,000-80,000 sources. Including Category 3 sources would add approximately 5,500 licensees to the data system. The NRC would need to dedicate considerable resources to ensure that its system could adequately manage all Category 1, 2 and 3 source data.

We believe that if Category 3 sources are included in the NSTS, it has the potential to dilute the effectiveness of this tracking system for Category 1 and 2 sources due to the sheer volume of sources that would be added and the number of transactions that would be taking place each year.

The proposed enhancements indicate a gap exists where transaction information provides a level of protection that is not otherwise present. However, no vulnerability assessment has been performed to support this argument. No evidence has been provided that addition of Category 3 sources to the NSTS will generate a timely response to missing or unauthorized shipments.

If Category 3 sources are included in the Part 37 security requirements, it will most likely "lower the bar" and reduce the overall security for licensees that also possess Category 1 and 2 sources, due to the added burden and cost to implement these security requirements for a large number of sources.

The AAPM believes the increased burden of adding Category 3 sources to the system is not supported by the risks presented by Category 3 quantities of radioactive material.

Usability/End-User Usability

Usability is closely related to the robustness of the NRC's reporting system. The AAPM cautions against increasing reporting requirements for Category 3 sources and urges the NRC to assess the end-user usability of their data reporting system. Currently, credentialing to get direct access to either NSTS or LVS is cumbersome, and can take almost one month. At the NRC's Public Meeting in January, NRC staff advised that about 30-40 percent of licensees engage in electronic versus manual reporting. Licensees, who do not report electronically, complete Form 748, and either fax or email it to the Agency. The present delay for entering data that is provided to the NRC by fax and email is up to 24 hours, but that delay would certainly increase under the burden of Category 3 sources. The NRC's system appears to be still developing and moving toward an all-electronic platform.

If Category 3 sources are included, the number of covered transactions of some stakeholders would increase dramatically. One stakeholder, at the public meeting in January, stated if Category 3 is included in source tracking, his radioisotope company would double its administrative burden based on transactions per day. Moreover, implementation of Category 3 security and accountability enhancements now under consideration by the NRC would likely force some licensees into using the NRC reporting system for the first time. This initial credentialing and adoption curve could be resource-laden and daunting given the current challenges presented by the reporting infrastructure. Any NRC rulemaking would require analysis of cost and benefit. The AAPM questions whether there would be any benefit to gain from increasing reporting requirements for Category 3 sources.

Maintain Caution Regarding Cybersecurity Vulnerability

The AAPM is concerned about the NRC enlarging its interlocking system of NSTS and LVS to incorporate Category 3 source data because of the potential increase in cybersecurity vulnerability. Including Category 3 sources in the system essentially would place "all eggs in one basket" for malicious actors, who can operate from anywhere in the world, to exploit vulnerabilities to steal information and pose new risks. The AAPM would urge the NRC to consider this cybersecurity risk in further aggrandizing and developing its NSTS and LVS system.

In summary, the AAPM does not support the security and accountability enhancements now under consideration by the NRC, including verification of

Category 3 licenses, inclusion of Category 3 sources in the NSTS, or expanding physical security requirements for Category 3 quantities of radioactive material. The AAPM believes that current NRC regulations governing use of sources are appropriate and sufficient to ensure public safety and security. Accordingly, the AAPM urges the NRC not to pursue any additional rulemaking on licensing, security or tracking requirements.

Thank you for the opportunity to comment. If you have any questions or require additional information, please contact Richard J. Martin, JD, Government Relations Specialist, at 571-298-1227 or Richard@aapm.org

Sincerely,

A handwritten signature in black ink that reads "Melissa C. Martin". The signature is written in a cursive style with a large, prominent "M" at the beginning.

Melissa Carol Martin, MS, FAAPM, FACMP
President, AAPM