March 9, 2017

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

Subject: (NRC-2016-0276, 82 FR 2399) Category 3 Source Security and Accountability; Comments of the American College of Radiology

The American College of Radiology (ACR)—a professional organization representing more than 36,000 radiologists, radiation oncologists, interventional radiologists, nuclear medicine physicians, and medical physicists—appreciates the opportunity to comment on the U.S. Nuclear Regulatory Commission's notice of evaluation of Category 3 source protection and accountability, published in the *Federal Register* on January 9, 2017 (NRC-2016-0276, 82 FR 2399). The agency indicated that the scope of the evaluation is limited to Category 3 quantities of the materials listed in Appendix E of 10 CFR Part 20, as well as the materials subject to physical security requirements in 10 CFR Part 37. Therefore, a potential NRC expansion of source tracking, license verification, and physician security requirements would include Category 3 quantities of Iridium-192 sources used in High-Dose Rate (HDR) brachytherapy—the most common brachytherapy procedure.

General Comments

As a general comment, the ACR recommends that NRC use a risk-informed approach to evaluating any possible expansion of NRC's tracking, license verification, and increased physical security over Ir-192 HDR sources. In terms of tracking and verification, adding these sources would represent a substantial, and potentially overwhelming, increase in the volume of sealed sources handled by NRC's systems and staff. The agency would need to ensure adequate staffing and resources to support significantly expanded National Source Tracking System (NSTS), License Verification System (LVS), and Web Based Licensing (WBL) activities, including enhancing responsiveness for any newly impacted licensees. It took years to implement these programs for a relatively limited number of licensees with Category 1 and 2 quantities of the materials in question—there are potentially several thousand more Category 3 licensees. The NRC would also need to consider collaborations with Agreement States to ensure process compatibility and interoperability.

Additionally, the ACR has serious concerns related to patient privacy (e.g., via surveillance of sources), practicality, and cost of expanding 10 CFR Part 37 physical security requirements to Ir-

192 HDR sources in medical facilities. We urge NRC to consider risk together with other factors—including the public health benefit of patient access to HDR brachytherapy services, the unique nature of the clinical environment, and the difficulties experienced by medical licensees currently subject to Part 37 (e.g., Cesium-137 irradiators)—when determining the added value of expanding Part 37 to include Category 3 quantities of medically used isotopes such as Ir-192.

Responses to Specific NRC Questions of Interest

General Questions Related to License Verification

3. If the NRC changed the regulations to limit license verification only through the LVS or the transferee's license issuing authority for transfers of Category 3 quantities of radioactive material, should licensees transferring Category 3 quantities to manufacturers and distributors be excepted from the limitation?

Yes, medical licensees transferring Ir-192 HDR sources back to the manufacturer should be exempted. Typically, an ongoing, bilateral relationship would exist between a medical licensee and a manufacturer such that perpetual or even occasional license verification using these systems to return HDR sources to the manufacturer would be of unsubstantiated security benefit despite the administrative burden. Consider that these transfer verification methods are reportedly regarded as burdensome even for single source transfers at no more than a quarterly frequency between the same one or two manufacturers. Moreover, the credentialing process for medical physicists/licensee workers needing access to the LVS on behalf of licensees takes approximately one month (per NRC estimates) and is non-transferrable to the other licensees the medical physicists/workers may serve.

General Questions Related to the NSTS

1. Should Category 3 sources be included in the NSTS? Please provide a rationale for your answer.

No, we believe there is insufficient evidence from NRC regarding current risk or security benefit that would outweigh the concerns of adding Category 3 quantities of Ir-192 to the NSTS at this time. HDR sources are transferred more frequently than Category 1 and 2 quantities of the materials tracked in the current version of the NSTS program, and there are significantly more of these sources. Thus, if NRC were to expand NSTS this exponentially, the agency must be cautious to ensure the NSTS program (system, processes, support, and staff) is not overwhelmed, and that licensees are not subject to administrative burden in the absence of quantifiable benefits to support any such expansion.

The ACR is also concerned that medical use license fees would need to increase even more vigorously that they have in recent years to fund the infrastructure, staffing, and other resources that support the NSTS and related activities, despite the indeterminate return on investment in terms of safety and security. Such costs would inevitable be passed on to patients and drive up the cost of healthcare.

Other Questions

1. Should physical security requirements for Category 1 and 2 quantities of radioactive material be expanded to include Category 3 quantities?
The ACR believes that any decision to expand NRC's physical security requirements to Ir-192 HDR sources should be risk-informed and considerate of the preexisting physical security/cybersecurity realities of the healthcare setting. The NRC should account for the public benefit of HDR brachytherapy access, and consider how prohibitively expensive and misaligned security controls could ultimately discourage healthcare facilities from providing these services to patients.

Moreover, patients of HDR brachytherapy procedures could be directly impacted by certain physical security requirements in 10 CFR Part 37. Current NRC licensees subject to Part 37 are required to provide continuous/direct monitoring of the source with live and recorded video surveillance by qualified personnel. For some licensees this is done in collaboration with local law enforcement agencies. Surveillance systems and continuous/direct video monitoring of the sources during their use in patient care would introduce additional technological risks and cybersecurity/privacy concerns, potentially bringing NRC rules in conflict with other federal rules and protections (HIPAA, etc.) and certainly deterring healthcare facilities already beleaguered with persistent information technology threats, such as ransomware, attempted data breaches, etc. We encourage NRC to communicate with the U.S. Department of Health and Human Services (HHS) Office of Civil Rights (OCR) to better understand the rapidly increasing frequency and scope of cybersecurity attacks on healthcare providers specifically over the past few years, and the added risk introduced by continuous/direct video surveillance monitoring/recording of patient care in progress.

Thank you in advance for your consideration of these comments. As always, the American College of Radiology welcomes the opportunity for continued dialogue with the NRC on all medical use issues. Should you have any questions on the points addressed herein, or if we can otherwise be of assistance, please do not hesitate to contact Gloria Romanelli, ACR Senior Director of Government Relations, at 703-716-7550, or Michael Peters, ACR Director of Legislative and Regulatory Affairs, at 703-716-7546.

Sincerely,

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Chair, Board of Chancellors
American College of Radiology