HEALTH PHYSICS SOCIETY

Specialists in Radiation Safety

March 9, 2017

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

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Subject: NRC Request for Information related to Category 3 source protection and accountability

The Health Physics Society[1] (HPS) is a professional organization whose mission is to promote excellence in the science and practice of radiation safety. The HPS appreciates the opportunity to provide comments in response to the information request published January 9, 2017 relating to Category 3 source protection and accountability.

The HPS is responding with comments in the attached document. Attached you will find specific comments to the information requested in the Federal Register notice.

The HPS appreciates this opportunity to provide input into the regulatory process. If you have any questions regarding these comments, please feel free to contact the HPS Agency Liaison, Craig Little, at 970-260-2810 or by email at agencyliaison@hps.org.

Sincerely,

Eric W. Abelquist

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[1] The Health Physics Society is a non-profit scientific professional organization whose mission is to promote the practice of radiation safety. Since its formation in 1956, the Society has grown to include over 4,000 scientists, physicians, engineers, lawyers, and other professionals representing academia, industry, government, national laboratories, the department of defense, and other organizations. Society activities include encouraging research in radiation science, developing standards, and disseminating radiation safety information. Society members are involved in understanding, evaluating, and controlling the potential risks from radiation relative to the benefits. Official position statements are prepared and adopted in accordance with standard policies and procedures of the Society.

Background

The Nuclear Regulatory Commission (NRC) published in the Federal Register (Vol. 82, No. 5, 1/9/2017, NRC-2016-0276) a request for input from licensees, Agreement States and the public regarding potential revisions to regulations or processes requiring Category 3 source protection and accountability. In response to a Government Accountability Office (GAO) investigation and report, "Nuclear Security: NRC Has Enhanced the Controls of Dangerous Radioactive Materials, but Vulnerabilities Remain" (GAO-16-330), the NRC staff was directed to evaluate Category 3 source security issues. Category 1 and Category 2 radioactive sources are subject to increased security requirements in 10 CFR 37. The current regulations do not define Category 3 sources, but the NRC has considered Category 3 to be less than the Category 2 threshold but more than one tenth of it.

Summary Position

There would be little improvement in safety and security by including Category 3 sources in the security requirements of 10 CFR 37. There would however, be increased administrative and operational costs that would not improve safety while adding additional complications related to the management of such sources.

General Questions Related to License Verification

1. **Should the current methods for verification of licenses prior to transferring Category 3 quantities of radioactive material listed in 10 CFR 30.41(d)(1)-(5), 10 CFR 40.51(d)(1)-(5), and 10 CFR 70.42(d)(1)-(5) be changed such that only the methods prescribed in 10 CFR 37.71 are allowed?**
   No, the current regulations are sufficient. The vast majority of such sources are transferred from the manufacturer to and from licensees where the source is used and subsequently returned to the manufacturer. These transactions are between organizations with an established business relation for understood purposes.

2. **Would there be an increase in safety and/or security if the regulations were changed to only allow license verification through the NRC's License Verification System (LVS) or the transferee's license issuing authority for transfers of Category 3 quantities of radioactive material? If so, how much of an increase would there be?**
   For routine transactions replacing radioactive sources, such as those in medicine, such transfers are between licensees with an extended relationship. Such a change would increase the cost of source replacements and transfers with a limited or non-existent increase in safety and/or security.

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?
Licensees returning sources to manufacturers and distributors should be exempt from the requirement to verify licenses through the LVS or license issuing authority. Sources are usually returned as part of a source replacement transaction. A requirement for LVS verification would add unnecessary work and delay with no improvement in safety or security.

4. **Is there anything else we should consider when evaluating different methods of license verification prior to transferring Category 3 quantities of radioactive material?**
Any change to the regulations governing Category 3 sources should provide consideration to source replacement program for known licensees with established relationships. The same end result as the proposed rule 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 licensees.

General Questions Related to the NSTS

1. **Should Category 3 sources be included in the NSTS? Please provide a rationale for your answer.**
Category 3 sources should not be added to the NSTS. Such an addition will vastly increase the number of sources in the NSTS and the number of transactions with minimal safety and security improvements. Medical facilities and radiography companies use High Dose Rate Brachytherapy (^{192}Ir) (HDR) that are exchanged approximately four times a year throughout the year. These facilities and vendors already work together to ensure source delivery and receipt. If a shipment is not received, as expected, regulators are already promptly notified.

2. **If Category 3 sources are included in the NSTS, should the NRC consider imposing the same reporting requirements currently required for Category 1 and 2 sources (10 CFR 20.2207(f))?**
If Category 3 sources were to be included in NSTS, inventory verification would be required. However, since many of these sources are short-lived replacement sources, it would require routine changes to the inventory and identification numbers for the sources leading to an increase administrative burden to NSTS and licensee staff with little or no safety and security benefit.

3. **Should the NRC consider alternatives to the current NSTS reporting requirements for Category 1 and 2 sources to increase the immediacy of information availability, such as requiring the source transfers to be reported prior to, or on the same day as, the source shipment date?**
A requirement for 'immediate' reporting for routine exchange of Category 3 sources would create an extensive administrative burden on manufactures, licensees and NSTS staff with little or no safety and security benefit. Since many of these sources are preplanned exchanges, NRC should consider prior reporting of the shipments to the licensee and the return to the manufacturer/vendor in one reporting transaction.

4. **Would there be an increase in safety and/or security if the regulations were changed to include Category 3 sources in the NSTS? If so, how much of an increase would there be?**
   Any increase in safety and/or security would be minimal if it exists at all. The proposed rule indicates 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 National Source Tracking System will generate a timely response to missing or unauthorized shipments.

5. **Is there anything else we should consider as part of our evaluation of including Category 3 sources in the NSTS?**
   Inclusion of Category 3 sources in NSTS should be based on a comprehensive risk analysis that takes into consideration existing licensing control and an extensive history of the control of such sources. Inclusion should be based on a net increase in safety and security with system design considerations given to the additional recordkeeping transactions. If Category 3 sources are included in the National Source Tracking System, 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 and the number of transactions.

Specific Questions for Licensees Related to License Verification

1. **It currently takes approximately one month to get credentialed to access the LVS. If you currently do not have online access to LVS, and NRC establishes new requirements for license verification involving Category 3 quantities of radioactive material, would you be inclined to sign up for online access, or would you use alternative methods for license verification such as emailing the NRC Form 748 "Manual License Verification Report" to the LVS Help Desk or calling the license-issuing regulatory authority directly?**
   Many licensees would have limited need to sign-up for the LVS as most transactions are return of sources to a manufacturer. For the infrequent use, many licensees would likely prefer an option of email a verification request. For those more technologically capable, online access should be easy to request and simple to use when necessary.

2. **Approximately how many transfers involving Category 3 quantities of radioactive material do you do monthly? What percentage involves transfers directly to/from a manufacturer?**
   Medical licensees with HDR sources and radiography companies could expect to exchange four sources per year that are received from and returned to the sealed source manufacturer.

3. **Should license verification be required when transferring to an established manufacturer?**
   No, that will add work and delay with no benefit. If the manufacturer shipped a new source to a licensee with a source return packet, it is reasonable to assume the manufacturer is still licensed to receive the old source. Rechecking their license with every shipment would cause

unnecessary delays in returning old sources that would result in increased staff doses due to the continued presence of the old source.

4. **Do you have online access to LVS? If so, have you experienced any issues with the LVS? Do you have any recommendations on how to improve LVS?**

Specific Questions for Licensees Related to the NSTS

2. **Do you have online access to the NSTS? If so, have you experienced any issues with the NSTS? Do you have any recommendations on how to improve the NSTS?**
   Annual reconciliation of sources on the NSTS is easy to perform and efficient. However, transferring and receiving sources on the NSTS can be confusing from the multiple options for the same process, especially for transactions involving licensees out of the United States. With that said, the NSTS Help Desk has always been very helpful in guiding licensees through the process.

Other Questions

1. **Should physical security requirements for Category 1 and 2 quantities of radioactive material be expanded to include Category 3 quantities?**
   The physical security requirements for High Dose Rate Brachytherapy could complicate patient care with questionable safety and security benefit. HDR patient therapy is already very stressful for the patient as this treatment places high dose rate sources in contact with the patient. Existing Category 1 and 2 security requirements are inconsistent with the medical and operational needs of radiation therapy.

2. **Some Category 3 sources are covered under a general license (10 CFR 31.5). Should the NRC consider establishing maximum quantities in general licensed devices, thereby reserving authorization to possess Category 1, 2, and 3 quantities of radioactive material to specific licensees?**
   It would be reasonable for category 1, 2 and 3 quantities of radioactive materials to require a specific license.