DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

www.nih.gov

March 10, 2017

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

Dear Ms. Bladey:

This is a submittal of comments following the NRC public request for comment on Category 3 Source Security and Accountability proposal (Docket ID: NRC-2016-0276). Specific questions posed by the NRC have been addressed below:

Specific to license verification

1. 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?

   No; it would add an administrative burden to licensees following the requirements in the existing 10 CFR 30.41(c) which already requires licensees to "verify that the transferee's license authorizes the receipt of the type, form, and quantity of byproduct material to be transferred." By restricting the pathway to perform that verification, the transfer process will be less efficient. Furthermore, there is concern that by adding Category 3 sources to the LVS it would increase the risk of malicious access to critical licensee information, since more licensees would require access and be able to see this data. Thus, overall this proposal would cause a <u>decrease</u> in safety and/or security.

2. 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, they should be excepted especially for medical institutions transferring brachytherapy sources such as Ir-192 during routine source changes. This transfer process is performed on a frequent (typically quarterly) basis, with close involvement by the manufacturer and distributor of the new source; since they are providing a new source at the same time, it is nonsensical to require licensees to verify through the LVS that the company is authorized to receive the old source back.

General Questions Related to the NSTS

1. 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?

   The safety/security of Radioactive Material in Quantities of Concern (RAMQC) is inversely proportional to the amount of data available and how secure that data is kept. Although the NSTS database is a credentialed-access site, there is still the risk of data loss as in any electronically based file. Thus there would be a decrease in safety/security overall. Similar to the response to the first question, there would also be a significant decrease in the efficiency of radioactive material transfers, due to this additional burden of recordkeeping. Furthermore, Category 3 sources are notoriously mobile sources, and maintaining a constant physical inventory database may prove to be unmanageable.

Specific Questions for Licensees Related to License Verification

1. Would you be inclined to sign up for online access, or would you use alternative methods for license verification?

   The NIH already has online access capabilities for the LVS (and the NSTS) so this question is a moot point for us. However, additional individuals at the NIH will be required to have access, which increases the burden for NRC tracking as well as increases the burden of procedural requirements for NIH staff to follow. There is an annual security training requirement, for example, that must be met and tracked.

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?

   The proposed change primarily affects the clinical oncology program at the NIH, due to our use of a High Dose Rate (HDR) brachytherapy source of Ir-192. We currently perform one transfer every quarter (3 months) for a total of four transfers per year. The number of transfers that occur are exclusively to/from original equipment manufacturers (OEM).

3. Should license verification be required when transferring to an established manufacturer?

   The NIH does not believe that license verification is required in these cases. The new HDR source is delivered and installed by the OEM and the old source is removed and returned to the factory by the OEM.

Specific Questions for Licensees Related to the NSTS

1. Would you be inclined to sign up for online access or would you use alternative methods for NSTS reporting?

The NIH already has online access capabilities for the NSTS (and the LVS) so this question is a moot point for us. However, additional individuals at the NIH will be required to have access, which increases the burden for NRC tracking as well as increases the burden of procedural requirements for NIH staff to follow. There is an annual security training requirement, for example, that must be met and tracked.

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 should absolutely not be imposed, as they would be excessively burdensome and not at all commensurate with the risk level of Category 3 sources. If the concern is aggregation of Category 3 sources so as to approach Category 2 quantities, the NRC can track those licensees that are accumulating large quantities of Category 3 licensed material. The NRC can also establish license criteria that inhibit the accumulation of excessive amounts of Category 3 material through proper licensing conditions.

   This specific proposal may also be contrary to other federal statutes and regulations. The NIH uses HDR units for clinical treatment of patients. If cameras and recording video are required, this may be a violation of HIPAA regulations that protect patient privacy.

   It is difficult to envision a workable implementation of physical security controls in an active clinical setting. There is constant movement in and out of patient treatment areas, and immediate response to patient needs necessarily overrides any thought of source security. Furthermore, reactionary law enforcement response to a clinical area is always problematic, for patient, visitor, and staff well-being. Based on years of experience with implementing physical security requirements for Category 1 and 2 quantities of radioactive material, immediate police dispatch to the scene is nearly very always due to a nuisance alarm, and simply causes unnecessary concern and criticism of protocols, which erodes public trust in law enforcement activities.

   Implementation of physical security controls would also necessitate a program of "trustworthy and reliability" of all individuals with the need to access the source. This would naturally add to the licensee workload to track, certify, document, renew, and annually train this population of clinical staff. This added workload would be burdensome and not lead to any increase in safety/security of the source; individuals involved in the use of an Ir-192 source for brachytherapy procedures are already held to a high ethical standard of conduct due to their direct patient interaction. Implementation of a formal T&R program for these personnel will not contribute to an increased level of safety/security but will instead be a regulatory burden on security staff and affected individuals.

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

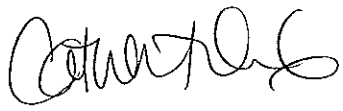
authorization to possess Category 1, 2, and 3 quantities of radioactive material to specific licensees?

It does seem prudent for the NRC to consider the continued authorization issue and setting maximum quantity limits, especially for Category 3 sources that may present a waste disposal problem to the public if not properly managed. However, it is not necessary to create massive regulatory hurdles that will adversely affect small companies whose only role with general licensed devices and quantities of radioactive material may be the storage of devices that contain unimportant quantities of radioactive material for proper device operation.

General comments:

The NIH uses cyclotrons to provide a number of radionuclides for medical research. One of the by-products of certain production lines is Co-60. The regulation specified in 10 CFR 20.1003 defines a nationally tracked source. However, this definition does not include activated material, which is present in and around all cyclotrons (in the form of Co-60 among other radionuclides). The Category 3 limit for Co-60 is 830 mCi; the Category 2 limit is 8.2 Ci. Will licensees be responsible for tracking this radionuclide under the proposed Category 3 changes if they become final? This will present real challenges both to licensees and the regulatory authority.

We hope the NRC finds these comments useful. If you have any questions or need additional clarification on our submittal, please contact me at 301-594-1303 or via e-mail at cribaudo@nih.gov.



Catherine Ribaudo, M.S.
Radiation Safety Officer

cc: Dr. Bradford Wood, Chair, RSC, NIH