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Category 3 Sources Security and Accountability Re-Evaluation.

General comments regarding the philosophy of this response.

The security and accountability of high level Category 1 and 2 sources are well established, per 10CFR37. Category 1 and 2 sources are used for specifically licensed and highly specialized applications. Category 3 sources are used in much wider areas of beneficial uses to the public, such as diagnostic and therapeutic medicine, non-destructive testing, and quality assurance for manufacturing processes and first responders' instrumentation for radiological emergencies. As there is wide-ranging use of these sources, correspondingly, there are many more of these sources in daily use. It is our view that the inclusion of all Category 3 sources under the full security and accountability requirements of 10CFR37 would add significant costs to health care, the inspection and maintenance of the nation's infrastructure (roads and bridges), to manufacturing processes, and to federal, state and local emergency response operations. As the on-going alternative technology research has not yet developed full replacement for the use of sealed sources, we anticipate that the cost of full compliance with existing Category 1 and 2 source regulations, would lead to 1) a loss of cancer treatment options, with an increase of patient mortality, 2) a decrease in infrastructure safety, with a corresponding increase of public mortality, 3) a higher cost of manufactured goods, and 4) a degradation of radiological emergency response capability, which would lead to a greater public mortality rate in the event of a radiological event. The smallest Category 3 source activity is a factor of 10 lower than the smallest Category 2 activity. The concern seems to be that an aggregated amount of Category 3 activity sources has the potential be obtained to meet a Category 2 threshold. This could be a range of 2 of the higher activity Category 3 sources to 10 of the lowest activity Category 3 sources. Therefore, we believe that a Graded Approach to the security and accountability to Category 3 sources should be considered for the preservation of public health and safety. Additionally, there seems to be a question if the Categories pertain to only sealed sources or to any form of radioactive material, which should also be addressed.

# General Questions Related to License Verification.

1. No, we believe that current methods of license verification for Category 3 sources should not be changed to only meet the reporting methods of 10CFR 37.31. A graded approach to this activity should be explored, as described in our comments on the philosophy of this response.

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- 2. We believe that there would be an increase of the source safety and security if Category 3 sources were capable of being checked in some form but not in the NRC License Verification System (LVS) or the licensees transferring authority, as LVS currently exists. Currently LVS queries the National Source Tracking System (NSTS), for source information. NSTS contains information on sources only and not all forms of radioactive materials. As part of the Graded Approach, perhaps LVS in its current format can be used for Category 1 and 2 source transactions. Perhaps a second license system that contains all radioactive materials licenses (without the NSTS query) so that verification for Category 3 and two sources and other forms of radioactive materials could be performed, would be a security asset. Alternately, requiring a regulatory concurrence of license validity would also be a security asset.
- 3. License verification through LVS or transferee's license issuing authority, or any license verification system for Category 3 sources, for manufacturers or distributors should be carefully considered, and a Graded Approach might be considered. For example, if a hospital is under contract for periodic replacement of radioactive materials with the manufacturer, perhaps an annual verification of the manufacturer's license can be considered. Distributors of radioactive material may or may not have the same possession limits and security requirements in place as a manufacturer and licenses should be confirmed. As transfers can be performed between licensees, including service providers, or facilitated by service providers, license verification should be required.
- 4. An addition verification of the material to be transferred, per USNRC's RIS 2014-08, Use of Aftermarket Sources, should be performed to ensure that the materials are being legally transferred to the licensee.

# General Questions Related to the NSTS.

- No, not all Category 3 sources should be added to the NSTS. It is our belief that a Graded Approach should be considered. Perhaps there could be a factor of 5 activity trigger of a factor of 5 (instead of 10) for inclusion in NSTS. Alternately, instead of adding Category 3 sources to the existing NSTS, perhaps a mirror NSTS for lower activity source tracking could be explored. A mirror system would not degrade the security and reporting requirements of 10CFR37 for Category 1 and 2 sources, and a Graded Approach for Category 3 sources security might be easier to implement.
- 2. No, the NRC should not consider the same NSTS reporting requirements for Category 3 sources, as for Category 1 and 2 sources, as we believe a Graded Approach would best serve public health and safety, while enhancing the security of Category 3 sources.
- 3. As NSTS is not a real time system, inclusion of Category 3 sources would not increase the immediacy of inclusion of these sources on the system. That being said, we believe that reporting transfers of Category 3 sources should be considered for accountability purposes.

- 4. Yes there would be an increase of safety and security of Category 3 sources for including Category 3 sources in NSTS; however a cost benefit analysis should be performed. If our general philosophy comments are taken into consideration, would public health and safety be degraded and to what extent?
- 5. With the increase of the number of sources entered into NSTS, there is the very real possibility of the increase of having duplicate source serial numbers. Prior to NSTS, manufacturers did not seem to be creative in serial numbering systems and we have found identical serial number systems used between manufacturers.

### Specific Questions for Licensees Related to License Verification.

- 1. We are already registered for access to LVS. Many of our clients are not and would most likely use alternative methods of reporting, just as they do for NSTS.
- 2. How many sources transferred is proprietary information.
- 3. Unknown, no guidelines are established as the definition of an "established" manufacturer.
- 4. Yes, we have online access to LVS. Many license inquiries are redirected to the issuing agency.

### Specific Questions for Licensees Related to NSTS.

- 1. We are already registered for access to NSTS. Many of our clients are using the alternative methods of reporting.
- 2. Any NSTS issues are resolved by the help desk. They are extremely helpful when something occurs, usually a reset of Internet Explorer.

### Specific Questions for Agreement States.

We are not an Agreement State, so cannot answer these questions.

### Other Questions.

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1. We believe that a Graded Approach should be taken for physical security of Category 3 sources, with a specific approach to the aggregate quantity of Category 3 sources. Perhaps there could be a factor of 5 activity trigger (instead of 10), depending on what information the NRC receives from hospitals, first responders and other entities that use different quantities of these materials. It would be much harder to accumulate 5 sources instead of duplicating and order for 2 sources.

2. Yes, if the increase of security for Category 3 sources is determined to be beneficial and not degrading to public health and safety; then a revision of general licenses should be considered. We believe that all Category 1 and 2 sources should require a specific license and be subject to security requirements. For Category 3 sources, we believe that the cost benefit analysis should be performed, and that the benefits of the use of the material be included, not just the activity.

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