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To protect, promote & improve the health  
of all people in Florida through integrated  
state, county & community efforts.



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Governor

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Vision: To be the Healthiest State in the Nation

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March 10, 2017

Irene Wu  
Office of Nuclear Material Safety and Safeguards  
U.S. Nuclear Regulatory Commission  
Washington, D.C. 20555-0001  
(Sent only via Email [Irene.Wu@nrc.gov](mailto:Irene.Wu@nrc.gov))

Re: Docket ID NRC-2016-0276, Category 3 Source Security and Accountability

Dear Ms. Wu:

Please accept the following comments in response to NRC's Federal Register Docket ID NRC-2016-0276, Category 3 Source Security and Accountability.

#### **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?**

We believe that the current methods are sufficient for transferring radioactive materials. From the background information the failure that GAO discovered was one individual failing to follow procedures and not a systemic wide failure.

- 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?**

We do not believe that there would be an increase in safety or security requiring licensees to use LVS for transferring quantities of Category 3 materials. Especially quantities aggregated up to category 3 quantities. This requirement would easily be defeated by performing multiple transfers of quantities under category 3 quantities.

- 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?**

We believe that transfers to known licensed manufacturers, distributors, waste processors, and commercial disposal sites should be exempted. These entities are well known and highly regulated.

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**4. Is there anything else we should consider when evaluating different methods of license verification prior to transferring Category 3 quantities of radioactive material?**

If NRC is to track transfers of quantities of category 3 radioactive materials, it should be limited only to individual sources that are at the high end of category 3. This would only include individual sources that larger than 50% of category 2 activity (including any generally licensed sources). It would not include any aggregation of radioactive materials.

**General Questions Related to the NSTS**

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

We do not support the inclusion of category 3 source in the NSTS. The current system of accountability of category 3 sources is adequate to protect public health and safety. There is no systemic failure of the current process only a localized failure of an individual not following procedures. Localized failures will occur regardless of the system in place. Inclusion of these sources in NSTS would be a tremendous cost burden to licensees and Agreement States. NRC has not demonstrated that inclusions of category 3 sources would improve health and safety.

**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))?**

No.

**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?**

No.

**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?**

No.

**Specific Question for Agreement States Related to the NSTS**

**1. The NRC currently administers the annual inventory reconciliation process on behalf of the Agreement States. This process involves providing hard copy inventories to every licensee that possesses nationally tracked sources at the end of the year, processing corrections to inventories, and processing confirmations of completion of the reconciliation into the NSTS. The process involves a significant amount of staff time and resources from November to February. If the Agreement States were to adopt administration of the annual inventory reconciliation process and if Category 3 sources were included in the NSTS, what would the additional regulatory burden be on the Agreement States to perform the annual inventory reconciliation for Category 1, 2, and 3 sources?**

It would be a tremendous burden on the Agreement States.

The regulations require licensees to report the annual reconciliation to NSTS. This is a "National" tracking system and the Agreement States do not have access to all the data nor should they. It would require a rule change to require licensees to submit the reconciliation report to both NSTS and their agreement state for the state to have the authority to reconcile something not required to be reported to them. Even with this rule change each Agreement State would be allowed to complete this reconciliation anyway they choose. The decision would be based on resources available and would vary between the 37 Agreement states. This would be a regulatory and cost burden to the Agreement State and licensees, especially licensees who have licenses in multiple Agreement States and NRC.

### **Specific Question for Agreement States Related to the License Verification**

**1 Approximately how many licenses do you authorize for Category 1, 2, and 3 quantities of radioactive material?**

NRC has the number of category 1 and 2 licenses in NSTS.

We estimate that we have 330 licenses that are authorized to possess category 1, 2, and 3 quantities of radioactive materials. Of this group it includes ~90 HDR licenses, ~15 fixed gauge licensees. This number also includes ~130 medical use licensees and 26 nuclear pharmacies authorized to possess 1 curie of radioactive materials authorized for 10 CFR 35.400 uses. These medical licenses are included since FDA authorizes the use of Co-60 for interstitial and intracavitary treatment of cancer and the category 3 quantity for Co-60 is 810 millicuries.

**2. If license verification through the LVS or the transferee's license issuing authority is required for transfers involving Category 3 quantities of radioactive material, would you encourage the use of LVS among your licensees, or plan for the additional burden imposed by the manual license verification process?**

We would encourage the use of LVS.

**3. If license verification through the LVS or the transferee's license issuing authority is required for transfers involving Category 3 quantities of radioactive material, would you consider adopting the Web-Based Licensing System (WBL) to ensure that the most up-to-date licenses are available for license verification using the LVS or voluntarily provide your Category 3 licenses (similar to what some Agreement States do now for Category 1 and 2 licenses) to be included in WBL, or would you do neither and prefer licensees to use the manual license verification process?**

See below

**4. What would the impact in time and resources be on your program to handle the additional regulatory oversight needed for Category 3 licensees if license verification through the LVS or the transferee's license issuing authority was required for transfers involving Category 3 quantities of radioactive material?**

We would provide NRC copies of the license. We would not adopt WBL because it does not fit our business processes in licensing, inspection, billing, etc.

This would increase the number of licenses to determine whether to send them to NRC five-fold and would be large resource burden. We would look at the most cost efficient method to assure we don't miss one. (For example, last year we completed 1,998 licensing actions.) We may decide to send NRC all of our completed licensing actions and NRC can determine if they meet the criteria to be entered into WBL.

**Other Questions.**

- 1. Should physical security requirements for Category 1 and 2 quantities of radioactive material be expanded to include Category 3 quantities?**

No.

From the background information the failure that GAO discovered was one individual failing to follow procedures and not a systemic wide failure.

- 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?**

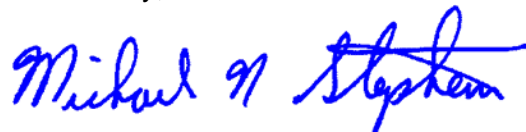
If NRC is to limit the quantities possess under a general license then it should be limited only to individual sources that are at the high end of category 3. This would only include individual sources that larger than 50% of category 2 activity. It would not include any aggregation of radioactive materials.

NRC should consider reevaluating the concept of a "General License" and determine if it is needed.

NRC should consider either requiring a specific license for radioactive materials or have the radioactive material exempt. The concept of a general license that allows untrained, unmonitored personnel to use and possess radioactive material based on the potential radiation dose received in a year has several flaws.

Please contact me if you have any questions or need further clarification. My phone number is (850) 245-4043 or you may reach me by e-mail at [Mike.Stephens@FLHealth.gov](mailto:Mike.Stephens@FLHealth.gov).

Sincerely,



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