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Category 3 Source Security and Accountability

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RULES AND PROCEDURES

General Comment

See attached file(s)

Attachments

JJM-2017-09_Comments to NRC-2016-0276

SUNSI Review Complete
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International Isotopes Inc.

March 7, 2017

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

**Subject: Comments to Federal Register Notice – January 9, 2017
Category 3 Source Security and Accountability
Docket ID: NRC-2016-0276**

Dear Ms. Bladey,

International Isotopes Inc. (INIS) appreciates the opportunity to provide comments to the January 9, 2017 Federal Register Notice (FRN) regarding Category 3 Source Security and Accountability. As you may be aware, INIS is a sealed source manufacturer licensed by the U.S. Nuclear Regulatory Commission (NRC). INIS manufactures a wide range of sealed sources ranging from low activity calibration and reference sources to high activity cobalt 60 sources utilized in medicine, industry and research. As a manufacturer of Category 1 and 2 sealed sources INIS is subjected to the US NRC Part 37 regulations and routinely uses the National Source Tracking System (NSTS) and License Verification System (LVS).

I reviewed the July 2016 Government Accountability Report (GAO-16-330), the staff requirements memorandum SRM-COMJMB-16-001, and other documents relevant to the topic and I participated in the January 31st Category 3 Source and Accountability Public Meeting. I understand the concern the GAO sting operation has generated and appreciate the NRC's efforts to address this concern but I don't believe expanding the scope of existing regulations to include Category 3 sources into the NSTS and LVS systems would have changed the outcome of the GAO operating. The GAO obtained the license because of the lack of due diligence during the pre-licensing phase of issuing a license. The LVS and NSTS systems and the Part 37 regulations had no role in pre-licensing activities.

I question the argument that expanding the LVS and NSTS requirements to Category 3 materials and sources would prevent a Category 3 licensee from obtaining a Category 2 quantity of materials by procuring materials from multiple suppliers. I suppose the theory is that the LVS and NSTS systems would signal to the appropriate regulator that a receiving licensee was collecting a Category 2 quantity of material when they were only licensed to possess up to a Category 3 quantity of material. As a user of both the NSTS and LVS systems I am not sure if this is a realistic assumption. When I use the LVS system to verify a license the system does not require that I input a quantity of material that is being requested. I review the license that is provided by the LVS and I verify that the quantity and form of the material being requested is authorized by the license.

Another point made in GAO-16-330 was that of counterfeited licenses; *“Further the NRC does not specifically require that the validity of category 3 licenses be verified by the seller with the NRC or the agreement states - creating the risk that licenses could be counterfeited...”*. I would agree that when the LVS is used prior to conducting a transfer the validity and accuracy of the license being verified is ensured and that it would be highly unlikely to transfer radioactive materials to a counterfeited license. This being said, would the effort needed to include all of the Category 3 licenses into the WBL be justified in order to address a theoretical deficiency? There is no data to suggest that the license verification methods for Category 3 and below quantities utilizing the current regulatory requirements (§§30.41, 40.51 and 70.42) do not adequately protect the public health and safety.

In general, INIS does not believe expanding the WBL, NSTS and LVS systems to include Category 3 quantities of radioactive materials is warranted and we strongly discourage expansion of NSTS to include Category 3 sources. We do believe that including licenses that authorize the possession of Category 3 quantities of radioactive material into the WBL system would ensure the accuracy and validity of these licenses prior to transferring radioactive materials but the resources needed to expand and maintain this capability would need to be justified against the perceived benefits.

Additional comments to the questions provided in the FRN are included in the attachment to this letter. Please contact me at 208.524.5300 or via email at jjmiller@intisoid.com if you have any questions or comments regarding this letter.

Sincerely,



John J. Miller, CHP
Radiation Safety & Regulatory Compliance Officer
JJM-2017-09

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 methods of verifying a recipient's license or authorization prior to transferring Category 3 quantities of radioactive materials provides a sufficient level of safety and security commensurate with the quantity of radioactive material involved. No changes to the regulator sections referenced above are warranted.

2. *Would there be an increase in safety and/or security if the regulations were changed to only allow license verification through the 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 there would be an increase in the level of safety and security if license verification was conducted through the LVS. We believe that the accuracy and validity of the licensee being verified would be assured but it is not clear if this would result in an increase in the level of safety or security that is currently provided by the current regulatory requirements.

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 exempted from the limitation?*

As proposed the exception is arbitrary and no basis is provided to support it. The intent to limit the regulatory burden on the users of Category 3 sources is understandable but a better exemption may be that license verification utilizing the LVS is not required when returning Category 3 quantities of material to the original supplier. In this scenario, the licensee returning the Category 3 quantity is confident that the receiving licensee is authorized to possess the material because the receiving licensee had originally supplied the material. It would also be important to stress that the license must still be verified in accordance with §§30.41, 40.51 and 70.42 as applicable.

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

We believe that the current methods of verifying a recipient's license prior to transferring Category 3 quantities of radioactive materials adequately protects the public health and safety. Verifying a license using the LVS system prior to transferring Category 3 quantities of radioactive materials would ensure the validity and accuracy of the license being verified and would thereby prevent the transfer of Category 3 quantities of

radioactive materials to a counterfeited license. The questions now become; (1) is this a legitimate concern? And (2) does this concern justify the resources required to expand and maintain the WBL and LVS systems? We believe the answer to these questions is no.

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 do not believe there would be any benefit to include Category 3 sources into the NSTS. Expanding NSTS to include Category 3 sources could overwhelm the system making it counterproductive. We acknowledge that Category 3 sources could result in physical harm if mishandled but we believe that the regulatory requirements that are currently in place adequately addresses the risks associated with this level of radioactivity. It is also important to note that most if not all Category 3 sources that are in use are registered in the sealed source and device registry and are specifically listed on the end user's license and are routinely inventoried and leak tested.

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))?*

The NSTS is a tracking system that is intended to follow high risk sources throughout their lifecycle from the time that they are manufactured until the time the sources are disposed of, destroyed or decayed below the reporting threshold. What point is there to include Category 3 sources into the NSTS if the current reporting requirements are not applied? Inclusion of Category 3 sources into the NSTS system becomes mute if the source is not tracked through the lifecycle, which is accomplished through reporting. The fact that this question is specifically being asked brings into question the rational to include Category 3 sources into the NSTS.

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. This question implies that the NSTS and LVS systems can be used in concert so that when the LVS system is utilized to verify a license prior to transferring Category 1 or 2 quantities of radioactive material, the LVS system would be capable of authorizing or denying the planned transfer by verifying the receiving licensee's current NSTS inventory against their possession limit. The NSTS system is a database that is intended to track high risk sources through their lifecycle and the LVS system is a database that allows the transferring licensee to verify a recipient's authorization to possess the Category 1 or 2 quantities of radioactive material that they have requested. We believe it is up to the recipient licensee to ensure that the quantity of radioactive material that they have requested is within their remaining possession authorizations.

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?*

We do not believe there would be any safety or security benefit if the regulations were changed to include Category 3 sources in the NSTS. In fact, there could be a decrease in safety and security if an end user decides it is easier to place disused Category 3 sources into long term storage instead of returning a disused Category 3 source to the manufacturer or supplier for end of life management options such as recycling or disposal.

5. *Is there anything else we should consider as part of our evaluation of including Category 3 sources in the NSTS?*

We believe the NSTS is fulfilling the US' obligation to the IAEA Code of Conduct through the establishment of a national register of radioactive sources, that at a minimum includes Category 1 and 2 sources. Going beyond this to include Category 3 sources would need to be justified with a risk assessment and cost benefit analysis. Without knowing specific details on the number of additional users that would be affected by such an expansion, we can only assume that the resources that would be necessary to expand and maintain the expansion of the WBL, NSTS and LVS systems would be significant and that these resources could be better utilized by the affected licensees and regulators.

Specific Questions 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 e-mailing the NRC Form 749 "Manual License Verification Report" to the LVS Help Desk or calling the license-issuing regulatory authority directly?*

We currently utilize the LVS system.

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?*

As a source manufacturer, we consider this proprietary information and would prefer to provide answers to this question in a follow-up phone conversation.

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

This question appears to be addressing Objective 1.a.ii. of the NRC/Agreement State Working Group License Verification and Transfer of Category 3 Sources (ML16197A474) Charter and it is not clear if the question is intended to include Category 1 and 2 source transfers as well. It seems that the intent of the question is to reduce the regulatory burden associated with the use of the LVS. If this is the case, then why not expand this to any established licensee?

Along these same lines the §37.71 (a) and (b) requirement to verify a license utilizing the LVS “prior to” the transfer is not clear. Does the term “prior to” mean within 24 hours, within 1 week, within 30 days? If these transfers are routine, occurring several times a month to the same licensee or if the transfer is for a bulk quantity of material with deliveries staggered over a period of time is license verification required “prior to” each of the transfers made to the licensee.

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?*

Yes, I have on-line access.

There are times when the “Contact Agency Alert” window appears and no explanation is given as to why the code appears, just that verification should be conducted through the regulating agency. If an incorrect amendment number was inserted or if the license number was typed incorrectly additional information could be provided to the user that would allow the person to correct the error and proceed with the verification.

Being able to access the system through a wireless network would be desirable.

Including the Sealed Source and Device Registries into the LVS would be an improvement, so that users of sources and devices could verify that they have the most up to date SS&DR for the source and/or device in their possession.

Specific Questions Related to NSTS

1. *It currently takes approximately one month to get credentialed to access the NSTS. If you currently do not have online access to the NSTS and NRC establishes new requirements for the tracking of Category 3 sources in the NSTS, would you be inclined to sign up for online access or would you use alternative methods for NSTS reporting such as e-mailing or faxing the NRC Form 748 “National Source Tracking Transaction Report” to the NSTS Help Desk?*

We currently utilize 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?*

Yes, I have on-line access.

Being able to make corrections to a source after it has been transferred is not possible, and correction have to be made through the help desk.

Having to shut down the browser after logging off in order to log back on is annoying.

Wireless access would be ideal.

The NRC should provide guidance on the intent of the NSTS system, which should be limited to the tracking of sealed sources that are intended for or have been commercially distributed. As it is now “radioactive material that is sealed in a capsule or closely bonded, in a solid form and which is not exempt from regulatory control” language found in the §20.1003 definition of a “nationally tracked source” encompasses radioactive materials that should not be included in the NSTS. For example, capsules of bulk material

that will be utilized for source manufacturing, radioisotope targets, inner source capsules or incomplete sealed sources that have not been released for distribution, and if the NSTS was to include category 3 "sources" individual 1 mm x 1mm Co-60 pellets would meet the §20.1003 definition of a nationally tracked source. The intent of NSTS was to track a Category 1 or 2 sealed source through its life cycle and was not intended to include all forms of radioactive materials contained in a capsule or closely bonded.

Specific Questions for Agreement States Related to License Verification

No comments to the questions in this section.

Other Questions

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

No. We believe that the existing safety regulations provide an adequate and appropriate level of security for Category 3 and below quantities of radioactive material.

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?*

We are not aware of how many such sources would be affected but it seems reasonable to establish maximum quantities of radioactive materials in generally licensed devices. Reserving the authorization to possess Category 1, 2 and 3 quantities of radioactive material to specific licensees would be warranted if data exists that indicates there are generally licensed devices containing these quantities of radioactive materials that pose a safety or security risk.