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Secretary,
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

Attn: Rulemaking and Adjudication Staff

Subject: Comments on the proposed rule relating to the Expansion of the National Source Tracking System
RIN 3150-A129 [NRC-2008-0200]

These comments are submitted on behalf of the Nuclear Sector Coordinating Council - Radioisotopes (NSCC-R). NSCC-R Membership includes a diverse range of interested stakeholders/licensees (source manufacturers, gamma plant owners, radiography companies, universities, medical, and gauge users)

The final rule establishing the National Source Tracking System (NSTS) reflected the IAEA Code of Conduct recommendations that are consistent with the NRC's responsibilities under the Atomic Energy Act, including the protection of the public health and safety. The implementation date for the NSTS has been extended to January 31st, 2009.

The principal purpose of the NSTS is to provide reasonable assurance of timely detection of either the theft or diversion of radioactive materials sufficient to constitute quantities which should be of concern regarding the construction of a radiological dispersion device. This is consistent with the Code of Conduct, which is to prevent unauthorized access or damage to, and loss, theft or unauthorized transfer of, radioactive sources

We believe that the implementation of the NSTS for Category 1 and 2 sources will be useful and effective at meeting the stated purpose; however expanding the NSTS to include Category 3 and 1/10th of Category 3 is significantly premature and unwarranted for the following reasons:

- o The NSTS has not been fully implemented or trialed for Category 1 and 2 sources.
- o There has not been an accurate assessment of the regulatory burden on the Regulatory Authorities or licensees with the proposed expansion
- o There has been no consideration of the impact on the requirements for General licensees.
- o Many NRC initiatives and actions already in place.
- o The proposed rule is inconsistent with the IAEA Code of Conduct
- o Inclusion of Category 3 and 1/10th Category 3 sources does not present the same relative risk as reasonably established for higher activity Category 1 and 2 sources.

Detailed comments for each of these reasons are provided in the attached document.

675 McDONNELL BOULEVARD
HAZLEWOOD, MO
63042

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Finally, as discussed during the April 30, 2008 public Commission meeting, "Briefing on Materials Licensing and Security," NRC has a vast range of ongoing and interrelated source security activities that have the potential for significant impact on NRC, the Agreement States and licensees nationwide. These activities include the NRC-Agreement State Materials Program Working Group, the Independent Review Panel final report, the Radiation Source Security and Protection Task Force, the Radiation Sources Subgroup, the Cesium Chloride Subgroup, the Alternate Technologies Subgroup, the National Academy Study on Source Use and Replacement, rulemakings and security orders, as well as other activities. Members of NSCC-R have participated in many of these activities along with the DHS initiatives to assure accurate information is provided so that the best decisions can be made

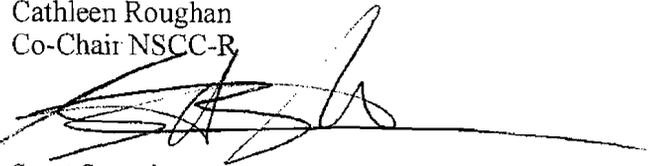
Industry strongly encourages NRC staff to ensure that all these activities are thoroughly coordinated, integrated and risk prioritized such that Federal, State and licensee resources are expended on the highest risk activities. To date, it is not clear that such a risk informed decision making process for source security has been conducted and results applied.

We believe at this time, with the combined efforts by both the regulatory authorities and licensees implementing the existing regulations, this is adequate to assure the safety and security of the identified high risk radioactive sources and there is no required need to expand the NSTS for Category 3 and below sources.

We appreciate the opportunity to provide these comments on the proposed rule and shall be happy to provide clarification or additional information if required.

Sincerely,

Cathleen Roughan
Co-Chair NSCC-R

A handwritten signature in black ink, appearing to read "Scott Surovi", written over a horizontal line.

Scott Surovi
Co-Chair, NSCC-R

Attachment

1) The NSTS not implemented for Category 1 and 2 sources

The implementation of the tracking system for category 1 and 2 sources has been significantly delayed from its original implementation date by NRC and to date no licensee has seen a working pilot of the system. From the industry perspective, it is not clear if the current required system is workable or effective. Prior to any consideration of whether to include Category 3 and below, the system has to be tested and proven with the Category 1 and 2 sources.

It is industry standard that any computer database of this size, complexity and number of different users with different software must be validated before full scale implementation through pilot programs and test cases. If this has been done, it has not been done with any industry involvement, who will be the primary users and the ones entering the data and using the system. Without performing any pilot program with the actual users, the initial data for Category 1 and 2 transactions will likely result in many discrepancies upon launch in Jan 2009. These would need to be resolved and assure the system is operational for the higher risk sources before any expansion should be considered for the lower activity sources. This will also give valuable information as to the actual time and impact on both the Regulatory agencies and the licensees, as this is currently unknown.

The NRC preamble to the rulemaking mentions credentialing users of the database for security reasons, but there is no information on how this will be done. It is not clear how many credentials will be given per licensee, many licensees have several facilities where sources are used and transferred so some licensees will need the ability to credential several employees. Again, this system needs to be trialed and proven effective with the smaller number of Category 1 and 2 licensees (1300) before rolling out to the larger quantity of Category 3 and 1/10 Category 3 licensees (3500).

2) Estimate of Regulatory Burden

We do not believe the estimate of burden to be accurate. The estimated burden on licensees is unfounded, as licensees (the users) have not seen a draft version of the database. Without knowledge of how the database works or how it is going to be integrated makes it impossible to assess how much time and effort needs to be expended to use the database for both the initial start up and ongoing day to day usage. An accurate assessment of the burden can only be made once the licensees have viewed the database and experienced how it works.

The estimate of number of transactions that will take place does not appear to be accurate. For a single source there may be as many as 3-5 transactions to be entered including, the manufacture, transfer to end user, end user receipt, end user return to manufacturer or disposal and final receipt. For sources going to a gauge manufacturer and subsequent installation into a gauge for an end user there will be potentially be 6-7 transactions for each source. An informal poll of one of the larger manufacturers demonstrates that the number of sources manufactured and put into the system on an annual basis may be as many as 4000 from one manufacturer. This results in the number of additional transactions ranging from 12,000-28,000; this increased number of transactions needs to be extrapolated across the entire industry to get the total number. This is

well in excess of what the NRC assumed. Although a good portion of this should be covered under a manufacturer's data download, it is a huge number of transactions that would need to be reviewed. With such a large number of entries into the system there is the potential for many discrepancies to occur which would have to be resolved, using both licensee and regulatory authority resources.

The CRCPD has stated that the regulatory burden on the Agreement States has been significant to date to get data for the Category 1 and 2 sources. It is unknown how much additional time may be needed to gather the information on Category 3 and 1/10 Category 3 as each state is very different and would have to handle the data differently.

Further, as stated in our 12 May 08 letter, we believe it is presumptuous and premature for the NRC to extrapolate potential cost burdens for the possible inclusion of Category 3 and 1/10th Category 3 sources when no such system is currently in place for the priority Category 1 and 2 sources (implementation date 31st January, 2009). Stakeholders such as, source manufacturers, radioactive device OEMs and large licensees have had no direct involvement in the NSTS since fall 2006. Additionally no test programs have been trialed or training given to potential participants.

The estimated annual cost given in the OMB for expansion for Category 3 and one tenth Category 3 was \$7.7 M each for the first three years and \$7 M every year after that. We do not consider that the supposed benefits of the expansion of the NSTS justify this potential expenditure; in fact we believe that should such a budget be available, then the primary aims of the NSTS would be better served by allocation of such funds to supporting the existing regulatory requirements in place and to take action to ensure disposal sites for the secured disposal of sealed sources that are surplus to industry requirements. This is a significant issue, due to the loss of Barnwell for the disposal of Category 3 and below sources, many small licensees will have no route of disposal resulting in a much more important security concern that needs to be addressed.

3) Consideration on impact on General Licensees

The proposed rulemaking is only for Part 20 and Part 32 "Specific domestic licenses to manufacture or transfer certain items containing byproduct material" and doesn't cover any changes to Part 31 "General domestic licenses for byproduct material". Many of the Category 3 and 1/10 Category 3 sources are used under a General license (GL) under 10 CFR Part 31.

The Generally Licensed devices have been the focus of regulatory interest by NRC, the Agreement States, licensees and all agree that the generally-licensed versus specifically-licensed sealed source and device regulatory structure requires a complete and detailed review from a risk perspective, so that the appropriate level of licensing is applied to ensure safety and security. This issue was covered by NRC staff in SECY-06-0094 and in SECY-07-0147. Also, the Organization of Agreement States and the State of Florida have both petitioned NRC on issues relating to the Generally Licensed source and devices and have expressed their support for an overhaul of the GL program regulatory framework.

This review of the current program would, among other things, determine whether various types of sources and devices should be regulated through general or specific licenses, and whether other mechanisms such as a general registration program are appropriate based on the risk of the source or device. It is important to consider that, as NRC staff have stated, the most fundamental difference between a general and specific licensee is that the potential specific licensee must file an application with the regulator for approval prior to the receipt, possession and use of licensed material. This process subjects the applicant to a level of scrutiny by the regulator that far surpasses that applied by the regulator to the general license applicant or holder. Also, as discussed above, 10 CFR §31.5 and § 40.22 potentially allow a licensee to possess and use at least Category 2 quantities in GL sources that are not captured by the NSIS since the NSIS is limited to specific licensees.

If this review results in a change in how General Licenses are handled there would be proposed rulemaking that would significantly increase the number of specific licenses that would be subject to additional regulatory review and in entering sources into the NSIS. This would result in major fundamental changes for the current GL users and require issuance of specific licenses to a new population of users. This will take significant costs and resources for both the regulators and the licensees. NRC have stated that a proposed GL rule may be available later this year, the impact of this must be reviewed before there is any consideration of expanding the NSIS beyond Category 1 and 2 sources.

4) NRC Actions in Process

NRC has already implemented many regulatory actions and requirements that have enhanced the security of all sources and these should be given time to be fully integrated and be effective before another layer of regulatory requirements are put in place.

The NRC has significantly enhanced its pre-licensing verification methods in the last few months performing site visits etc to ensure only authorized facilities and personnel obtain a license down to Category 3 quantities. This, along with the existing licensing demands necessary for the operation of source manufacturing, the registration of radioactive devices, their distribution, pre-licensing verification, transfers of sources under existing security orders to verify new users and the flagging of significant changes in ordering patterns, and the subsequent inspection and enforcement of all these existing requirements, provide a thorough regulatory environment and data base that allows adequate "safeguarding" of the "sources". While it is suggested in the proposed rule that "adding such sources to the NSIS would provide for increased accountability for these sources because there would be a near real-time knowledge (sic) of source whereabouts and an ability to confirm an individual licensee's account of their sources" we do not believe that such inclusion would significantly improve on the current accountability. Neither do we understand how extension of the NSIS to Category 3 sources would aid in preventing nor indeed enabling the earlier identification of malicious activities over and above the existing licensing, audits and inspections carried out on licensees by the NRC or Agreement states.

In addition NSCC-R concerned that Agreement State resources, already stretched thin in some states due to the increased control of sources and fingerprinting requirements imposed in 2005 and 2007, will be further exacerbated by the need to dedicate resources to implement an expanded NSTS for lower-risk sources in the absence of a clear public health and safety basis to do so. Clearly, it is not in anyone's interest - including the public's - to have scarce regulatory resources diverted from higher-risk source activities to much lower-risk source activities. The same could be said for certain licensees who might divert scarce resources from related or unrelated safety activities to increase tracking of relatively lower risk sources

5) IAEA Code of Conduct

The proposed rule goes beyond what the IAEA Code of Conduct recommended in terms of categorization of sources. The IAEA Safety Guide, No. RS-G-19, "Categorization of Radioactive Sources" specifically cites in section 2.3 that "categories should not be subdivided as this would imply a degree of precision that is not warranted and would lead to a loss of international harmonization." Implementation of the proposed rule would make the requirements inconsistent with all the other countries, resulting in additional burden to licensees in the US compared to licensees in other countries, thereby putting the US licensees at an operational and competitive disadvantage

6) Risk Analysis

The inclusion of Category 3 and 1/10 Category 3 is based on the belief that aggregation would result in licensees having Category 2 quantities. NRC has already implemented security orders for licensees that exceed Category 2, so these would be in force if there were an aggregation. There have been no other reasons stated for the inclusion of Category 3 in the NSTS. There has been no clear risk analysis to determine if aggregation is really a potential problem or not, it appears that it is the NRC's belief that aggregation is a problem but this has not been demonstrated. As stated previously the burden on licensees is completely unfounded because it is based on assumptions of how the industry would use the NSTS, but this not been even tested. As stated in our May 12, 2008 letter on the OMB considerations the regulatory analysis is flawed as it is based on inaccurate assumptions.

In the initial comments of the proposed expansion, 12 out of 18 comments were against the expansion of the NSTS. None of these comments have been resolved satisfactorily and it is still unclear what the basis is for the proposed expansion

7) Specific Comments on the Federal Register Notice

On page 19754, NRC states that "Based on its consideration of the comments and of the results of the Regulatory Analysis, the Commission is proceeding with the proposed rule for expansion of the NSTS." This statement implies that a firm agency decision has been made to expand NSTS as described in the proposed rule. However, on the previous page, NRC asks 3 specific questions to gather additional information concerning the number of impacted licensees, number of sources captured by the expanded categories and their activities, as well as information on

transactions of these sources. These statements of consideration appear internally inconsistent and raise the question as to the basis for the apparent NRC decision to proceed with rulemaking to expand the NSTS as described in this proposed rule. This NRC request for information compounded with the fact on page 19753 that 12 of 18 previous commenters opposed expanding NSTS, raise serious concerns with the basis of the proposed rule. Also, industry is unaware of any specific NRC activity involving licensees or stakeholders, beyond the “one-time” accounting of Category 3 sources, to gather relevant information and better inform the regulatory analysis for the proposed rule.

Further, on page 19756, NRC states that it is “interested in determining whether specific requirements for tracking should also be included in 10 CFR Part 110 and specifically invites comment on this question.” Without additional detail on NRC’s intent with regard to the import and export of these lower risk sources, it is difficult to comment on the need for or type of specific requirement appropriate for imported sources.

Rulemaking Comments

From: Surovi, Scott J [Scott.Surovi@Covidien.com]
Sent: Friday, June 27, 2008 9:25 AM
To: Rulemaking Comments; Annette Vietti-Cook
Cc: Roughan, Kate; Surovi, Scott
Subject: Comments: National Source Tracking System
Attachments: NSCC-R Comments.pdf; NSCC-R Comments.Attachment.pdf

Importance: High

Attached please find comments offered on behalf of the Nuclear Sector Coordinating Council - Radioisotopes (NSCC-R) regarding the proposed rulemaking relating to the expansion of the National Source Tracking System (NSTS). I apologize for this late submission, though hope that you will include these comments and dialog as part of your rulemaking process.

Please contact me if you have any questions and/or require further information.

Thank you in advance for your assistance.

Regards,

Scott

Scott J. Surovi

Co-Chair, Nuclear Sector Coordinating Council - Radioisotopes (NSCC-R)

Scott J. Surovi

Transportation Compliance Manager, North America
Covidien (formerly Tyco Healthcare/Mallinckrodt)
675 McDonnell Boulevard (EC-4)
St. Louis, MO 63042 USA

T: 314/654-7444

C: 314/267-9142

F: 314/654-9183

www.covidien.com

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Priority: Urgent
Importance: high
From: "Surovi, Scott J" <Scott.Surovi@Covidien.com>
To: <Rulemaking.Comments@nrc.gov>, <annette.vietti-cook@nrc.gov>
CC: "Roughan, Kate" <Kate.Roughan@qsa-global.com>, "Surovi, Scott"
<Scott.Surovi@Covidien.com>
Return-Path: Scott.Surovi@Covidien.com
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