PR 20 and 32 (73FR19749)

Rulemaking Comments



From:

BELL, Denise [dxb@nei.org] on behalf of KILLAR, Felix [fmk@nei.org]

Sent:

Wednesday, June 25, 2008 4:22 PM

Subject: Attachments: Request for Comments on "Expansion of the National Source Tracking System" 06-25-08 NRC Comments on Expansion of the National Source Tracking System.pdf;

06-25-08 NRC Comments on Expansion of the National Source Tracking

System Enclosure.pdf

June 25, 2008

DOCKETED USNRC

Ms. Annette L. Vietti-Cook Secretary of the Commission U.S. Nuclear Regulatory Commission Washington, DC 20555-0001 June 25, 2008 (4:50pm)

OFFICE OF SECRETARY RULEMAKINGS AND ADJUDICATIONS STAFF

ATTENTION:

Rulemakings and Adjudications Staff

Subject: Request for Comments on "Expansion of the National Source Tracking System" RIN 3150-Al29. Proposed Rule, 73 Federal Register 19749 (April 11, 2008).

Project Number: 689

Dear Ms. Vietti-Cook:

The Nuclear Energy Institute (NEI) is submitting the following comments on the proposed rule: "Expansion of the National Source Tracking System" (NSTS) RIN 3150-Al29, Proposed Rule, 73 Federal Register 19749 (April 11, 2008). These comments are based on input from NEI's members which will be impacted by the rulemaking. The comments reflect the members' concerns.

The proposed rule seeks to amend the NSTS final regulations governing the reporting of sealed sources in commerce that were promulgated on November 8, 2006 (71 FR 65686). The stated basis of the need for the expanded NSTS in this rulemaking evolves, in part, from the terrorist attacks in the United States on September 11, 2001; the International Atomic Energy Agency's (IAEA) revisions of the Code of Conduct on the Safety and Security of Radioactive Sources; and the Government Accountability Office's findings regarding the potential for aggregation of lower risk sources (GAO-07-1038T). In preparing these comments, NEI has reviewed other related publicly available information such as staff papers and independent reports on source security. NEI appreciates the opportunity to provide industry comments on the NSTS proposed rule.

Felix M. Killar, Jr.

Enclosure

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June 25, 2008

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The proposed rule seeks to amend the NSTS final regulations governing the reporting of sealed sources in commerce that were promulgated on November 8, 2006 (71 FR 65686). The stated basis of the need for the expanded NSTS in this rulemaking evolves, in part, from the terrorist attacks in the United States on September 11, 2001; the International Atomic Energy Agency's (IAEA) revisions of the Code of Conduct on the Safety and Security of Radioactive Sources; and the Government Accountability Office's findings regarding the potential for aggregation of lower risk sources (GAO-07-1038T). In preparing these comments, NEI has reviewed other related publicly available information such as staff papers and independent reports on source security. NEI appreciates the opportunity to provide industry comments on the NSTS proposed rule.

¹ NEI is the organization responsible for establishing unified nuclear industry policy on matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include all utilities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect/engineering firms, fuel fabrication facilities, materials licensees, and other organizations and individuals involved in the nuclear energy industry.

Ms. Annette L. Vietti-Cook June 25, 2008 Page 2

On behalf of radioactive materials licensees nationwide, NEI continues to support NRC's efforts to enhance the security of IAEA Category 1 and 2 sources through deployment of the NSTS now scheduled for January 2009. NEI does not support expansion of the NSTS to include lower risk sources (Category 3 and 1/10th of Category 3) at this time for the following reasons. First, expanding the NSTS to include lower risk sources when it is not yet available to regulators or licensees to track high risk sources—the purpose for which it was designed--is premature from both a technical and practical perspective. Secondly, industry believes that scarce regulatory and licensee resources would be much more effectively utilized, from a safety and security perspective, by enhancing existing regulatory tools. Such tools include the licensing, inspection and enforcement programs and related regulatory guidance, and closer coordination with affected licensees, the Agreement States and other Federal agencies on issues of mutual interest and concern. We offer additional insights and information on these matters for your consideration in the enclosure to this letter.

Finally, as discussed during the April 30, 2008 public Commission meeting, "Briefing on Materials Licensing and Security," NRC has a cornucopia 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, but are not limited to, 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, and rulemakings and security orders. Industry strongly encourages NRC to ensure that such 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.

Therefore, we believe this rulemaking to expand NSTS is not warranted or necessary. We encourage NRC to deploy the NSTS, as originally intended, so that both the regulators and licensees can gain experience with the system before considering any expansions to it.

If we can provide further information that would assist in resolving the concerns expressed in this letter, please contact me at 202-739-8126; fmk@nei.org.

Sincerely,

Felix M. Killar, Jr.

Fly M. Kelny

Enclosure

Industry Comments on the Proposed Rule for Expansion of the National Source Tracking System

I. Expansion of the National Source Tracking System is Premature from a Technical Perspective

Expansion of the National Source Tracking System (NSTS) to include sources below the International Atomic Energy Agency's (IAEA) Category 1 and 2 levels is premature from a technical perspective. It is premature because there is the potential within the *existing* regulatory framework for a general licensee—who is not subject to the current or proposed NSTS requirements—to possess and use at least Category 2 quantities of material. Radioactive sources of similar radiological risk or hazard should be regulated more uniformly and consistently from a public health, safety and security perspective.

It has long been recognized by NRC, the Agreement States, some licensees and independent observers that the generally-licensed (GL) versus specifically-licensed (SL) sealed source and device regulatory framework warrants a comprehensive review from a risk perspective. This issue was discussed at length by NRC staff in SECY-06-0094 and most recently in SECY-07-0147. Also, the Organization of Agreement States and the State of Florida petitioned NRC on related GL program matters and have expressed their support for an overhaul of the GL regulatory framework on more than one occasion.

According to the staff, the holistic review of the GL program would, among other things, determine whether various types of sources and devices should be regulated through a GL or SL, 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 stated above, current NRC regulations in 10 CFR §31.5 and § 40.22 potentially allow a licensee to possess and use at least Category 2 quantities in GL sources and devices that are not captured by the NSTS since the NSTS requirements appear to be limited to specific licensees.

Finally, any effort to revise the existing regulatory framework for GL sources and devices has the potential to result in a rulemaking that would significantly increase the number of SL sources that would be subject to NSTS requirements. If this occurs, additional costs would be incurred for both NRC and the Agreement States, as well as affected licensees nationwide, to capture and track those newly designated sources. Therefore, it is premature to expand the NSTS beyond Category 1 and 2 until such time that a comprehensive review of the existing GL regulatory framework is conducted. NRC officials have publicly stated that a proposed GL rule

might be available later this year. Such timing supports industry's position to wait until a GL rulemaking is well underway, if not completed, before revisiting the decision of *whether* to expand the NSTS beyond Category 1 and 2 sources.

II. Expansion of the National Source Tracking System is Premature from a Practical Perspective

The proposed expansion of the NSTS to capture sources below Category 2 is premature from a practical perspective as well. The original scope and purpose of the NSTS was to track, monitor and account for the nationwide use of Category 1 and 2 sources. However, NSTS development and deployment has experienced significant technological delays (years) and increased costs, and is not in use today by NRC and its licensees, much less by the Agreement States and the other 85% of radioactive materials licensees nationwide which they regulate. In addition, the Agreement States and affected licensees who would be subject to the expanded NSTS rule have had little to no visibility of the system and how it will work. As a result, there is not sufficient information or data on which to evaluate the validity, accuracy and completeness of the reporting burden estimated by NRC in the Regulatory Analysis (e.g., estimates for certain required actions range from 2 minutes per transaction to 20 hours of computer programming per licensee).

At minimum, NRC, Agreement States and licensees should gain experience with tracking the higher-risk Category 1 and 2 sources in NSTS for about two years and make system modifications accordingly. In addition, NRC should fully engage stakeholders to complete the GL rulemaking discussed above, before revisiting the decision of *whether* to expand NSTS. Such an approach is more efficient and effective considering the high NRC cost of developing and expanding the NSTS (see discussion in section IV below), as well as the associated costs for implementation by the Agreement States and licensees nationwide.

Further, IAEA Safety Guide, No. RS-G-19, "Categorization of Radioactive Sources" specifically states that existing source "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." Industry supports the IAEA position and suggests that subdivision of certain source categories is unwarranted at this time.

III. Inherent Tracking Limitations with NSTS

There are inherent tracking limitations with NSTS as the system is described in the proposed rule. Most importantly, the rule is silent on GL sources and devices that, in theory, could be subject to the rule since some GL devices contain Category 3 or $1/10^{th}$ of Category 3 sources. Also, the rule also does not explicitly use the term "specific license" when discussing licensees who are subject to the rule. These facts, coupled with the fact that the proposed rule does not amend Parts 31 and 40 to make GL licensees subject to the NSTS rule, leads industry to believe that the proposed rule is limited to SLs. If this interpretation is true, then not all Category 3 and $1/10^{th}$ of Category 3 sources in use today are captured by the proposed rule as implied in

the statements of consideration. The final rule needs to explicitly discuss this distinction to provide clarity and help avoid any unnecessary confusion by licensees or stakeholders.

Also, a source of confusion for some existing GLs could occur when a Part 32 source manufacturer—a specific licensee who is subject to NSTS--enters data into NSTS on a GL source that it manufactured. The source is then eventually distributed to a GL--who is not subject to NSTS—so the GL source data is essentially "dead on arrival" into NSTS because it will no longer be tracked by the manufacturer or the GL source recipient. It is not clear from the proposed rule if NRC will track GL sources entered into NSTS until such time that the source decays below the 1/10th of Category 3 level. If industry's understanding of NRC's expectations regarding manufacturers' responsibilities for tracking GL or SL sources is incorrect, this should be clarified in the final rule.

IV. The Proposed Requirements Are Unnecessary

The NRC has not provided sufficient evidence to suggest that existing requirements and the current enhanced regulatory approach to source security is not adequate to oversee licensed activities and ensure public health and safety. Specifically, the NRC and Agreement States have guidance in place for the conduct of additional screening and "pre-licensing" visits during the initial licensing process to further ensure that byproduct material specific licenses are issued only to legitimate persons. This guidance was further revised in response to the Government Accountability Office's audit of NRC's licensing process during the spring of 2007 (GAO-07-1038T, dated July 12, 2007). As such, the regulator's role in, and emphasis on, ensuring that source recipients are legitimate has significantly increased.

Byproduct materials licensees have been for years and are currently subject to 10 C.F.R. §30.41, "Transfer of byproduct material." This requirement explicitly describes the licensee's responsibility to ensure that, prior to the transfer of GL or SL material, the licensee verify that the recipient is authorized to receive the type, form and quantity of the byproduct material to be transferred. Agreement State regulations have comparable requirements in place for their licensees. These requirements could be enhanced as an alternative to the proposed rule, yet this option is not discussed in the proposed rule. Also, specific licensees possessing quantities of certain sources that, individually or in the aggregate, meet or exceed the Category 2 level are already subject to the NRC orders for increased control of sources (and corresponding Agreement State requirements). Thus, enhanced tracking, control and monitoring of higher risk sources of concern below the Category 2 level is in place today.

NRC's statement that it needs to be in a position to monitor the "real-time tracking" of certain sources is somewhat unfounded, in that, who better to track such sources in "real-time" than legitimate licensees whom the regulator has scrutinized prior to licensing and is responsible for overseeing licensee compliance with applicable requirements. Also, licensees are currently required to inventory radioactive sources; therefore, additional requirements should be reviewed and analyzed to ensure compatibility with existing requirements and to minimize or eliminate any redundancy.

Also, spending NRC resources to expand NSTS now also seems counter intuitive to the NRC statement that expansion of the NSTS would "increase public confidence." Specifically, public confidence would likely be increased more if NRC were to use these resources (i.e., \$7.7 million/year for the first 3 years for initial NSTS deployment and operation and \$7 million each year thereafter for NSTS operation) to enhance its existing regulatory programs, increase its coordination with the Agreement States, and solicit input from affected licensees after gaining experience with tracking Category 1 and 2 sources rather than imposing new requirements to expand NSTS at this time. Further, these costs will rise if, as a result of the GL rulemaking, some GL sources and devices are converted to SLs and thus are subject to the NSTS requirements.

Finally, NEI is somewhat 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 and licensee resources diverted from higher-risk source activities to much lower-risk source activities.

V. The Proposed Information Collection Requirements Do Not Satisfy the Paperwork Reduction Act

As stated in NEI's May 13, 2008 letter to the Office of Management and Budget in response to this NSTS proposed rule, the Paperwork Reduction Act intends to improve the "responsibility and accountability" of OMB and all other federal agencies to Congress and to the public for reducing the burden of federal reporting and information collection requirements (See 44 U.S.C. 3501(1), (2) (11). The Act criteria include, but are not limited to, "an evaluation of the need for the collection of the information," "a specific, objectively supported estimate of the burden," and a "test of the collection program through a pilot program, if appropriate."

Industry does not believe that the proposed information collection requirements are necessary for the proper performance of NRC or Agreement State functions. Rather, we believe that there is no evidence to suggest that NRC's stated concern regarding the "potential" for individuals to accumulate sources in quantities to reach the Category 2 level has been observed or is likely to occur if the NRC and Agreement States continue with their existing regulatory programs, fully implement the "pre-licensing guidance" and consider dedicating additional resources for even more rigorous licensing, inspection and enforcement programs to ensure licensee compliance with existing requirements. NRC also states that expanding the NSTS will "improve regulatory knowledge." Industry believes that the regulator's knowledge would be improved and increased by considering certain enhancements to its existing programs, e.g., more frequent contact with the licensee by the regulator, rather than relying on new record keeping and reporting requirements.

Also, as stated in item I. above, licensees subject to the expanded NSTS do not have experience with or sufficient information or data regarding the system on which to evaluate the

validity, accuracy and completeness of the reporting burden estimated by NRC in the proposed rule. A fully functioning NSTS to track Category 1 and 2 sources would provide this needed experience for regulators and licensees, and could be considered a "pilot program" as suggested by the Paperwork Reduction Act. It should also be noted that licensees authorized for Category 1 or 2 sources are, in many cases, not the same licensees authorized for Category 3 or lower sources. Finally, it is this group of licensees with lower risk sources who have not had visibility of NSTS since they were not the subject of the original NSTS requirements promulgated in 2006.

VI. Specific Comments on the Federal Register Notice

- 1. 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 a question as to the basis for the proposed rule, particularly since 12 of 18 previous commenters opposed expanding NSTS. 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.
- 2. 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.
- 3. On page 19757, NRC states that Agreement States will be able to view source data and information on licensees under their jurisdiction but would not be able to view information on licensees in other States. The basis for this information restriction is not obvious. NEI is of the opinion that NSTS information should be shared between NRC and the Agreement States which regulate 85% of materials licensees nationwide. Also, certain categories of licensees routinely work across State borders with licensed material. We believe that all regulators should have access to NSTS data to facilitate enhanced tracking of sources that are subject to NSTS requirements.
- 4. Understanding and applying the term "transfer" to source tracking is fundamental to implementing and complying with the rule, yet it is not defined in the proposed rule. While it is discussed in the statements of consideration, consideration should be given to further defining it in the final rule should NRC proceed with this rulemaking.

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