

RULEMAKING ISSUE AFFIRMATION

June 10, 2009

SECY-09-0086

FOR: The Commissioners

FROM: R. W. Borchardt
Executive Director for Operations

SUBJECT: FINAL RULE: EXPANSION OF THE NATIONAL SOURCE TRACKING
SYSTEM (RIN 3150-A129)

PURPOSE:

The purpose of this paper is to request Commission approval to publish a final rule in the *Federal Register* that would amend Parts 20 and 32 of Title 10 of the *Code of Federal Regulations*. The amendments expand the National Source Tracking System (NSTS) to include additional specific licensees that possess sealed sources containing the International Atomic Energy Agency (IAEA) Category 3 threshold quantities of radioactive material. The final rule requires these licensees to report transfers of control of their Category 3 sources and to perform an annual reconciliation of actual inventory compared to that reported in the NSTS.

SUMMARY:

In November 2006, the U.S. Nuclear Regulatory Commission (NRC) issued a final rule to establish a national system for tracking of certain sealed sources. The rule requires specific licensees who possess IAEA Category 1 and 2 sources to report certain inventory and transfer information to the NSTS, launched on December 30, 2008. In proceeding with this current rulemaking, the staff has considered whether the existing NSTS should be expanded to include Category 3 or 1/10th of Category 3 sources to improve accountability of these sources and to reduce the potential for lower activity sources being accumulated (aggregated) to higher activity levels for potential malevolent use. Based on technical and policy considerations, a regulatory

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analysis, and consideration of public comments on the NSTS expansion proposed rule, the staff is requesting Commission approval to publish a final rule in the *Federal Register* that would amend 10 CFR Parts 20 and 32 to expand the NSTS to include Category 3 source reporting beginning November 30, 2012.

BACKGROUND:

The NRC published a final rule in the *Federal Register* on November 8, 2006 (71 FR 65686), establishing a national system for source tracking whereby specific licensees who possess IAEA Category 1 and 2 sources are required to report information on the manufacture, transfer, receipt, disassembly, and disposal of nationally tracked sources. Licensees were required to report their initial inventories by January 31, 2009 (72 FR 59162). While preparing the final rule establishing the NSTS for Category 1 and 2 sources, the staff provided the Commission with options for expanding the NSTS to provide enhanced accountability for IAEA Category 3 sources (SECY-06-0094; April 24, 2006). In response to the paper, the Commission issued a Staff Requirements Memorandum (SRM) dated June 9, 2006, that directed staff to prepare a proposed rule to consider expanding the NSTS to include Category 3 sources.

In 2007, the Senate Committee on Homeland Security and Government Affairs, Permanent Subcommittee on Investigations, released a staff report recommending that the NRC consider including Category 3 sources in, at that time, the proposed NSTS. Concerns were also raised by the Government Accountability Office (GAO) in its report (GAO Testimony, GAO-07-1038T, "Actions Taken by NRC to Strengthen Its Licensing Process for Sealed Radioactive Sources," July 12, 2007) recommending improved pre-licensing guidance including mandatory site visits for new applicants, periodic oversight of license application reviewers, and improved measures to prevent counterfeiting of licenses.

In response to these concerns, NRC staff provided the Commission with a GAO Action Plan in SECY-07-0147. The Action Plan included a recommendation that the scope of the NSTS rulemaking be expanded to include sources at a level of 1/10th of Category 3. The Commission approved the staff's Action Plan on September 18, 2007, in the SRM for SECY-07-0147.

In an SRM dated March 26, 2008, the Commission approved publication of the proposed rule on the expansion of the NSTS (SECY-08-0031, March 6, 2008) and the proposed rule was published in the *Federal Register* (73 FR 19749; April 11, 2008). The proposed rule sought public comment on expanding NSTS to include sealed sources greater than or equal to 1/10th of Category 3 threshold levels. The comment period closed June 25, 2008, and 19 comment letters were received from States, licensees, industry organizations, and individuals.

DISCUSSION:

Almost all of the comment letters on the proposed rule were opposed to expanding the NSTS as proposed for the following reasons: 1) The rule is premature and should be delayed to allow time to refine the burden estimates in the regulatory analysis using actual experience from the operational NSTS for Category 1 and 2 sources; 2) The NSTS should be fully operational and successfully tracking Category 1 and 2 sources before the NRC adds a potentially significant number of Category 3 and high-end Category 4 sources (either specifically-licensed sources or certain currently generally-licensed sources) to the system; and 3) There needs to be additional justification of the security risks posed by these sources before incurring the additional burden

of tracking their location from production to disposal. The comments are discussed in detail in Enclosure 1, the *Federal Register* notice (FRN) for this final rule.

A review of the 19 comment letters and the NSTS operating experience gained since December 2008 contributed to a re-evaluation by the staff of the source tracking threshold levels. For example, several commenters indicated that staff's assumption representing annual new source production by manufacturers was too low and these commenters provided more accurate information. Comments and experience to date indicate that licensees are more prone to fax their transactions to the NRC instead of using the on-line NSTS. As a result, the staff revised the regulatory analysis to support the final rule. The revised cost of expanding the NSTS to include Category 3 quantities of radioactive material (\$13.7 million) is about 40 percent of the cost of expanding the NSTS to include 1/10th of Category 3 sources (\$33.5 million). It is important to note that staff is undertaking initiatives to increase the number of NSTS users that enter data on-line, instead of by fax. If successful, these efforts would reduce the cost to about \$11.2 million over ten years for tracking Category 3 sources. Additional details are in the regulatory analysis. Even with improved licensee reporting, staff believes that the increased burden and expense to track sources at the 1/10th of Category 3 threshold values is not justified and recommends that threshold levels should be set at Category 3.

Expanding the NSTS to include Category 3 sources would allow NRC to track sources that the IAEA defines as dangerous, and it is plausible that individual sources at the high end of Category 3 activity could be aggregated to reach a Category 2 activity level since only a few are needed to aggregate to Category 2. The staff gave careful consideration to the issues related to tracking sources at 1/10th of Category 3, but at this time tracking sources at this lower level is not recommended considering the benefits gained in source accountability. If conditions warrant it at a later date, the staff will reconsider the tracking of 1/10th of Category 3 sources. Staff considered the issues associated with Category 3 and 1/10th of Category 3 threshold values as discussed in Items 1 and 2 below. In Item 3 below, the staff summarizes its conclusion on expanding the NSTS to the threshold values of Category 3.

1. Expanding the NSTS to Include Category 3 Sources

The following items form the rationale to include Category 3 sources in the NSTS:

- a) **The potential exists to aggregate Category 3 sources to a Category 2 level:** Category 3 sources could be aggregated to Category 2 levels, as they represent sources with activity levels that range from just below the Category 2 threshold down to 1/10th of the Category 2 threshold. Thus, at the high end of Category 3, it would only take a few sources to aggregate to Category 2. Major categories of licensees who possess Category 3 sources include those with fixed industrial gauges; those who conduct well-logging operations; medical facilities with brachytherapy machines; and some radiographers with relatively low activity sources. Because these sources are widespread in use by industry, there is a potential that aggregation could occur to Category 2 levels. Adding Category 3 sources to the NSTS with its inventory and tracking requirements will provide increased accountability of these dangerous sources due to timely knowledge of source whereabouts and an ability to confirm an individual licensee's account of its nationally tracked sources within one business day of a transaction.

- b) **The additional burden to track Category 3 sources is justified given the benefit in improved source accountability:** Adding Category 3 sources to the NSTS will result in an increased burden to the NRC, Agreement States, and to the licensed industry. The existing NSTS has approximately 1,300 NRC and Agreement State licensees. An expanded NSTS will add approximately 1,000 licensees who possess Category 3 sources. The regulatory analysis supporting this final rule estimates a total cost of about \$14 million over a 10-year analysis period to expand the NSTS to include Category 3 sources. Staff believes this additional cost is justified, given the additional accountability of these sources and the potential risks they pose if misused.
- c) **Category 3 sources are defined as dangerous sources by IAEA:** The IAEA defines Category 3 sources (as well as Category 1 and 2 sources) as dangerous sources because these sources could, if not under control, give rise to an exposure sufficient to cause severe deterministic effects.
- d) **The NSTS design can accommodate additional sources:** The NSTS was designed to accommodate Category 3 sources and licensee information, and this feature can be implemented at reasonable cost. If appropriate resources are applied, the inclusion of Category 3 sources in an expanded NSTS will not detract from the performance of tracking higher-risk Category 1 and 2 sources.

2. Other Regulatory Alternatives

The staff evaluated a regulatory alternative to expand the NSTS to include 1/10th of the Category 3 threshold. The principal rationale to include these lower activity level sources is the potential to aggregate them to create the equivalent of a Category 2 source. The staff analyzed the net impacts of expanding the NSTS to 1/10th of Category 3, estimating total cost of about \$33 million over a 10-year analysis period.

Based on the lower level of radioactive material in the 1/10th of Category 3 sources and their limited potential to aggregate to Category 2, the staff recommends not including sources below Category 3 in the NSTS at this time. Staff believes that the costs are not justified given the lower potential to aggregate these sources to a Category 2 level compared to the potential to aggregate Category 3 sources to a Category 2 level.

The staff also evaluated an alternative that would require licensees only to report source inventory data, at year-end, rather than continuous tracking. This was evaluated for Category 3 and 1/10th of Category 3 sources. The total costs of these regulatory alternatives are on the order of \$5 million and \$13 million, respectively, over the 10-year analysis period. However, these alternatives would not provide knowledge of source transactions in a timely manner and would not provide a confirmatory cross-check of transactions from manufacturers to specific recipients, and follow-on transfer and receipt of sources to other licensees, to guard against and prevent the aggregation of sealed sources for potential malevolent use.

3. Staff's Conclusion Regarding Expansion of the NSTS

Based on the discussion in Items 1 and 2, above, the staff has concluded that it is appropriate to expand the NSTS to include sources that are in Category 3 threshold, but not to 1/10th of this value. Expanding the NSTS to Category 3 sources would enable the NRC to use a common platform to monitor source transactions that could be aggregated into the equivalent of a Category 2 source. Tracking specific transactions of these sources enhances accountability and allows the NRC and Agreement States to detect situations where a licensee's aggregate sources create larger and possibly more dangerous quantities of radioactive material.

The final rule would expand the existing NSTS by requiring licensees with Category 3 sources to report information to the NSTS on the manufacture, transfer, receipt, disassembly, and disposal of specifically-licensed sources. With an expanded NSTS, NRC can be alerted to discrepancies between transaction reports of manufacturing and distribution licensees, and of individuals to whom the shipment of sources is being made. The data from the NSTS will be used in conjunction with other data management systems to provide for better source accountability. Expanding the NSTS is part of an integrated source management program, consistent with international obligations and with the recommendations in the IAEA *Code of Conduct on the Safety and Security of Radioactive Sources* (Code of Conduct) for development of a national register of radioactive sources. Although no tracking system like NSTS can ensure the physical protection of sources, it will provide greater source accountability than currently provided for regulatory oversight.

Some Category 3 sources are contained in generally licensed devices. At the present time, such devices are exempt from the reporting requirements of NSTS. In this context, the staff has a separately proposed General Licensing rulemaking, in SECY-08-0137 dated September 15, 2008. This rulemaking proposes to change the requirements for generally licensed devices so that the Category 3 sources in those devices would only be possessed by specific licensees, and thus those licensees would be subject to the reporting requirements of an expanded NSTS. It was estimated that there are 400 general licensees that possess Category 3 sources and 1,000 general licensees that possess 1/10th of Category sources (i.e., a total of 1,400 current general licensees that possess sources less than Category 2 levels but greater than or equal to 1/10th of Category 3 levels). On May 1, 2009, the Commission approved the publication of the General Licensing proposed rule for a 75-day public comment period. Based on the current schedule, the General Licensing final rule is expected to be published in February 2010 with an effective date in April 2010 (60 days after publication) and an implementation date in July 2010 (150 days after publication). Thus, approximately 400 newly created specific licensees in the General Licensing final rule who possess previously generally licensed devices containing a Category 3 source would be subject to the NSTS reporting requirements.

Staff considered two options for the implementation date of this final rule that would apply to NRC and Agreement State licensees. Those two options were October 31, 2010, and November 30, 2012. After working with the Organization of Agreement States, Inc. (OAS), the Conference of Radiation Control Program Directors, Inc. (CRCPD), and the Department of Energy (DOE) staff, the staff recommends that the implementation date of this final rule be November 30, 2012. Pursuant to 10 CFR 20.2207(g), which is unchanged in this final rule, licensees would be required to complete a reconciliation of their Category 3 source inventories by January 31, 2013. The staff has extended the date for this initial reconciliation to January 31, 2014, in amended 10 CFR 20.2207(h). The reason for this extension is that little change is

expected in the NSTS information for Category 3 sources over the 2 month period from November 30, 2012, to January 31, 2013, and the inventory reconciliation in 2013 would impose a burden on licensees, Agreement States and the NRC without a corresponding benefit. The following impediments argue against an October 31, 2010, implementation date.

If the Commission approves publication of the NSTS expansion final rule, October 2009 is a likely month of publication provided the Office of Management and Budget (OMB) approves the information collection requirements. The NSTS expansion final rule is classified as Agreement State Compatibility Category "B." Current NRC policy requires that Agreement States adopt equivalent regulations or legally binding requirements no later than 3 years after a final rule becomes effective unless the Commission determines otherwise. If the implementation date is October 31, 2010, for both NRC and Agreement States, OAS and CRCPD staff indicated that Agreement States would require emergency actions (i.e., issuing orders or using license conditions) because very few States could promulgate the rule by that date. States' staff suggested that emergency action is not supported by the risk assessment in the NSTS expansion final rule. Many States can only use the emergency rulemaking if there is a dire circumstance, such as one involving national security, which is not the case with the NSTS expansion final rule. Also, some States must issue orders to licensees prior to imposing a license condition because license conditions are perceived as an agreement between the State regulator and the licensee.

In addition, to ensure that the Category 3 data entered into NSTS can be verified and will not disrupt the functioning of NSTS for Category 1 and Category 2 source reporting, both NRC and Agreement State licensees with Category 3 sources must be reporting into the system beginning in the same month. If, instead, licensees enter their data into the system in different phases or in "waves," then there will be "open transactions" which will not reconcile within the NSTS. An example of such an open transaction is a manufacturer or a distributor who reports transferring of a source but the organization receiving the source does not report its receipt. Or receipt of a source is reported for which the manufacturer or distributor has not entered the source into the system. Setting the NSTS expansion implementation date on November 30, 2012, would allow both NRC and Agreement State affected licensees to begin reporting at the same time and will make it more likely that the Category 3 data in the NSTS will be able to be verified with a minimum number of open transactions.

OAS and CRCPD continue to hold their views that the final rule is premature and should be delayed. Agreement State licensees represent about 80 percent of the licensees who must report information into the NSTS. For the NSTS to provide nationwide coverage of Category 3 sources, including data from approximately 400 current general licensees, the Agreement States must incorporate the NSTS expansion final rule and General Licensing amendments into their regulatory framework by issuing legislation, regulations, or other legally binding requirements that are effective prior to the implementation date of this final rule. We are therefore recommending the Agreement States adopt the NSTS expansion final rule requirements by August 30, 2012, to ensure these legally binding requirements are in place before the implementation date of the regulations.

In working with the DOE to develop this final rule, DOE staff requested a minor change to final rule text in 10 CFR 20.2207(b) after the close of the proposed rule public comment period. The change clarifies information contained in the NSTS final rule (71 FR 65690; November 8, 2006) that licensees who transfer control of a nationally tracked source to DOE are required to report

the transfer in the NSTS. The Office of the General Counsel determined that the change requested by DOE imposes no additional requirements and is not a substantive modification. The change has been added to the final rule text.

OUTCOME OF THIS FINAL RULE: ADVANCING NRC'S STRATEGIC GOALS:

This rulemaking was conducted in an open process. The proposed rule was published in the *Federal Register* for a 75-day public comment period. The final rule is consistent with NRC's strategic objective and performance goals. The expanded NSTS will provide greater source accountability and, in conjunction with other related activities (e.g., web based licensing, pre-licensing site visits, and increased controls orders), improve the control of radioactive sources and protect public health and safety.

AGREEMENT STATE ISSUES:

On May 11, 2009, a copy of the draft final rule FRN was provided to the Agreement States for review. The Executive Boards of the OAS and the CRCPD provided comments, and the NRC has received 26 letters from individual states. All of these letters are in the Agencywide Documents Access and Management System (ML091410471). All of the States, except one, are opposed to the NSTS expansion final rule. Most of the letters cited a risk that implementing the rule will shift limited personnel resources away from what they believe are more near-term and tangible health and safety aspects of radiation protection. States reported hiring freezes and planned furloughs. One State estimated the expansion to Category 3 sources would require 1,000 additional staff hours to implement the rule. During a presentation on the NSTS at the annual CRCPD meeting in May 2009, a member of the public requested that the Commission consider releasing this Commission paper early to the public, soon after receipt of the paper from the staff.

Many of the States insist that the existing NSTS is not effective, and 24 comment letters stated that the NSTS should not be expanded until the NRC resolves existing NSTS problems. The States described existing NSTS software problems, such as automatic termination of session, inability to print inventories, delays in entering transactions submitted to the NRC contractor, an inoperable radionuclide decay function, among others. Many licensees have opted to send their transaction reports to the NRC by fax, and the NRC currently has a data entry backlog. The States are concerned about the validity and tracking potential of the NSTS for Category 1 and Category 2 sources, and lack confidence that planned improvements to the NSTS system will be implemented prior to the staff's recommended November 30, 2012, implementation date. To assist additional affected licensees in implementing the final rule, NRC will provide the licensees with written guidance and hands-on training. The guidance document will be available at training workshops conducted before the implementation date of the rule.

Most of the States would like to see a risk assessment of Category 3 sources before the NRC considers expanding the NSTS. Several States believe that the NRC has taken a "piece meal" approach to security related issues, and the rulemakings, orders and license conditions are placing a genuine strain on State and licensee resources.

The Standing Committee on Compatibility was provided the draft final rule for review of compatibility and adequacy designation prepared by the NRC staff. The Standing Committee on Compatibility reviewed the rule in accordance with the "Policy Statement on Adequacy and

Compatibility of Agreement State Programs" approved by the Commission (62 FR 46517) and the categorization process for NRC program elements in NRC Management Directive 5.9 "Adequacy and Compatibility of Agreement State Programs." The Committee agrees that the amendments in the final rule are a matter of compatibility between the NRC and the Agreement States and that the compatibility designations for the amended sections should be Compatibility Category B. The Committee also recommended setting a date three months prior to the final rule implementation date for the States to have their legally binding requirements in place. This Committee's membership includes Agreement State representatives.

RECOMMENDATIONS:

That the Commission:

1. Approve for publication in the *Federal Register* the enclosed notice of final rulemaking (Enclosure 1).
2. To satisfy the requirement of the Regulatory Flexibility Act, 5 U.S.C. 605 (b), certify that this rule, if promulgated, will not have significant impact on a substantial number of small entities. This certification is included in the attached *Federal Register* notice.
3. Note:
 - a. The Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification and the reasons for it, as required by the Regulatory Flexibility Act, 5 U.S.C. 605(b);
 - b. A final Regulatory Analysis has been prepared for this rulemaking (Enclosure 2);
 - c. The staff has determined that this action is not a "major rule," as defined in the Congressional Review Act (CRA) of 1996 [5 U.S.C 804(2)] and will confirm this determination with OMB. The appropriate Congressional and Government Accountability Office contacts will be informed;
 - d. The appropriate Congressional committees will be informed;
 - e. A press release will be issued by the Office of Public Affairs when the final rulemaking is filed with the Office of the Federal Register; and
 - f. The final rule contains amended information collection requirements subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, et seq.) that must be submitted to the OMB for its review and approval before publication of the final rule in the *Federal Register*.

RESOURCES

To complete the rulemaking itself, less than a 0.1 full-time equivalent position will be required. These resources are included in the current Office of Federal and State Materials and Environmental Management Programs (FSME) budget for Fiscal Year (FY) 2009. Implementation of NSTS expansion, however, will require the authorization of currently

unbudgeted out-year resources the level of which is yet to be determined. The staff agrees with States' comments that the rollout of NSTS for Category 1 and Category 2 sources has been troublesome and is yet to satisfy all of the original functional requirements. FSME program funds will need to be budgeted for activities before operation of the expanded system, such as software modifications and version control, Category 3 implementation guidance, and public workshops as training sessions.

COORDINATION:

The Office of the General Counsel has no legal objection to the final rulemaking. The Office of the Chief Financial Officer has reviewed this Commission Paper for rulemaking resource implications and has no objections. The rule suggests changes in information collection requirements that must be submitted to, and approved by OMB, before the final rule is forwarded to the *Federal Register* for publication.

/RA/

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Enclosures:

1. Final Rule: *Federal Register* notice
2. Regulatory Analysis
3. Congressional Review Act Forms

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EDATS: SECY-2009-0283

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