# RULEMAKING ISSUE AFFIRMATION

April 6, 2006 SECY-06-0080

FOR: The Commissioners

FROM: Luis A. Reyes

**Executive Director for Operations** 

SUBJECT: FINAL RULE: NATIONAL SOURCE TRACKING OF SEALED

SOURCES (RIN 3150-AH48)

## PURPOSE:

To request Commission approval of a process for issuance of a final rule that would amend Parts 20 and 32 of Title 10 of the *Code of Federal Regulations*. The amendments would establish the regulatory foundation for the National Source Tracking System.

## SUMMARY:

In recent years, there has been increased interest in the security of radioactive material. An interagency working group on radiological dispersal devices (RDD) was formed to investigate the control of nuclear material. The International Atomic Energy Agency (IAEA) Board of Governors approved a major revision to the IAEA "Code of Conduct on the Safety and Security of Radioactive Sources" (hereafter Code of Conduct). To address recommendations from the RDD Working Group and in the Code of Conduct, NRC formed a National Source Tracking Working Group in November 2003 to develop a national source tracking system. A Steering Committee and an Interagency Coordinating Committee were also formed. The proposed rule on National Source Tracking was published for public comment on July 28, 2005. The Energy Policy Act of 2005 contains a provision that requires the NRC to issue regulations establishing a mandatory source tracking system not later than one year after enactment of that legislation (August 8, 2006). The final rule would require licensees to report transactions involving the

CONTACT: Merri Horn, NMSS/IMNS

(301) 415-8126

manufacture, transfer, receipt, disassembly, and disposal of nationally tracked sources to the National Source Tracking System. The basis for the final rule would change from promotion of the common defense and security to protecting the public health and safety. Staff plans to send a paper to the Commission that will address less than Category 2 sources near the end of April 2006. In early 2007, staff plans to issue a Regulatory Information Summary (RIS) on the importance of submitting accurate information to the National Source Tracking System. The resources required to complete the rulemaking, 0.1 full-time equivalent positions, are included in the current budget.

## **BACKGROUND:**

As a result of the terrorist attacks in the United States on September 11, 2001, the U.S. Nuclear Regulatory Commission (NRC) has undertaken a comprehensive review of nuclear material security requirements, with particular focus on radioactive material of concern. In June 2002, NRC and the U.S. Department of Energy (DOE) established an interagency working group on RDDs to investigate how to improve the control of nuclear material. The RDD Working Group recommended that a national source tracking system be developed to better understand and monitor the location and movement of sources of concern. This recommendation is contained in the May 2003, joint DOE/NRC report, entitled "Radiological Dispersal Devices: An Initial Study to Identify Radioactive Materials of Greatest Concern and Approaches to Their Tracking, Tagging, and Disposition."

The Commission has also supported U.S. Government efforts to establish common international guidance for the safety and security of radioactive materials of concern. This effort has resulted in a major revision to the Code of Conduct. The revised Code of Conduct was approved by the IAEA Board of Governors in September 2003. The U.S. Government has formally notified the Director General of the IAEA of its political commitment to the current Code of Conduct. The Code of Conduct contains a recommendation that each IAEA Member State should develop a national register of radioactive sources that should include Category 1 and 2 radioactive sources as described in Annex 1 of the Code of Conduct.

As part of the effort to improve the security of radioactive sources, NRC initiated development of a national tracking system for radioactive sources of concern. It formed the National Source Tracking Working Group in November 2003, the SafeSource¹ Steering Committee in December 2003, and the Interagency Coordinating Committee in February 2004, to aid in the development of the National Source Tracking System.

In a Staff Requirements Memorandum (SRM) dated June 30, 2005, the Commission approved publication of the proposed rule on National Source Tracking (SECY-05-0092, May 18, 2005). It was published in the *Federal Register* on July 28, 2005 (70 FR 43646). The comment period closed October 11, 2005, and 33 comment letters were received. NRC also held two public meetings on the proposed rule during the comment period. The first meeting was held in Rockville, Maryland, on August 29, 2005, and the second meeting was held in Houston, Texas, on September 20, 2005. Approximately 90 people attended the two meetings, with 17 individuals providing comments. The overall commenter mix on the proposed rule included

<sup>&</sup>lt;sup>1</sup>SafeSource is the name for the overall project that includes the web-based licensing project, the interim database project, and the national source tracking project.

Federal agencies, States, licensees, industry organizations, and individuals. The comments are discussed in detail in the Federal Register notice (Enclosure 1).

The President signed the Energy Policy Act of 2005 (Act) into law on August 8, 2005. It contains a provision on national source tracking that requires NRC to issue regulations establishing a mandatory tracking system for certain radiation sources in the United States. The regulations must be issued no later than 1 year after the date of the Act's enactment. The Act requires the tracking system to: (1) enable the identification of each radiation source by serial number or other unique identifier; (2) require reporting within 7 days of any change of possession of a radiation source; (3) require reporting within 24 hours of any loss of control of, or accountability for, a radiation source; and (4) provide for reporting through a secure internet connection. The Act further requires NRC to coordinate with the Secretary of Transportation to ensure compatibility, to the maximum extent practicable, between the tracking system and any system established by the Secretary of Transportation to track shipments of radiation sources. The Act defines radiation source as a Category 1 source or a Category 2 source as defined in the Code of Conduct and any other material that poses a threat, as determined by the Commission, by regulation, other than spent nuclear fuel and special nuclear materials.

This final rule on National Source Tracking meets the requirements of the Energy Policy Act of 2005 applicable to source tracking. The provisions of this final rule are also consistent with the RDD report recommendations for development of a national source tracking system and with the Code of Conduct recommendation that a source registry be established.

Source tracking is only one aspect of NRC's efforts to enhance the control of radioactive material of greatest concern. The National Source Tracking System alone will not ensure the physical protection of sources, but it will provide greater source accountability. This final rule complements the final security rule on import/export of radioactive material that was published in the *Federal Register* on July 1, 2005. The National Source Tracking System is also aligned with the controls imposed on irradiator, manufacturer and distributor, and other materials licensees and on the transportation of radioactive materials in quantities of concern.

All these activities, along with current regulations, form NRC's foundation for control of radioactive material. All these activities are integrated and complement each other. For example, the advance notifications required by the import/export final rule will be recorded in the National Source Tracking System database. The additional controls imposed on materials licensees include provisions on shipments and transfers of radioactive material. The staff will codify the security and control requirements currently being imposed in future rulemakings. Current regulations require licensees to immediately report to NRC or the appropriate Agreement State any lost, stolen, or missing licensed material at thresholds that include the Category 1 or Category 2 level. This final rule, however, only addresses National Source Tracking, and includes the requirements necessary to directly support the system; it does not address other control measures, source transportation, or the reporting of lost/stolen sources.

#### **DISCUSSION:**

The final rule will establish the regulatory framework for the National Source Tracking System for NRC licensees. The final rule will require licensees to report to the National Source Tracking System the manufacture, transfer, receipt, disassembly, and disposal of nationally tracked sources. The transaction for disassembly of sources was added to the final rule based on comments received from industry. Basic information to be collected will include the manufacturer, model number, serial number, radioactive material, activity, and manufacture date for each source. In addition, information on the facilities involved in the transaction (facility name, address, license number, and name of the individual preparing the report) will be collected, as well as the transaction date. For transfers, the estimated arrival date will also be required. Actual transportation of the sources will not be tracked in the National Source Tracking System. For transactions that involve the source as part of a waste shipment or disposal, the licensee will need to provide the waste manifest number and the container identification for the container with the source. Waste brokers and personnel at disposal facilities will not be expected to open the container to verify that the source is included.

Licensees will be able to provide information on-line, by electronic batch file, mail, fax, or telephone. Each licensee will be required to report its initial inventory of nationally tracked sources. Licensees will be required to report all inventories of Category 1 nationally tracked sources by March 15, 2007, and all inventories of Category 2 nationally tracked sources by March 30, 2007. To ease the burden on licensees, the initial loading of information will be from the interim database. Each licensee that has reported source information to the interim database will be provided a copy of that source information and will be allowed to update it so that the inventory information is accurate by these dates. Transaction reporting for Category 1 and Category 2 sources will begin on March 15, 2007, and March 30, 2007, respectively. These dates are different from those in the proposed rule and reflect the earliest dates by which system development could be completed and the system operational. The system is expected to be operational no earlier than March 2007 and no later than June 2007. If the database is not ready in time to support the March dates, an administrative rule will be conducted to change the reporting dates. Specifying the earlier date in the rule allows us to take advantage of any potential early completion of the system.

To ensure that the information in the National Source Tracking System is up to date, the final rule will require that licensees report transaction information by the close of the next business day after the transaction occurs. The data in the National Source Tracking System will be considered Official Use Only - Security Related Information. The Information will not be considered to be either Safeguards Information or Safeguards Information - Modified Handling.

Information submitted to the National Source Tracking System must be complete and accurate in all material respects as required by NRC regulation. Licensees will be required to correct any error(s) in previously filed reports and to submit missing reports within 5 business days of the discovery of the error(s) or missed report. Each licensee will also be required to annually reconcile the information in the National Source Tracking System against its actual inventory. Each licensee also will be required to report that its information in the system is correct. The reconciliation process will be conducted in January of each year. This date was changed from June in the proposed rule to reflect the implementation date and in response to comments. These steps will promote the accuracy and reliability of the information in the system. In

addition, NRC plans to issue a RIS in early 2007 to remind licensees of the importance of providing accurate information to the system.

The final rule defines the term "nationally tracked source" as a sealed source containing a quantity of radioactive material equal to or greater than the Category 1 or Category 2 levels listed in the new Appendix E to 10 CFR Part 20. For the purpose of this rulemaking, the term "nationally tracked source" does not include material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet. The definition is based on the Code of Conduct and is consistent with the definition of sealed sources elsewhere in NRC regulations, and with definitions contained in Agreement State regulations.

The radionuclides to be included in the National Source Tracking System are the 16 radionuclides from the IAEA Code of Conduct and an additional four radionuclides added at the request of DOE. Because section 651(e) of the Energy Policy Act of 2005 places discrete sources of radium (Ra)-226 under NRC regulatory authority, Ra-226 is being added to Appendix E. The source tracking system that the Act requires NRC to establish covers "radiation sources" as defined in the Act (Category 1 or Category 2 sources and any other material as determined by the Commission other than spent nuclear fuel and special nuclear materials). Three plutonium (Pu) isotopes (Pu-236, Pu-239, Pu-240) are being removed from Appendix E because these isotopes are not "radiation sources" within the meaning of the Act. Two other Pu isotopes (Pu-238 and Pu-239/Be) are being retained in Appendix E because they are listed in the Code of Conduct.

The final rule also will require manufacturers of nationally tracked sources to assign unique serial numbers to all of the nationally tracked sources that they manufacture. This change is necessary because sources will be tracked within the National Source Tracking System by a combination of the manufacturer, model, and serial number.

Licensees currently are required to report lost or stolen sources to the NRC Operations Center or to their Agreement State regulator. Information on lost or stolen sources currently is placed in the Nuclear Material Events Database (NMED); this practice will continue. Agency staff will obtain the information on lost or stolen nationally tracked sources from the event reports and/or NMED and then enter the information into the National Source Tracking System. This approach avoids a duplication in reporting by licensees to both the Operations Center or Agreement State and the National Source Tracking System. This approach also responds to the Working Group and Steering Committee concern that licensees might report the information to the National Source Tracking System, believe that they had made all the necessary reports, and fail to report to the Operations Center. The information needed for the National Source Tracking System would not satisfy the information required for an event report. Information on destroyed sources (for example, a source destroyed in a fire or while being retrieved by a well-logging rig) would also be obtained from the event reports or NMED.

The SafeSource Steering Committee reevaluated the underlying basis for the national source tracking rule. The Steering Committee recommends the basis of the rule be changed to protection of the public health and safety from promotion of the common defense and security. The logic for the change in basis is provided in Enclosure 1. Because this represents a policy change for the National Source Tracking System the staff has prepared two versions of the Federal Register Notice and Regulatory Analysis. The first version (Enclosures 2 and 3) would

be used if the Commission were to change the basis of the rule to public health and safety. The change in basis would mean that NRC would publish a Federal Register notice of the basis change for a 20-day public comment period. The basis change would be published for public comment while the information collection for the final rule is being reviewed by OMB. The Federal Register notice for the basis change is provided as Enclosure 4. The second version (Enclosures 5 and 6) would be used if the Commission decided to retain common defense and security as the basis for the rule.

NRC specifically requested public comment on six topics: inclusion of Category 3 sources in the tracking system, inclusion of Ra-226 sources, inclusion of temporary job site reporting in the tracking system, waste shipment inspections, quality assurance, and data protection. These topics are addressed in subsections A through F of Section III of Enclosure 1. No changes to the rule were made as a result of the comments received on these topics.

Inclusion of Category 3 sources and temporary job site transfers in the tracking system generated the most interest from the stakeholders, with the majority of commenters opposed to the inclusion. Only six commenters supported the inclusion of Category 3 sources in the National Source Tracking System. Reasons cited for supporting Category 3 source tracking included the concern that an accumulation of smaller sources poses a risk, Category 3 sources posing a threat nearly comparable to Category 2 sources, prevention of the possible entry of sources into the scrap metal industry, use of the data to monitor market trends, and use of the data for allocating resources for programs to identify and develop alternative technologies.

Most of the commenters opposed to the inclusion of Category 3 level sources cited the increased burden that would be imposed on licensees and NRC. Several pointed out that many of the Category 3 sources are lower risk and do not pose a significant terrorist threat in comparison to Category 1 and Category 2 sources. Commenters expressed concern that inclusion of Category 3 sources would bog down the system development process, hinder the timely implementation of the system, and potentially degrade the quality of the information in the database. Even some commenters that supported the inclusion of Category 3 did not want the inclusion to slow down the requirements for reporting Category 1 and Category 2 source transactions.

At this point staff does not have adequate information to support the inclusion of Category 3 sources. In addition to the concerns from commenters mentioned, there also are issues related to possession of Category 3 sources under a general license that need to be addressed before a final decision can be made. In addition, the Radiation Source Protection and Security Task Force, established by the Energy Policy Act of 2005, will be reviewing whether changes to the National Source Tracking System are necessary, including whether Category 3 sources should be included. NRC staff recommends making the National Source Tracking System operational before adding another tier of sources and licensees. The staff will continue to evaluate adding Category 3 sources to the tracking system. If a decision is made to include Category 3 sources in the National Source Tracking System, there would be a separate rulemaking for that purpose. The staff is currently developing a paper that will address options for dealing with less than Category 2 sources. The paper will be provided to the Commission in late April of 2006.

Commenters opposed to the inclusion of reporting transactions at temporary job sites noted that the information reported would not add any value. The information would be out of date before it was reported because licensees may visit several temporary job sites in a given day.

Commenters also noted that due to the transitory nature of temporary job sites, there may be no easy means of providing the information (i.e., no computer, internet, fax, etc. at the remote locations). Several commenters felt that the risk of error would be increased due to the amount of movement of the sources on a daily basis and that the influx of this "less than meaningful" information would compromise the integrity of the entire database. Three States supported the inclusion of transfers of sources to temporary job sites. However, two of the three States only supported the reporting if the temporary job site involved crossing state lines. The other State argued that security at temporary job sites could be easily compromised and reporting would provide information on what sources are on the state highways.

The staff does not recommend the inclusion of temporary job site transfers. Additional security and control measures have been imposed on these licensees via Orders or other legally-binding requirements. The reporting of transfers between temporary job sites would impose a large additional burden on the industry without a corresponding benefit. The information reported would be out of date by the time it could be reported and could call into question the validity of the data in the system.

The final rule is consistent with NRC's strategic objective and performance goals. The final rule will continue to ensure the protection of the public health and safety and the environment, as well as continue to ensure the secure use and management of radioactive materials. While the final rule does not change the physical protection requirements for nationally tracked sources, the changes are part of a comprehensive radioactive source control program. The National Source Tracking System will provide greater source accountability, and, in conjunction with other activities, will result in improved security of nationally tracked sources. Information in the National Source Tracking System will enable NRC to better risk-inform its inspection and security program for byproduct material licensees by helping NRC to focus on those licensees that actually possess nationally tracked sources, thus making NRC actions more effective and efficient.

This rulemaking was conducted in an open process. The proposed rule was published in the *Federal Register* for a 75-day public comment period, and two public meetings were held during the public comment period. To assist licensees in implementing the final rule, NRC will provide licensees with written guidance and hands-on training. The guidance document will be available when the system has been fully developed, and will be used at training workshops NRC will conduct before the implementation date of the reporting requirements.

# AGREEMENT STATE ISSUES:

A copy of the draft final rule Federal Register notice was posted on NRC's Technical Conference Forum so the Agreement States could have an early opportunity for review. The National Source Tracking System, including the proposed rule, was also discussed at the Organization of Agreement States' annual meeting in October 2005.

Six Agreement States (Arkansas, Iowa, Kansas, Oklahoma, Texas, and Washington) provided comments on the draft Federal Register notice. Many of the comments expressed support for the manner in which NRC dealt with the public comments. The States also provided some editorial comments which the staff has incorporated as appropriate. Oklahoma, Kansas, Washington, and Arkansas all agreed that Category 3 sources should not be tracked. However, Kansas and Oklahoma stated that the inclusion of an annual inventory of Category 3

sources would be appropriate. The reporting of an annual inventory of Category 3 sources is beyond the scope of this rulemaking and is being addressed as part of the separate staff evaluation mentioned above.

Kansas and Oklahoma state that reporting every use at a temporary job site would be burdensome. However, both States believe that a temporary job lasting 24 hours or more and that involves a reciprocity notification should be reported. These States would like the information for checking what sources are within their borders. The system will not include information on reciprocity. Transfers of a source within the system are actually changes in possession of the source. A temporary job site does not include a change in possession. The staff concludes the additional burden on licensees is not justified, and reporting of temporary jobsite transfers should not be required.

Kansas and Oklahoma both believe that the States should have a role in confirming that the reconciliation process is being properly carried out. They believe that it should be part of the Agreement State's inspection process. They also suggested that licensees should be required to keep a record of each year's reconciliation including any corrections or differences. The final rule does not require licensees to maintain copies of the records submitted to the National Source Tracking System. NRC staff believes that this is an unnecessary burden on licensees because the system itself maintains an electronic record of every data change that is made. If a State is interested in the specific reports, the State can access the information through the system itself.

Arkansas, Iowa, Kansas, Washington, and Oklahoma object to designating the rule as Compatibility Category "NRC." Iowa, Kansas, Washington, and Oklahoma suggest a Compatibility Category of "B." They state that this would permit the Agreement States to regulate the National Source Tracking System consistent with the existing framework to implement Increased Controls. Washington notes the benefit in having NRC maintain a central database and that NRC would keep the function of tracking the sources. Kansas and Oklahoma prefer the states be responsible for inspection and enforcement to ensure licensee compliance with the source tracking rules. Kansas and Oklahoma also would like specific recognition of the ability of states to include an annual inventory of less than Category 2 sources.

Arkansas asserts that basing the rule on common defense and security will result in dual regulation of Agreement State licensees, which is particularly burdensome and troubling for these licensees. Arkansas notes that with this designation, the total enforcement of the rulemaking rests with the NRC. The Agreement States routinely conduct health and safety inspections and have established working relationships with their licensees. Arkansas points out that past experience has indicated that the states have not been willing to use 274i agreements when dealing with common defense and security matters. Arkansas expresses concern about the number of NRC staff available to conduct inspection of Agreement State licensees for compliance with this rulemaking. Arkansas argues that without Agreement State assistance, the database for the sources would probably not be completed in a timely manner and that enforcement and inspections should begin as quickly as possible. Arkansas further argues that delays because of NRC staffing issues could adversely affect the accuracy of the data and the effectiveness of the tracking system. The Agreement States would be available to inspect and ensure and assist in the accuracy of the system. Arkansas recommends that the Agreement States be allowed to adopt the NRC regulations relating to documentation

requirements for the tracking system while NRC would continue to maintain the computer database under common defense and security. Arkansas indicates that the enforcement of the rule could simply be health and safety.

The SafeSource Steering Committee met to readdress the issue of compatibility. The Steering Committee agreed with the arguments presented by the Agreement States and recommended that the basis of the rule should be changed to protection of the public health and safety. The Steering Committee viewed this as being consistent with the framework provided in the Orders for increased controls. See Enclosure 1 for additional information on the recommendation for the basis change. Under this approach, Agreement States will need to issue legally binding requirements for their licensees which can be accomplished through promulgating a comparable rule, issuing orders, or adding or revising individual license conditions. The Agreement States will have approximately 6 months in which to implement the legally binding requirements. The Agreement States will be responsible for ensuring implementation of the rule by their licensees, including inspection and enforcement.

NRC staff has analyzed the final rule in accordance with the procedures established within Part III of the Handbook to Management Directive 5.9, "Categorization Process for NRC Program Elements." Staff has determined that the final rule is an immediate mandatory matter of compatibility and should be classified as Compatibility Category "B." The NRC program elements in this category are those that apply to activities that have direct and significant transboundary implications. An Agreement State should adopt program elements essentially identical to those of NRC.

#### COMMITMENTS:

The staff will provide a paper to the Commission that will address options for dealing with less than Category 2 sources. The paper will be provided to the Commission near the end of April 2006.

The staff plans to issue a RIS on the importance of submitting accurate information to the National Source Tracking System. The RIS will be issued in early 2007.

# **RECOMMENDATIONS:**

#### That the Commission:

- 1. <u>Approve</u> for publication in the *Federal Register* the attached notice of the basis change (Enclosure 4).
- 2. <u>Approve</u> for publication in the *Federal Register* the attached notice of final rulemaking (Enclosure 2). If substantive comments are received on the basis change, the staff will resubmit the final rule package to the Commission for approval. If no substantive comments are received, the staff will submit the final rule to the Office of the Secretary for signature.
- 3. To satisfy the requirement of the Regulatory Flexibility Act, 5 U.S.C. 605 (b), <u>certify</u> 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.

## 4. 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 3);
- 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 has confirmed this determination with the Office of Management and Budget (OMB). The appropriate Congressional and Government Accountability Office contacts will be informed (Enclosure 7);
- 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, 0.1 full-time equivalent positions will be required. These resources are included in the current budget.

## 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 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/

Luis A. Reyes, Executive Director for Operations

#### Enclosures:

- 1. Basis Change Rationale
- 2. Rule Federal Register notice public health and safety
- 3. Regulatory Analysis public health and safety
- 4. Federal Register notice -basis change
- 5. Rule Federal Register notice common defense and security
- 6. Regulatory Analysis common defense and security
- 7. CRA forms

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/RA/ Luis A. Reyes, Executive Director for Operations

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