

## RULEMAKING ISSUE NOTATION VOTE

March 6, 2008

SECY-08-0031

FOR: The Commissioners

FROM: Luis A. Reyes  
Executive Director for Operations

SUBJECT: PROPOSED RULE: EXPANSION OF NATIONAL SOURCE  
TRACKING SYSTEM (RIN 3150-AI29)

PURPOSE:

The purpose of this paper is to request Commission approval to publish a proposed rule in the *Federal Register* that would amend 10 CFR Parts 20 and 32 of Title 10 of the *Code of Federal Regulations*. The proposed amendments would expand the current National Source Tracking System (NSTS) to include additional licensees who possess sealed sources containing greater than or equal to 1/10th of International Atomic Energy Agency (IAEA) Category 3<sup>1</sup> threshold levels. The proposed rule would require these additional licensees to report transactions involving the manufacture, transfer, receipt, disassembly, or disposal of these nationally tracked sources. This paper does not address any new commitments.

SUMMARY:

In November 2006, the U.S. Nuclear Regulatory Commission (NRC) issued a final rule to establish a national system for tracking of certain sources. The rule requires licensees who possess IAEA Category 1 and 2 sources to report certain inventory and transaction information to the NSTS, currently scheduled to be launched in January, 2009. In proceeding with this current rulemaking, the staff has considered whether the existing NSTS should be expanded to

CONTACTS: Michael Williamson, FSME/DILR  
(301) 415-6234

Frank Cardile, FSME/DILR  
(301) 415-6185

include Category 3 (or lower) sources to improve accountability and control over these sources and to reduce the potential for lower activity sources being accumulated (aggregated) to higher

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<sup>1</sup> Sources referred to as "1/10th of Category 3" were formerly referred to as "Category 3.5" sources. To be consistent with IAEA terminology, the term "Category 3.5" has been changed to "1/10th of Category 3."

activity levels. Based on technical and policy considerations, and a regulatory analysis, the staff is requesting Commission approval to publish a proposed rule in the *Federal Register* that would amend 10 CFR Parts 20 and 32 to expand the NSTS to include sources greater than or equal to 1/10th of the IAEA Category 3 threshold.

#### BACKGROUND:

As a result of the September 11, 2001, attacks in the United States, NRC has undertaken a comprehensive review of nuclear material security requirements, with particular focus on risk-significant radioactive materials of concern. These materials have the potential to be misused in the absence of proper security measures. As part of this effort, the U.S. Government made a non-legally binding commitment to the IAEA Code of Conduct for safety and security of radioactive sources (henceforth referred to as the Code), which included a national registry of sources. Consequently, NRC issued a final rule in the *Federal Register* on November 8, 2006 (71 FR 65686), to establish a national system for source tracking. Under this program, licensees who possess IAEA Category 1 and 2 sources are required to report information on the manufacture, transfer, receipt, and disposal of nationally tracked sources. The implementation date for the NSTS has been extended to January 31, 2009.

In the 2006 rulemaking, the Commission specifically invited and received comments on whether Category 3 sources should be included in the NSTS (71 FR 65692). In response to the public comments received, the Commission noted that at that time it did not have adequate information to support inclusion of Category 3 sources in the NSTS; however it also noted that it was working to collect additional information by conducting a one-time survey of sources at a level of 1/10th of Category 3. It was also noted that a final determination on what additional sources should be included in the NSTS would be deferred to a subsequent rulemaking, which is the subject of this rulemaking.

During the process of 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 controls for IAEA Category 3 sources (SECY-06-0094, April 24, 2006). In response to that paper, the Commission, in a staff requirements memorandum (SRM) dated June 9, 2006, directed the staff to collect the additional information noted above. The Commission also requested that the staff prepare a proposed rule which would consider expanding the NSTS to include Category 3 sources. Subsequently, in response to recommendations made by the U. S. Government Accountability Office regarding security issues in NRC's materials program, the staff provided the Commission with an Action Plan (SECY-07-0147, August 25, 2007) which included, as Recommendation S-2b, an action item indicating that the scope of the rulemaking to expand the NSTS should also include sources equal to 1/10<sup>th</sup> of Category 3. On September 18, 2007, the Commission approved the staff's Action Plan in SRM-SECY-07-0147.

#### DISCUSSION:

The IAEA source categorization scheme<sup>2</sup> includes five categories that are based on the potential for sources to cause deterministic health effects to persons exposed to them. Sources in Category 1 and 2 are considered to be the most "dangerous" because they can pose a high risk to human health if not managed safely and securely. Category 3 sources are less than the

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<sup>2</sup> RS-G-1.9 "Categorization of Radioactive Sources"

Category 2 threshold and the Category 3 threshold is equal to or greater than 1/10th of Category 2; the Category 4 threshold quantities are 1/100th of the Category 3 quantities. At the lower end of the categorization system, sources in Category 5 are the least dangerous; however, even these sources could give rise to doses in excess of the dose limits if not properly controlled.

In the rulemaking establishing the NSTS for Category 1 and 2 sources, specific rationale was provided for establishing tracking and initial inventory requirements for start-up purposes of the NSTS for Category 1 and 2 sources. In that rulemaking, it was noted that the U.S. Department of Energy (DOE)/NRC analysis of potential health effects from use of sources in a Radiological Dispersal Device or a Radiological Exposure Device identified radionuclide “quantities of concern” to be in a range similar to the IAEA Category 2 threshold values. Therefore, to allow alignment between domestic and international efforts to increase safety and security of radioactive sources, NRC adopted the IAEA Category 2 values and used them as a threshold in its November 2006 rulemaking decision regarding sources requiring tracking and inventorying in a national source tracking system.

In preparing this proposed rule, the staff has determined that there is a need to enhance the tracking of lower activity sources to improve accountability of these sources and to provide additional protection against aggregation of these sources to higher activity levels (e.g. above the Category 2 threshold). At issue is the extent appropriate for expanding the NSTS beyond Category 2, i.e., should the NSTS be expanded to include IAEA Category 3 sources or should it be expanded even further to include sources that are 1/10th of the Category 3 threshold (which would actually be a subgroup of the high-end of activities in the Category 4 source range). The staff considered, separately, the issues associated with adding each of these categories as discussed in Items 1 and 2, below.

### 1. Expanding the NSTS to Include Category 3 Sources

The staff believes that there is a need to enhance the accountability of Category 3 sources through improved tracking of these sources. The IAEA’s Code contains basic principles that the IAEA believes are necessary for the safe and secure use of radioactive materials. In the Code, the IAEA defines Category 3 sources (as well as the Category 1 and 2 sources) as “dangerous sources,” i.e., a source that could, if not under control, give rise to exposure sufficient to cause severe deterministic effects. The Code does not require tracking of sources below the Category 2 threshold. However, within the Code’s framework, individual member states may choose to track smaller sources. On the basis of its inclusion in the Code, the staff believes it is reasonable to include these Category 3 sources in the NRC’s source tracking system.

In addition, there is a potential for aggregation of Category 3 sources to a Category 2 level. This is considered by the NRC to be a “quantity of concern.” Category 3 sources could be readily aggregated to Category 2 levels, as part of a concerted effort to do so, 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, sources at the high end of the range of activities in Category 3 can be at levels just below the threshold of a Category 2 source, meaning that it could take only a few sources to aggregate to Category 2. Major categories of licensees who possess Category 3 sources include fixed industrial gauges, well-logging operations, and brachytherapy machines. Because these sources are thus relatively widespread in use and relatively broadly used in industry, there would be potential for aggregation of sufficient numbers of them to

Category 2 levels. Adding these sources to the NSTS with its initial inventory for startup and tracking requirements will provide for increased accountability and control of these sources because there would be a near real-time knowledge of source whereabouts and an ability to confirm an individual licensee's account of their sources.

Adding Category 3 sources to the NSTS would result in increased burden to the NRC and to the licensed industry for implementation and maintenance of the expanded NSTS. In the Regulatory Analysis (Enclosure 2) for this rulemaking, the staff analyzed the additional costs and benefits of expanding the NSTS to Category 3 levels. The existing NSTS has approximately 1,300 NRC and Agreement State licensees. An expanded NSTS including Category 3 sources would add approximately 1,000 licensees. As estimated in the Regulatory Analysis, the resultant overall annual cost to the industry and to the NRC would be approximately doubled as a result of this expansion. However the Regulatory Analysis concluded that this additional burden would be reasonable to incur given the additional improvement in accountability and control of these sources, and resultant enhancement of NRC's ability to protect public health and safety.

In addition to burden on licensees, there could be burden on NRC's tracking system itself due to the addition of licensees. The Commission in its June 9, 2006, SRM specifically directed the staff to consider whether an expanded NSTS would impact the NRC's ability to monitor Category 1 and 2 sources. The staff does not expect that expansion of the NSTS will compromise the information technology (IT) aspects of the NSTS due to the capabilities incorporated into the NSTS software. Since the IT design and software are flexible and expandable, the NSTS can accommodate the anticipated number of licensees and sources and the corresponding tracking activities. Although additional effort will need to be expended to monitor an expanded NSTS, NRC should be able to continue to adequately monitor the expanded NSTS and identify possible aggregation of sources if those resources are provided.

As previously stated, the Commission has received public comment on the issue of including Category 3 sources in the NSTS. Briefly stated, there were commenters that supported inclusion of Category 3 sources in the NSTS for some of the same reasons noted above, whereas a larger number of commenters opposed the inclusion of Category 3 sources based on the relatively low risk they present compared to the perceived large increased burden of adding these sources to the NSTS. In further considering these comments during this current rulemaking, the staff believes that it has considered the concerns of the commenters, pro and con, and evaluated the additional burdens which the rule would impose, in reaching its decision to include Category 3 sources in the NSTS.

Based on the IAEA definition of Category 3 as "dangerous" and the potential for aggregation to Category 2 quantities of concern, the staff believes that the same information to be included in the NSTS for Category 1 and Category 2 sources is also needed for Category 3 sources. Expanding the scope of the NSTS would provide NRC with information regarding purchases/transactions of sufficient numbers of Category 3 sources that could be aggregated into the equivalent of Category 2 sources. Tracking specific transactions of Category 3 sources enhances accountability and would detect situations where a licensee's aggregate sources would create larger (more dangerous) quantities.

## 2. Considerations of Expanding the NSTS to Include Sources at 1/10th of Category 3

The staff also gave consideration to expanding the NSTS to sources below the Category 3 threshold, specifically to include a subset of IAEA Category 4 sources that are in the high end of the Category 4 radioactivity range (i.e., at a level of 1/10th of the Category 3 threshold) because of the potential for them to be aggregated to Category 2.

A principal rationale for including sources at 1/10th of the Category 3 threshold is the potential that a sufficient number of these higher-activity Category 4 sources could be obtained and aggregated to create the equivalent of Category 2 sources. These “high-end” Category 4 sources can be at levels just below the threshold of a Category 3 source, which is about 1/10th of the threshold of a Category 2 source, meaning that it would require about 10-12 of these sources to aggregate to Category 2. These high-end Category 4 (1/10th of Category 3) sources are possessed by the same licensees noted above, namely those with fixed industrial gauges, well-logging operations, and brachytherapy machines, and, as noted above, are relatively widespread in use and relatively broadly used in industry, thus allowing for the potential for aggregation of sufficient numbers of them to Category 2 levels.

As noted above for Category 3 sources, the staff estimated the additional costs and benefits of expanding the NSTS to 1/10th of the Category 3 threshold. As noted in the Regulatory Analysis, an expanded NSTS to include 1/10th of Category 3 sources would add approximately 2,500 licensees with a resultant overall annual cost to the industry that would be approximately doubled again. The staff recognizes that there is likely to be an expansion of calls to the help desk to clarify NSTS reporting requirements. With regard to the burden on the NSTS software and NRC resources, the staff believes that the system can accommodate these additional sources and that application of appropriate resources would not result in the expanded NSTS diverting attention from the monitoring of higher-risk Category 1 and 2 sources.

Based on these considerations of the nature of the sources at 1/10th of Category 3, their potential to aggregate to Category 2, and the costs to the licensed industry and the NRC, the staff concluded, using information from the Regulatory Analysis, that the additional costs are reasonable to incur given the additional improvement in accountability and control of these sources. Thus, the staff concluded that it was appropriate to also include, in the NSTS, sources below the Category 3 threshold but greater than or equal to 1/10th of the Category 3 threshold.

Because the inclusion in the NSTS of these sources at a level of 1/10th of Category 3 has not been addressed in previous Commission rulemaking documents and because of the lower potential for aggregation than for the Category 3 sources, the staff suggests in the *Federal Register* Notice (FRN) that the NRC specifically invite comment on the inclusion of these sources at 1/10th of Category 3 in the NSTS and asks three specific questions in the FRN related to numbers of licensees, numbers and types of sources, and the nature of the transaction process, so as to better inform NRC's decision-making on the inclusion of sources greater than or equal to 1/10th of Category 3 in the NSTS.

### 3. Staff 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 and that also are greater than or equal to 1/10th of the Category 3 threshold. Expanding the NSTS to all sources greater than or equal to 1/10th of Category 3 would use the same web-based system as for Category 1 and 2 sources, thereby providing NRC with information regarding transactions involving sufficient

numbers of sources equal to or greater than 1/10th of Category 3 that could be aggregated into the equivalent of a Category 2 source. Tracking specific transactions of sources greater than or equal to 1/10th of Category 3, enhances accountability for more sources, and would detect situations where a licensee's aggregate sources would create larger (more dangerous) quantities. In addition, with an expanded NSTS, NRC can be alert to discrepancies between transaction reports of manufacturing and distribution licensees and of the persons to whom the shipment of sources is being made. Data from the NSTS could be used in conjunction with other data management systems to provide for better source accountability. Expanding the NSTS is part of a comprehensive radioactive source control program, as discussed in SECY-07-0147. Although neither the existing NSTS, nor an expanded NSTS, can ensure the physical protection of sources, they can aid in providing greater source accountability.

Based on the considerations noted above, the proposed rule would expand the existing NSTS by requiring licensees with sources greater than or equal to 1/10th of Category 3 to report information to the NSTS on the manufacture, transfer, receipt, disassembly, and disposal of specifically-licensed sources. The expanded NSTS would remain consistent with international obligations and consistent with recommendations in the IAEA Code of Conduct for development of a national register of radioactive sources.

The FRN for this proposed rule (Enclosure 1) contains specific information on the content of this expanded NSTS. Since the actions required for reporting by the additional licensees subject to the NSTS are the same as those for licensees currently within the scope of the NSTS, information in Enclosure 1 is based on the FRN for the final rule establishing the NSTS for IAEA Category 1 and 2 sources (71 FR 65686). The information in Enclosure 1 provides licensees new to the NSTS, i.e., those with sources greater than or equal to 1/10th of Category 3 with similar information as was provided in the FRN for the final rule establishing the NSTS for IAEA Category 1 and 2 sources.

The staff considered an alternate approach for this rulemaking which would be to simply require licensees with sources greater than or equal to either the Category 3 threshold or 1/10th of the Category 3 threshold to conduct and report inventories of the sources in their possession. However, this alternative would not provide the necessary knowledge of source transactions in a timely manner and, in addition, lack of transaction data from other licensees would not tend to lead to a cross-check for accurate reporting of inventories. In addition, there would still be significant costs incurred as a result of such a rule including the costs of setting up an account in the NSTS (including licensee credentialing); of conducting inventories; of marking serial numbers; of inspection; of preparing Agreement State regulations; and of NRC system monitoring, operation, and maintenance.

It should be noted that some Category 3 sources are contained in generally licensed devices. At the present time, generally licensed devices are exempt from the reporting requirements of the NSTS. In this context, the staff has a separate proposed rulemaking in progress which would expressly change the requirements for generally licensed devices so that these sources would only be possessed by specific licensees, and thus subject to the reporting requirements of an expanded NSTS.

The staff has met with DOE staff to discuss this rulemaking on the expansion of the NSTS to 1/10th of Category 3. DOE staff views were helpful and were considered in the development of this proposed rule. DOE's approach for expanding the NSTS for sources under their jurisdiction

is still under consideration and NRC staff plans to continue working with DOE to coordinate our approaches.

The proposed rule is consistent with NRC strategic objectives and performance goals. The proposed rule would continue to ensure the protection of public health and safety and the environment, as well as continue to ensure the secure use and management of radioactive materials. While the proposed rule would not change the physical protection requirements for nationally tracked sources, the proposed changes are part of a comprehensive radioactive source control program. The proposed expanded NSTS would provide greater source accountability. Information in the expanded NSTS will enable NRC to better risk-inform its inspection and programs for byproduct material licensees by helping NRC focus on those licensees that actually possess nationally tracked sources, thus making NRC actions more efficient and effective.

The rulemaking will be conducted in an open process. The proposed rule will be published in the *Federal Register* for a 75-day public comment period. The draft proposed rule was prepared with participation by Agreement State representatives and the draft proposed rule was provided to the Agreement States for preliminary review. It is anticipated that to assist licensees in implementing the requirements of an expanded NSTS that NRC would provide licensees with guidance similar to that done for the current NSTS regulation for IAEA Category 1 and 2 sources.

#### Agreement State Issues

A copy of the draft proposed rule FRN was provided to the Agreement States on December 17, 2007, so they could have an early opportunity for review.

Five Agreement States, Colorado, Iowa, Illinois, Washington, and Wisconsin provided comments on the draft FRN.

One State commented that there was an error on the draft table of Appendix E of 10 CFR Part 20. They noted that the Category 3 and 1/10th of Category 3 threshold levels were off by a factor of 10. The values listed were 1/100th of the of the threshold values not 1/10th and were corrected to be 1/10th of the threshold value. Three commenters commented on the effect that the rulemaking would have on generally licensed devices because the text of the rulemaking deals mainly with specifically licensed devices. This rulemaking applies to specifically licensed devices only; a separate rulemaking for generally licensed devices is currently in development. One commenter suggested that import licenses of Category 3 sources and 1/10th Category sources be extended if tracking at this level is determined to be necessary. In addition, they stated consideration should be given to clarify the intent of the transfer of sources for companies who have multiple licenses in different states. These comments were considered and not added to this rulemaking at this time. One commenter agreed with the text of the rulemaking and provided suggestions on ways to ease the burden and make the process of entering data into the NSTS more effective and efficient. Two commenters stated that the NSTS is not yet up and running and the NRC is premature in promulgating this rule. Currently as it stands, the NRC expects that the NSTS will be fully functional by the time this rule goes into final publication, therefore, the Agency will keep the current schedule for this rulemaking. A commenter from the State of Colorado inquired if the Increased Controls requirements (typically Category 1 and 2) applied to this rulemaking.

Increased Control requirements only apply to Category 3 and 1/10th of Category 3 sources if they are aggregated to Category 2 levels. One commenter stated that this rulemaking would add increased burden on their State and increase the number of sources tracked from 135 to 1,092. They also stated that 1/10th of Category 3 is inconsistent with the definition of a "dangerous source." However, the staff felt it was necessary to consider 1/10th of Category 3 source material in this rulemaking because of the issue of aggregation.

NRC staff has analyzed the proposed 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 proposed rule is 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. The Compatibility Category B is the Category that was assigned to the final rule for issuance of the NSTS for IAEA Category 1 and 2 sources.

#### RECOMMENDATIONS:

The staff recommends that the Commission:

1. Approve for publication, in the *Federal Register*, the proposed amendments to Parts 20 and 32 of 10 CFR (Enclosure 1).
2. Note:
  - a. That the proposed amendments will be published in the *Federal Register*, allowing 75 days for public comment.
  - b. That 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).
  - c. That a Regulatory Analysis has been prepared for this rulemaking (Enclosure 2).
  - d. That appropriate Congressional committees will be informed of this action.
  - e. That a press release will be issued by the Office of Public Affairs when the proposed rulemaking is filed with the Office of the Federal Register.
  - f. Office of Management and Budget (OMB) review is required and a clearance package will be forwarded to OMB no later than the date the proposed rule is submitted to the Office of the Federal Register for publication.

#### RESOURCES:

To complete and implement the rulemaking, 1.5 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 proposed 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 OMB no later than the date the proposed rule is forwarded to the *Federal Register* for publication.

***/RA/***

Luis A. Reyes  
Executive Director  
for Operations

Enclosures:

1. *Federal Register* Notice
2. Regulatory Analysis

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 20 and 32

RIN: 3150-AI29

Expansion of the National Source Tracking System

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Proposed rule.

**SUMMARY:** The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations to expand the current National Source Tracking System (NSTS) to include certain additional sealed sources. The proposed amendments would require licensees to report certain transactions involving these sealed sources to the NSTS. These transactions would include the manufacture, transfer, receipt, disassembly, or disposal of the nationally tracked source. The proposed amendment would also require each licensee to provide its initial inventory of nationally tracked sources to the NSTS and annually verify and reconcile the information in the system with the licensee's actual inventory.

**DATES:** Submit comments on the rule by (**insert 75 days after publication in the *Federal Register***). Submit comments specific to the information collection aspects of this rule by (**insert date 30 days after publication in the *Federal Register***). Comments received after the above date will be considered if it is practical to do so, but the NRC is able to assure consideration only for comments received on or before this date.

**ADDRESSES:** You may submit comments on the rule by any one of the following methods.

Please include the following number RIN 3150-AI29 in the subject line of your comments.

Comments on rulemakings submitted in writing or in electronic form will be made available to the public in their entirety in NRC's Agencywide Document Access and Management System (ADAMS). Personal information, such as your name, address, telephone number, e-mail address, etc., will not be removed from your submission.

Mail comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff.

E-mail comments to: [SECY@nrc.gov](mailto:SECY@nrc.gov). If you do not receive a reply e-mail confirming that we have received your comments, contact us directly at 301-415-1677. Comments can also be submitted via the Federal eRulemaking Portal <http://www.regulations.gov>.

Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 am and 4:15 pm Federal workdays. (Telephone 301-415-1677)

Fax comments to: Secretary, U.S. Nuclear Regulatory Commission at 301-415-1101.

You may submit comments on the information collections by the methods indicated in the Paperwork Reduction Act Statement.

Publicly available documents related to this rulemaking may be viewed electronically on the public computers located at the NRC's Public Document Room (PDR), O1 F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland. The PDR reproduction contractor will copy documents for a fee.

Publicly available documents created or received at the NRC after November 1, 1999, are available electronically at the NRC's Electronic Reading Room at <http://www.nrc.gov/reading-rm/adams.html>. From this site, the public can gain entry into ADAMS, which provides text and image files of NRC's public documents. If you do not have

access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the PDR Reference staff at 1-800-397-4209, 301-415-4737 or by e-mail to [pdr@nrc.gov](mailto:pdr@nrc.gov).

FOR FURTHER INFORMATION CONTACT: Michael Williamson, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-6234, e-mail, [mkw1@nrc.gov](mailto:mkw1@nrc.gov).

**SUPPLEMENTARY INFORMATION:**

- I. Background.
- II. Discussion.
  - A. Rationale for expanding the NSTS to include additional source categories.
  - B. Enhanced accountability provided by these amendments
  - C. Other considerations.
  - D. General content of the proposed rule.
- III. Discussion of Proposed Amendments by Section.
- IV. Criminal Penalties.
- V. Agreement State Compatibility.
- VI. Plain Language.
- VII. Voluntary Consensus Standards.
- VIII. Environmental Impact: Categorical Exclusion.
- IX. Paperwork Reduction Act Statement.
- X. Public Protection Notification.

XI. Regulatory Analysis.

XII. Regulatory Flexibility Certification.

XIII. Backfit Analysis.

## I. Background

After the terrorist attacks in the United States on September 11, 2001, the NRC conducted a comprehensive review of nuclear material security requirements, with particular focus on radioactive material of concern. This radioactive material (which includes Cobalt-60, Cesium-137, Iridium-192 (Ir-192), and Americium-241, as well as other radionuclides) has the potential to be used in a radiological dispersal device (RDD) or a radiological exposure device (RED) in the absence of proper security and control measures. The NRC's review took into consideration the changing domestic and international threat environments and related U.S. Government-supported international initiatives in the nuclear security area, particularly activities conducted by the International Atomic Energy Agency (IAEA).

In June 2002, the Secretary of Energy and the NRC Chairman met to discuss the adequate protection of inventories of nuclear materials that could be used in a RDD. At the June meeting, the Secretary of Energy and the NRC Chairman agreed to convene an Interagency Working Group on Radiological Dispersal Devices to address security concerns. In May 2003, the joint U.S. Department of Energy (DOE)/NRC report was issued. The report was entitled, "Radiological Dispersal Devices: An Initial Study to Identify Radioactive Materials of Greatest Concern and Approaches to Their Tracking, Tagging, and Disposition." One of the report's recommendations is development of a national source tracking system to better understand and monitor the location and movement of sources of interest. The full report

contains a list of radionuclides and thresholds above which tracking of the sources is recommended.

The NRC has also supported U.S. Government efforts to establish international guidance for the safety and security of radioactive materials of concern. This effort has resulted in a major revision of the IAEA Code of Conduct on the Safety and Security of Radioactive Sources (Code of Conduct). The revised Code of Conduct was approved by the IAEA Board of Governors in September 2003, and is available on the IAEA Web site. In particular, the Code of Conduct contains a recommendation that each IAEA Member State develop a national source registry of radioactive sources that includes at a minimum Category 1 and Category 2 radioactive sources as described in Annex 1 of the Code of Conduct. The source registry recommendation addressed 16 radionuclides.

The work on the DOE/NRC joint report was done in parallel with the work on the Code of Conduct and the development of IAEA TECDOC-1344, "Categorization of Radioactive Sources." The IAEA published this categorization system for radioactive sources in August 2005 in its Safety Series as RS-G-1.9, Categorization of Radioactive Sources. The report, available on the IAEA Web site, provides the underlying methodology for the development of the Code of Conduct thresholds. The categorization system is based on the potential for sources to cause deterministic effects and uses the 'D' values as normalizing factors. The 'D' values are radionuclide-specific activity levels for the purposes of emergency planning and response. The quantities of concern identified in the DOE/NRC report are similar to the Code of Conduct Category 2 threshold values, so to allow alignment between domestic and international efforts to increase the safety and security of radioactive sources, NRC has adopted the Category 2 values. The NRC considers IAEA Category 2 (and higher) to be risk-significant radioactive material that has a potential to result in significant adverse impacts that

could reasonably constitute a threat to the public health and safety, the environment, or the common defense and security of the United States.

Subsequently, the NRC published a final rule in the *Federal Register* on November 8, 2006 (71 FR 65686), establishing a national system for source tracking. Under this program, certain 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. This information is to be used to support the National Source Tracking System (NSTS) and will provide the NRC with a life cycle account for these sources and, thus, improve accountability and controls over them. The final rule establishing the 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 31, 2009 (72 FR 59162).

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 one of the objectives of the Code of Conduct which is to prevent unauthorized access or damage to, and loss, theft or unauthorized transfer of, radioactive sources.

In the 2005 proposed rulemaking, the Commission specifically invited comments on whether Category 3 sources should be included in the NSTS. In response to the public comments received, the Commission indicated that it was deferring a final determination on what additional sources should be included in the NSTS to a subsequent rulemaking (71 FR 65692). The Commission is now conducting that subsequent rulemaking.

## II. Discussion

In this rulemaking, NRC is proposing to amend its regulations to expand the NSTS to require licensees to report information on the manufacture, transfer, receipt, disassembly, and disposal of additional nationally tracked sources. In determining whether to expand the NSTS to include additional sources, the NRC has considered the need to balance the secure handling and use of the materials without discouraging their beneficial use in academic, medical, and industrial applications. Radioactive materials provide critical capabilities in the oil and gas, electrical power, construction, and food industries; are used to treat millions of patients each year in diagnostic and therapeutic procedures; and are used in technology research and development involving academic, government, and private institutions. These materials are as diverse in geographical location as they are in functional use.

Expanding the NSTS is part of a comprehensive radioactive source control program for radioactive materials of greatest concern, as discussed SECY-07-0147, "Response to U.S. Government Accountability Office Recommendations and other Recommendations to Address Security Issues in the U.S. NRC Materials Program," dated August 25, 2007. Although neither the currently planned NSTS, nor an expanded NSTS, can ensure the physical protection of sources, the NSTS can provide greater source accountability and, as part of an overall effort, 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, as well as common defense and security.

Section II of this preamble discusses the overall rationale for expanding the NSTS to include additional sources (Section II.A); how these amendments can improve accountability of

sources (Section II.B); and other considerations (Section II.C). The general content of the proposed rule is discussed in Section II.D.

## A. Rationale for Expanding the NSTS to Include Additional Source Categories

### A.1 Congressional Concerns/GAO Investigations.

Concerns by members of the U.S. Congress, and the Government Accountability Office (GAO), have been expressed regarding the aggregation of lower activity sources whose activity level, if taken together, could exceed the Category 2 threshold. Although a GAO investigation involved obtaining sources lower than Category 3 (i.e., in the low range of Category 4), the concerns expressed by members of Congress and the GAO over security issues associated with the NRC materials program have been considered in this rulemaking. Specifically, as a result of an investigation, GAO stated in its report (GAO Testimony, GAO-07-1038T, “Actions Taken by NRC to Strengthen Its Licensing Process for Sealed Radioactive Sources”, July 12, 2007) that NRC should regulate Category 3 sources more stringently (Recommendation B of the report) and that NRC should consider including Category 3 sources in the NSTS (Recommendation B.2).

### A.2 Recent NRC Actions.

In addition to the issues noted by the GAO, the NRC staff prepared SECY-06-0094, “Tracking or Providing Enhanced Controls for Category 3 Sources,” April 24, 2006, for the Commission’s review. This paper contained options for tracking and/or providing enhanced

controls for Category 3 sources. In response to that paper, the Commission provided direction to the NRC staff in SRM-SECY-06-0094, dated June 9, 2006, regarding enhanced controls for Category 3 sources. Specifically, the SRM noted that the staff should submit a proposed rule for the Commission to consider including Category 3 data in the NSTS.

Subsequently, in response to Recommendations B and B.2 of the GAO report discussed in this preamble, NRC staff provided the Commission with an Action Plan in SECY-07-0147. The Action Plan, entitled “Action Plan to Respond to Recommendations to Address Security Issues in the U.S. NRC Materials Program,” included, as Recommendation S-2b, an action 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 SRM-SECY-07-0147.

A.3. Considerations regarding the need for expanding the NSTS and the extent to which the NSTS should be expanded, i.e., what categories (or sub-groups of categories) of sources to be included.

A.3.1 The five IAEA Categories and the relative health and safety risk posed by sources in those Categories

The IAEA source categorization scheme includes five categories<sup>1</sup>. These categories are based on the potential for sources to cause deterministic health effects to persons exposed to them. Sources in Category 1 are considered to be the most ‘dangerous’ because they can pose a very high risk to human health if not managed safely and securely. At the lower end of the categorization system, sources in Category 5 are the least dangerous; however, even these

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<sup>1</sup> RS-G-1.9 “Categorization of Radioactive Sources.”

sources could give rise to doses in excess of the dose limits if not properly controlled. Based on analysis of potential health effects, each of the IAEA Categories contain radioactive material in sealed sources in quantities that can be characterized as follows:

Category 1: greater than or equal to the Category 1 threshold (e.g., for Cobalt-60 (Co-60): 810 Curies (Ci)); these sources are typically used in practices such as radiothermal generators, irradiators and radiation therapy.

Category 2: less than the Category 1 threshold but equal to or greater than the Category 2 threshold (which is 1/100th of Category 1); (e.g., for Co-60: 8.1 Ci); these sources are typically used in practices such as industrial gamma radiography and high and medium dose rate brachytherapy.

Category 3: less than the Category 2 threshold but equal to or greater than the Category 3 threshold (1/10th of Category 2); (e.g., for Co-60: 0.81 Ci); these sources are typically used in practices such as fixed industrial gauges involving high activity sources.

Category 4: less than the Category 3 threshold but equal to or greater than the Category 4 threshold (1/100th of Category 3); (e.g., for Co-60: 0.0081 Ci);

Category 5: less than the Category 4 threshold down to IAEA exempt quantities.

The scope of IAEA's *Code of Conduct on the Safety and Security of Radioactive Sources* is limited to Categories 1-3, i.e., those having the highest potential to cause permanent injury or death when used in a malevolent manner.

### A.3.2 Rationale in the existing NSTS rule for imposing the requirement to track Category 1 and 2 sources

In the rulemaking establishing the NSTS for Category 1 and 2 sources, specific rationale was provided for establishing tracking and inventory requirements for Category 1 and 2 sources. In that rulemaking, as discussed in Section 1 of this preamble, it was noted that the DOE/NRC analysis of potential health effects from use of sources in a RDD or a RED identified radionuclide “quantities of concern” to be in a range similar to the IAEA Category 2 threshold values. Therefore, to allow alignment between domestic and international efforts to increase safety and security of radioactive sources, NRC adopted the IAEA Category 2 values and used them as a threshold in its rulemaking decision regarding sources requiring tracking and inventorying in a national source tracking system.

### A.3.3 Discussion in the previous NSTS rulemaking for including additional IAEA Categories in the NSTS

In conducting the rulemaking to establish the NSTS, the Commission noted that Category 3 sources could be included in the NSTS in the future, citing the potential that a licensee possessing a large number of Category 3 sources could present a security concern. Therefore, as part of that rulemaking, the Commission sought comment and information on the issue of including Category 3 sources in the NSTS. These comments are summarized in Section II.C.2. Based on its review of those comments, the Commission, in issuing the final rule to establish the NSTS, noted that it did not have adequate information at that point in time to support inclusion of Category 3 sources in the NSTS, however, it also noted that it was

working to develop additional information by conducting a one-time survey of sources at a level of 1/10th of Category 3. The Commission then noted that, in that rulemaking, it was not making a final determination on what additional sources should be included in the NSTS and that if additional material is added to the NSTS, it would be done through subsequent rulemaking. The Commission is now conducting that subsequent rulemaking.

#### A.3.4. Rationale for inclusion of additional sources in an expanded NSTS in this rulemaking

In preparing this proposed rule, NRC has determined that there is a need to enhance the tracking of lower activity sources to improve accountability for these sources and to provide the ability to detect situations where a licensee's aggregate sources would create larger (more dangerous) quantities. At issue is the extent appropriate for expanding the NSTS beyond Category 2, i.e., should the NSTS be expanded to include IAEA Category 3 sources (as suggested in the June 9th, 2006 SRM) or should it be expanded even further to include sources that are 1/10th of the Category 3 threshold (as suggested in the August 25, 2007 Action Plan). Consideration was also given to expanding the NSTS to include sources in the low end of Category 4 or in Category 5. The rationales for expanding the NSTS to include Category 3 sources and to include lower category sources are provided in Sub-Sections A.3.4.1 and A.3.4.2, respectively.

##### A.3.4.1 Inclusion of Category 3 sources in the NSTS

The Commission believes that it is clear that there is a need to enhance the accountability and control of Category 3 sources (i.e., those that are greater than or equal to the

IAEA Category 3 threshold) through improved tracking of these sources. The following are the principal rationale for the Commission's decision regarding Category 3 sources:

- a) Category 3 sources are defined as dangerous by IAEA: The IAEA defines Category 3 sources (as well as the Category 1 and 2 sources) as "dangerous sources", i.e., a source that could if not under control give rise to exposure sufficient to cause severe deterministic effects, although it left to its individual member States whether it would be necessary to actually set up a tracking system for these sources.
- b) There is potential for aggregation of Category 3 sources to a Category 2 level: Category 3 sources could be easily aggregated to Category 2 levels, as part of a concerted effort to do so, 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, sources at the high end of the range of activities in Category 3 can be at levels just below the threshold of a Category 2 source, meaning that it would take only a few sources to aggregate to Category 2. Adding these sources to the NSTS with its inventory and tracking requirements will provide for increased accountability for these sources because there would be a near real-time knowledge of source whereabouts and an ability to confirm an individual licensee's account of their sources.
- c) Types of licensees that possess Category 3 sources: The major categories of licensees who possess Category 3 sources include those with fixed industrial gauges (level gauges, conveyor gauges, thickness gauges, blast furnace gauges, dredger, pipe gauges); those who conduct

well-logging operations; medical facilities with brachytherapy machines; and some radiographers with relatively low activity sources. Because these sources are thus relatively widespread in use and relatively broadly used in industry, there would be potential for aggregation of sufficient numbers of them to Category 2 levels.

d) Additional burden to comply with these requirements is considered reasonable to incur for the benefit in improved source accountability: Adding Category 3 sources to the NSTS would result in increased burden to the NRC and to the licensed industry for implementation and maintenance of the expanded NSTS. In the Regulatory Analysis for this rulemaking (summarized in Section XI of this FRN), the Commission analyzed the additional costs and benefits of expanding the NSTS to Category 3 levels. As noted in the Regulatory Analysis, the existing NSTS has approximately 1300 NRC and Agreement State licensees and an expanded NSTS under this proposed rule to include Category 3 sources would add approximately 1000 licensees. As estimated in the Regulatory Analysis, the resultant overall annual cost to the industry and to the NRC would be approximately doubled as a result of this expansion of the NSTS to Category 3, however the Commission believes that this additional burden would be reasonable to incur given the additional improvement in accountability for these sources.

e) Additional sources can be accommodated by the NSTS: As noted in Section II.C.1 of this preamble, the Commission believes that the existing NSTS system can accommodate these additional licensees and sources based on its expandability and flexibility and that, if NRC applies the appropriate

resources, that monitoring of the expanded NSTS would not divert attention from the monitoring of higher-risk Category 1 and 2 sources.

- f) Consideration of earlier public comment: In reaching its decision to include Category 3 sources, the Commission considered the comments received regarding inclusion of Category 3 sources during the rulemaking to establish the NSTS for Category 1 and 2 sources. These comments are summarized in Section II.C.2 of this preamble. Briefly stated, a number of commenters supported inclusion of Category 3 sources in the NSTS for some of the same reasons as previously noted, whereas a larger number of commenters opposed the inclusion of Category 3 sources based on the relatively low risk they present compared to the large increased burden of adding these sources to the NSTS. The Commission believes that it has considered the concerns of the commenters, pro and con, and evaluated the additional burdens which the rule would impose, in reaching its decision.

Based on the considerations previously noted, the definition of Category 3 as dangerous, and the potential for aggregation to Category 2, the Commission believes that the same information to be included in the NSTS for Category 1 and Category 2 sources is also needed for Category 3 sources. Expanding the scope of the NSTS will provide for Category 3 sources the same single source of information as collected for Category 1 and 2 sources. Although separate NRC and Agreement State systems contain information on Category 3 source licensees and the maximum amounts of materials they are authorized to possess, those systems do not record actual sources or their movements.

Thus, to address this lack of information on such issues as actual materials possessed, the NRC is proposing, as part of this proposed rule, to expand the NSTS to include sources greater than or equal to the IAEA Category 3 threshold levels. Expanding the NSTS to Category 3 sources would provide NRC with information regarding purchases/transactions of sufficient numbers of Category 3 sources that could be aggregated into the equivalent of Category 2 sources. Tracking specific transactions of Category 3 sources enhances accountability and would detect situations where a licensee's aggregate sources would create larger (more dangerous) quantities.

#### A.3.4.2 Inclusion of lower Category sources in the NSTS, in particular 1/10th of Category 3

The Commission has also given consideration to expanding the NSTS to sources below the Category 3 threshold. Specifically, the staff considered expanding the NSTS to include a subset of IAEA Category 4 sources that are in the high end of Category 4 (at a level of 1/10th of the Category 3 threshold). The staff also considered whether to expand the NSTS to include all of Category 4 (the Category 4 threshold is 1/100th of the Category 3 threshold) and Category 5.

A principal rationale for including sources at the high-end of the Category 4 range of activities (i.e., at 1/10th of Category 3) is the potential that a sufficient number of these higher-activity Category 4 sources could be obtained and aggregated to create the equivalent of Category 2 sources. These "high-end" Category 4 sources can be at levels just below the threshold of a Category 3 source, which is about 1/10th of the threshold of a Category 2 source, meaning that it would require about 10-12 of these sources to aggregate to Category 2 quantity. These high-end Category 4 (1/10th Category 3) sources are possessed by the same licensees noted to have Category 3 sources, namely those with fixed industrial gauges, those

who conduct well-logging operations, medical facilities with brachytherapy machines, and a few radiographers, and as previously noted, are relatively widespread in use and broadly used in industry, thus allowing for the potential for aggregation of sufficient numbers of them to Category 2 levels. As noted in this preamble for Category 3 sources, the Commission analyzed additional costs and benefits of expanding the NSTS to 1/10th of Category 3 levels. As noted in the Regulatory Analysis, an expanded NSTS to include 1/10th Category 3 sources would add approximately 2500 licensees with a resultant overall annual cost to the industry and to the NRC that would be approximately doubled again.

The Commission also considered including all of Category 4 sources (and/or Category 5) in the NSTS, however in both cases it was decided that, because of the magnitude of the thresholds of each of these categories and the lower likelihood that sources at the lower range of Category 4 or in Category 5 could be aggregated to the higher category levels, that they would not be included in the expansion of the NSTS.

Based on these considerations of the nature of the sources at 1/10th Category 3, their potential to aggregate to Category 2, and the costs to the licensed industry and the NRC, the NRC has decided to also include in the NSTS, sources below the Category 3 threshold, but greater than or equal to a 10th of the Category 3 threshold. This is consistent with the Code of Conduct which encourages countries to give appropriate attention to radioactive sources considered to have the potential to cause unacceptable consequences if employed for malicious purposes and to aggregation of lower activity sources. The Commission believes that the additional costs are reasonable to incur given the additional improvement in accountability for these sources, given their potential to be aggregated to more dangerous quantities. The Commission believes that the existing NSTS can accommodate these additional sources and

that the NRC can expend the additional resources to monitor these sources without detracting from the monitoring of Category 1 and 2 sources.

The NRC specifically invites comment on the inclusion of these sources at 1/10th Category 3 in the NSTS. The staff is interested in information concerning:

- (1) The number of additional licensees that would be impacted;
- (2) The number of sources between the Category 3 threshold and 1/10th of the Category 3 threshold that are possessed by licensees and the activity levels of those sources relative to both of those values;
- (3) How often these sources are involved in transactions (manufacture, shipping, receipt, disposal, etc) and the nature of the transaction process, including the ease of obtaining the sources and the cost of the sources.

This information will enable the NRC to make a more informed decision on the inclusion of sources greater than or equal to 1/10th Category 3 in the NSTS.

#### B. Enhanced accountability provided by these amendments.

The NSTS, as currently planned for Category 1 and 2 sources, is a web-based system that provides the NRC and Agreement States with information related to transactions involving nationally tracked sources. This information includes details of transfers of sources between manufacturers and licensees, and disposal sites, for IAEA Category 1 and 2 sources.

Expanding the NSTS to include additional nationally tracked sources would use the same web-based system as for Category 1 and 2 sources, namely providing the NRC with information regarding transactions involving sufficient numbers of these additional sources that could be aggregated into the equivalent of Category 2 source. By tracking specific transactions

involving these additional nationally tracked sources, the NRC will be in a better position to track aggregation of these sources and improve accountability for these sources. In addition, with an expanded NSTS, NRC can be alert to discrepancies between transaction reports of manufacturing and distribution licensees and of the persons to whom the shipment of sources is being made. Also, data from the NSTS could be used in conjunction with other data management systems to provide for better source accountability.

### C. Other considerations

#### C.1 Other alternative approaches for improving accountability require only inventorying of additional categories of sources.

Another alternative approach considered for this rulemaking would be to simply require licensees with sources greater than or equal to either the Category 3 threshold or 1/10th of the Category 3 threshold to conduct and report inventories of nationally tracked sources. However, this alternative would not provide the necessary near real-time knowledge of source transactions and, in addition, lack of transaction data from other licensees would not tend to lead to a cross-check for accurate reporting of inventories. In addition, there would still be significant costs incurred as a result of such a rule including the costs of setting up an account in the NSTS (including licensee credentialing); of conducting inventories; of marking serial numbers; of inspections, of preparing Agreement State regulations; and of NRC system monitoring, operation, and maintenance.

## C.2 Potential effects on the existing NSTS for Category 1 and 2 Sources

An important consideration in the NRC's decision to propose expansion of the NSTS is whether the expanded NSTS would divert attention from, or otherwise compromise the currently planned NSTS. In the SRM for SECY-06-0094, the Commission directed the staff to ensure that the NSTS is capable of being modified to include Category 3 sources, and that an expanded NSTS does not divert attention or resources from oversight of Category 1 and 2 sources.

This is an important consideration because activities to review new data in the NSTS for the lower activity sources that would now be a part of the NSTS should not divert NRC attention from reviewing and monitoring licensee inventorying and tracking of the higher Category 1 and 2 which present a higher risk to human health. It is expected that expansion of the NSTS will not compromise the information technology (IT) aspects of the NSTS due to the capabilities incorporated into the NSTS software. Because the IT design and software is flexible and expandable, it can accommodate the anticipated number of licensees and sources and the corresponding tracking activities under the proposed expansion of the NSTS. Thus, it is anticipated that implementation of the expanded NSTS can begin in the timeframe noted in Section D.7 of the preamble. In addition, although it is recognized that additional effort will be needed to monitor an expanded NSTS, NRC should be able to continue to adequately monitor both the Category 1 and 2 sources in the existing NSTS and the additional sources in the expanded NSTS and identify possible concerns with aggregation of sources, if it uses the appropriate additional resources which are discussed in the summary of the Regulatory Analysis, Section XI.

C.3 Previous comments received regarding inclusion of Category 3 sources in the NSTS during the rulemaking to establish the NSTS for Category 1 and 2 sources

Another consideration is the public comment received on the proposed rule for establishing the NSTS for IAEA Category 1 and 2 sources. As noted in Section I of this preamble, the proposed rulemaking the Commission specifically invited public comment. The public comments received on this subject were discussed in the November 6, 2006 final rule FRN establishing the NSTS.

The discussion in the final FRN noted that six commenters supported inclusion of Category 3 while eighteen commenters opposed it. Reasons given for supporting inclusion included that certain Category 3 sources pose comparable threats to Category 2; that there was concern over threats to national security from potential aggregation of Category 3 sources; that IAEA defines Category 3 sources as being dangerous and carrying a potential risk of harm warranting inclusion in a tracking system; and that these sources could be tracked with a modest additional investment. These commenters noted that the inclusion of Category 3 sources should not disrupt implementation of the NSTS for Category 1 and 2 sources. Commenters opposing inclusion of Category 3 sources in the NSTS generally cited the increased burden that would be imposed on licensees and the NRC. Most of these commenters did not provide specific numbers but indicated that inclusion of Category 3 sources would cause a significant increase in the number of transaction reports and unduly burden manufacturers and distributors. These commenters also noted that many of the Category 3 sources are lower risk and do not pose a significant threat compared to Category 1 and 2. These commenters were concerned that inclusion of Category 3 sources would bog down the NSTS and suggested that a better approach would be to require inventory reporting rather than

source transactions.

In response to all of these commenters, the Commission, in issuing the final rule establishing the NSTS for Category 1 and 2 sources, noted that it did not have adequate information at that point in time to support inclusion of Category 3 sources in the NSTS. The Commission also noted that it was working to develop additional information by conducting a one-time survey of sources at a level of 1/10th of Category 3. The Commission then noted that, in that rulemaking, it was not making a final determination on what additional sources should be included in the NSTS and that if additional material is added to the NSTS, it would be done through subsequent rulemaking, which is what the Commission is currently conducting. In preparing this proposed rule, the NRC has re-considered the relative concerns over accountability and control of these sources; the relative risk the sources may present; the potential for aggregation of lower activity sources to higher IAEA Category levels; and the flexibility and expandability of the existing NSTS to accommodate additional sources. Based on additional information developed, the NRC has also prepared a detailed regulatory analysis of the number of additional licensees and sources that would be included in an expanded NSTS and the effect on licensees, the Agreement States and the NRC. 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.

#### D. General Content of the Proposed Rule

Based on the considerations of Sections II.A – II.C, NRC is proposing to expand the NSTS by requiring licensees with additional nationally tracked sources to report information to the NSTS on the manufacture, transfer, receipt, disassembly, and disposal of nationally tracked

sources. The expanded NSTS would remain consistent with recommendations in the IAEA Code of Conduct for development of a national register of radioactive sources.

This section contains specific information on the content and implementation of this expanded NSTS. The actions required of the additional licensees with sources added to the NSTS are the same as those for licensees currently within the scope of the NSTS. The following discussion is based on supplementary information in the FRN for the final rule establishing the NSTS for IAEA Category 1 and 2 sources (71 FR 65686, November 8, 2006). This section is intended to provide licensees new to the NSTS, i.e., those with Category 3 sources and sources greater than or equal to 1/10th Category 3, but less than Category 2, with similar information as was provided in the FRN for the final rule for the establishment of the NSTS for IAEA Category 1 and 2 sources.

#### D.1 Definition of a Nationally Tracked Source.

A sealed source consists of radioactive material that is permanently sealed in a capsule or closely bonded to a non-radioactive substrate designed to prevent leakage or escape of the radioactive material. In either case, it is effectively a solid form of radioactive material which is not exempt from regulatory control. Under this proposed rule, the definition of a nationally tracked source would be revised to include sealed sources containing a quantity of radioactive material equal to or greater than the 1/10th Category 3 levels listed in the proposed amended Appendix E to 10 CFR Part 20. A nationally tracked source may be either a Category 1 source, a Category 2 source, a Category 3 source or, a 1/10th Category 3 source. 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. Material encapsulated solely for disposal refers to material that without the disposal packaging would not be considered encapsulated. For example, a licensee's bulk material that it plans to send for burial may be placed in a matrix (e.g. mixed in concrete), to meet burial requirements. The placement of the radioactive material in the matrix material may be considered encapsulating. This type of material would not be covered by the rule. However, if a nationally tracked source were to be placed in a matrix material, the sealed source would still be covered by the rule.

The specific radioactive material and activity levels covered by this proposed rule are listed in the proposed revised Appendix E to 10 CFR Part 20. These activity values are 1/10th of the Category 3 values in Table 1 of the IAEA Code of Conduct. The Code of Conduct recommends that at a minimum the radionuclides and the threshold values for Category 1 and 2 should be included in a national source registry. The U.S. Government has formally adopted these values to align domestic and international efforts to increase the safety and security of certain radioactive sources.

The Terabecquerel (TBq) values listed in Appendix E would be the regulatory standard. The curie (Ci) values specified are obtained by converting the TBq value. The Ci values are provided for reference only and are rounded after conversion. The curie values are not intended to be the regulatory standard.

#### D.2. Who Would Be Affected by This Action

The proposed rule would apply to any person (entity or individual) in possession of a Category 3 source or source greater than or equal to 1/10th of Category 3. It would apply to --

- Licensees with either NRC licenses or with Agreement State licenses;

- Manufacturers and distributors of Category 3 sources, and sources greater than or equal to 1/10th of Category 3;
- Medical facilities, radiographers, well-loggers, licensees using fixed gauges, and any other licensees that are the end users of nationally tracked sources;
- Disposal facilities and waste brokers; and
- Owners of a source that is not actively used or in long-term storage.

Nationally tracked sources (as the definition would be expanded by this proposed rule) include sources possessed by various types of licensees, but primarily by byproduct material licensees, and are used in the oil and gas, electrical power, construction, medical, food industries, and in technology research and development. The definition of nationally tracked sources would be modified by this rulemaking to include Category 3 and sources greater than or equal to 1/10th of Category 3 based on the activity level of the radioactive material.

Category 3 sources or, sources greater than or equal to 1/10th of Category 3 are typically used in devices such as medical brachytherapy units, well-logging, fixed gauges used throughout various industries, and radiography units in which the radioactivity has decreased from higher IAEA Category 2 levels due to radioactive decay.

### D.3 How information would be reported to the NSTS

Licensees have several methods for providing the required information under the existing NSTS (see Section D.4 of this preamble, for the specific information that would be reported to the NSTS). Under the proposed expanded NSTS, these methods would continue to include on-line, computer-readable format files, paper, fax, and telephone and are described below:

- Reporting information on-line: For most licensees, the most convenient, least burdensome method will be to report the information on-line. In this method, licensees can log on to the system and enter the required information by filling out a form on-line. To report information on-line, a licensee would need to establish an account with the NSTS. Once an account is established, the licensee would be provided with password information that would allow access to the on-line system. A licensee would have access only to information regarding its own material or facility; a licensee would not have access to information concerning other licensees or facilities. When logged on, the licensee could type the necessary information onto the on-line forms. Once a source is in the system, the licensee would be able to click on the source and report a transfer or other transaction. The identifying information would not need to be typed in a second time because information such as license number, facility name, and address would pop up automatically.
  
- Computer-readable format: Many licensees conduct a large number of transactions, especially manufacturing and distribution licensees. We recognize that most licensees have a system in which information on sources is maintained. The NSTS will be able to accept batch load information using a computer-readable format. This should ease the reporting burden for a licensee with a large number of transactions. The licensee would be able to electronically send a batch load using a computer readable format file that contained all of the transactions that occurred that day. The format could also be used for reporting the initial inventory. NRC and the entity responsible for developing the NSTS will work with licensees to develop the mechanism to accept batch load

information so that it is compatible with many of the existing systems in use by licensees.

- Paper submittals by mail, fax, or telephone: Licensees would also be able to complete a paper version of the National Source Tracking Transaction form and submit the form by either mail or fax. Licensees would also be able to provide transaction information by telephone and then follow-up with a paper copy.

#### D.4 Specific Information That Licensee Would Report Under the Expanded NSTS.

Under the requirements of the NSTS, the additional licensees covered by the NSTS would be required to conduct the following actions:

- Report their initial inventory of sources greater than or equal to 1/10th of Category 3 nationally tracked sources to NSTS;
- On an annual basis, reconcile and verify the inventory of sources greater than or equal to 1/10th of Category 3 possessed against the data in the NSTS;
- Complete and submit a National Source Tracking Transaction Report (i.e., NRC Form 748) after each transaction involving a Category 3 or a 1/10th of Category 3 source;
- Correct any errors in previously filed National Source Tracking Transaction Reports within five business days of the discovery; and
- For licensees who manufacture a Category 3 or 1/10th of Category 3 nationally tracked source, assign a unique serial number to each source.

How licensees would carry out these requirements is discussed in more detail in the following subsections.

#### D.4.1 Reporting Initial (current) Inventory to the NSTS.

As noted, licensees would be required to report their initial (i.e., current) inventory of nationally tracked sources by a specified date. Licensees would be required to report all sources greater than or equal to 1/10th of Category 3 to the NSTS by July 31, 2009.

To ease the implementation of the reporting process, information already in NRC's One-Time Data Collection would be downloaded to the NSTS. A licensee whose nationally tracked source information was reported to the One-Time Data Collection database would be provided a copy of its information and would need only to either verify the information or provide updated information. NRC staff and the entity that operates the NSTS will work with licensees to make sure the inventory information is correct. A licensee whose information was not reported to the One-Time Data Collection database would need to report the information on its nationally tracked source inventory by specified date above. Disposal facilities would not need to report sources that have already been buried or otherwise disposed.

#### D.4.2 Annual Reconciliation and Verification of Information in the NSTS.

Licensees would be required to reconcile their on-site inventory of nationally tracked sources with the information previously reported to the NSTS. This reconciliation would occur during the month of January of each year. This reconciliation would be necessary to maintain the accuracy and reliability of the National Source Tracking database. The licensee would be able to print a copy of the inventory information from the NSTS. Licensees without on-line access would receive a paper copy of the information in the NSTS. The licensee would

compare the information in the system to the actual inventory at the licensee's facility, including a check of the model and serial number of each source. This reconciliation would not require the licensee to conduct an additional physical inventory of its sources. Under current regulations, licensees are currently required to conduct physical inventories annually, semi-annually, or quarterly depending on the type of license. The licensee would be required to reconcile any differences by reporting the appropriate transaction(s) or corrections to the NSTS. The licensee would be required to verify by the end of January of each year that the inventory in the NSTS is correct. The first reconciliation would occur in January 2010.

#### D.4.3 Reporting Transaction Information to the NSTS.

Prompt updating of the NSTS is necessary for it to be useful and accurate. In order to capture information as soon as possible, licensees would be required to report information on nationally tracked source transactions by the close of the next business day after the transaction. To ease the burden on licensees, any of the methods for reporting the information listed in Section E.3 may be used. Specific transaction information that would be required is discussed in the following subsections.

##### D.4.3.1. Reporting Information on Source Manufacture.

Sources Manufactured in the United States: When a nationally tracked source is manufactured in the United States, the source manufacturer licensee would be required to report the source information to the NSTS. The information must be reported by the close of the next business day after manufacture and includes: manufacturer (make), model number,

serial number, radioactive material, activity at manufacture, and manufacture date for each source. The licensee must also provide its license number, facility name, as well as the name of the individual that prepared the report.

Recycled, Reconfigured and Disassembled Sources: Some sources are recycled, reconfigured, or disassembled. For example, a source that has decayed below its usefulness may be returned to the manufacturer for reconfiguration or disassembly. The decayed source may be placed in a reactor and reactivated, or placed in storage. The source retains its serial number, but now has a new activity. The new activity and creation date of the source must be reported to the NSTS.

Imported Sources: For every nationally tracked source that is imported, the facility obtaining the source would be required to report the information on the manufacture of the source to the NSTS by the close of the next business day after receipt of the imported source at the site. For the purposes of the NSTS, this would be considered the source origin unless the source had been previously possessed in the United States. The licensee would need to report the manufacturer (make), model number, serial number, radioactive material, activity at manufacture or import, and manufacture or import date for each source. The licensee must also provide its license number, facility name, address, as well as the name of the individual that prepared the report and the date of receipt. The licensee would also need to provide information on the facility (name and address) that sent the source and the import license number if applicable. Note: Only Category 1 and Category 2 sources including multiple sources that aggregate to at least a Category 2 level on a per shipment basis, require a specific NRC import license.

#### D.4.3.2 Reporting Information on Source Transfer.

Transfers between licensees: Each time a nationally tracked source is transferred to another facility authorized to use or possess the source, the licensee would be required to report the transfer to the NSTS by the close of the next business day. The licensee must report the recipient name (facility the source is being transferred to), address, license number, the shipping date, the estimated arrival date, and the identifying source information (manufacturer, model number, serial number, and radioactive material). The licensee also would need to provide its name, address, and license number, as well as the name of the individual making the report. For nationally tracked sources that are transferred as waste under a Uniform Low-level Radioactive Waste Manifest, the licensee would also have to report the waste manifest number and the container identification number for the container with the nationally tracked source.

Transfers where the source stays within the licensee's possession: Source transfer transactions only cover transfers between different licensees and/or authorized facilities. They do not include transfer to a temporary job site. Transactions in which the nationally tracked source remains in the possession of the licensee would not require a report to the NSTS. For example, a radiographer conducting business would not need to report transfers between temporary job sites, even if the temporary job site is located in another state or if the work is conducted under a reciprocity agreement.

Export of sources: Export of sources would be treated as a transfer. An export is considered a reversible endpoint (e.g., a place of use or storage that is not a temporary job site)

because the source can be imported back into the country. The export license number would be reported as the license number of the receiving facility. Note: Only Category 1 and 2 sources, including multiple sources that aggregate to at least a Category 2 level on a per shipment basis, are required to have a specific NRC export license. Most Category 3 and below sources can be exported under a general license in accordance with 10 CFR 110.23.

#### D.4.3.3. Reporting Information for Receipt of Sources.

Receipt of sources: A licensee would be required to report each receipt of a nationally tracked source by the close of the next business day. The licensee must report the identifying source information (manufacturer, model number, serial number, and radioactive material) and the date of receipt. The licensee also must include its facility name and license number and the name of the individual that prepared the report. In addition, the licensee must provide the name and license number of the facility that sent the source because this information is necessary to match the transactions.

Receipt of imported sources: If the source received is an import, the licensee would also need to report the source activity and associated activity date. The import license number would be reported as the license number of the sending facility.

Receipt of sources in a waste shipment: If a licensee receives a nationally tracked source as part of a waste shipment, the licensee must provide the Uniform Low-level Radioactive Waste Manifest number and the container identification for the container that contains the nationally tracked source. A waste broker or disposal facility are examples of

licensees that might receive a nationally tracked source as part of a waste shipment. These licensees would not be expected to open the waste container and verify the presence of the nationally tracked source; they may rely on the information from the licensee who shipped the source.

#### D.4.3.4 Reporting Information on Source Disposal.

Licensees sending a source for disposal: Licensees sending a source to a low-level burial ground for disposal would treat the transaction as a transfer (see Section D.4.3.2), and would report the types of information to be reported for a transfer, along with the waste manifest number and the container identification number.

Disposal facilities: Disposal of a source would be reported by the licensee conducting the actual burial in a low-level disposal facility or other authorized disposal mechanism. The disposal facility may rely on the information from the licensee that sent the waste for disposal and is not expected to open the waste container to verify contents. The disposal facility must report to the NSTS the date and method of disposal, the waste manifest number, and the container identification number for the container with the nationally tracked source. The disposal facility must also provide its facility name and license number, as well as the name of the individual that prepared the report. The report must be made by the close of the next business day.

#### D.4.3.5 Information Regarding Reporting (or Not Reporting) of other source endpoints

Decay of sources: One feature of the NSTS would be that the decay of a source would be automatically calculated so a licensee would not need to report an endpoint of decay. Once a source has decayed below 1/10th of Category 3 threshold level, it would no longer be considered a nationally tracked source, and the source would automatically be removed from a licensee's active inventory in the NSTS. The licensee would receive a notification that the source has decayed below the tracking level, and that transactions for this source no longer need to be reported. The data on the source, however, will be retained in the system.

Accidental destruction of sources: Licensees currently report accidental destruction of sources to the NRC Operations Center or to the Agreement States. NRC staff would enter the information from the event report into the NSTS. Because sealed sources are designed to be robust, accidental destruction should be and is rare.

Lost or stolen sources or source abandoned in a well: These endpoints would be captured by the NSTS. These events are already reported to either NRC or to the Agreement States. Licensees would not be required to report this information a second time to the NSTS. Agreement State licensees would continue to report to the Agreement State. NRC staff would obtain the information on these events from the event reports or the Nuclear Medical Event Database and enter the information into the NSTS.

#### D.4.4 Reporting Errors in Transaction Reports.

Data integrity for the NSTS is extremely important and necessary to keep the information correct and up-to-date. Licensees are expected to provide correct information to the NSTS and to double-check the accuracy of information before submission.

However, the NRC recognizes that some transactions may be missed and that errors may creep into the system over time. Typical reasons for discrepancies could be failure to report the receipt of a source, failure to report the transfer of a source to another licensee, finding a source that was missed during the reporting of the initial inventory, selection of the wrong model number, or incorrect typing of the serial number.

Each licensee would be required to correct any errors or missed transactions that it discovers, and to correct any of their inaccurate information in the NSTS, regardless of the origin of the error, within 5 business days of the discovery. Typing errors and errors such as inadvertent selection of the wrong model number need to be corrected in the system so that the information in the NSTS is correct. A licensee would be able to submit a corrected form that contains the correct information online or through any other permitted reporting mechanism at any time.

#### D.4.5 For Manufacturers, Assigning a Unique Serial Number to Sources.

The proposed rule would require manufacturers of nationally tracked sources to use a unique serial number for each source. The combination of manufacturer, model, and serial number will be used in the NSTS to track the history of each source.

#### D.5 Access to the Information in the NSTS and What Would It be Used For.

Information in the NSTS will be considered Official Use Only. This means that the information is to be protected and not disclosed to the general public. A licensee would be able to view its own data, but not data for other licensees. Agreement State staff would be able to view information on the licensees in their State, but would not be able to view information on licensees in other States. The one exception is information related to lost or stolen sources. Agreement State staff would be able to view the information on lost or stolen sources from all licensees. This will enable better coordination of recovery efforts. Other Federal and State agencies would also be able to view the information on lost or stolen sources and other information on a need-to-know basis.

Once fully operational, the expanded NSTS would be used for a variety of purposes. This standardized, centralized information will help NRC and Agreement States to monitor the location and use of nationally tracked sources; conduct inspections and investigations; communicate nationally tracked source information to other government agencies; verify legitimate ownership and use of nationally tracked sources; and further analyze hazards attributable to the possession and use of these sources.

#### D.6 Implementation and enforcement of the expanded NSTS:

Implementation and enforcement activities, whether the licensee population includes those possessing Category 1 and 2 sources only, or those possessing Category 3 sources or sources greater than or equal to 1/10th of Category 3, would be of a similar nature. The NSTS rule reporting requirements include reporting by licensees of an initial inventory, an annual

reconciliation of source inventory, and source transactions. The implementation process would include specific actions to make the affected licensee population aware of the amended requirements in 10 CFR Parts 20 and 32 through outreach with licensee groups/organizations, and information on the NRC website. In addition, at this time, guidance is in preparation for implementation of the NSTS for Category 1 and 2 licensees; similar guidance will be developed for Category 3 sources and sources greater than or equal to 1/10th of Category 3 licensees. Regarding enforcement action, in a manner similar to that for Category 1 and 2 licensees, NRC and the Agreement states would first need to identify licensees who had not reported the required inventory and transaction information, based on knowledge of the licensee population of interest, which would be determined by using the Licensee Tracking System and eventually by the Web Based Licensing (WBL), when operational.

#### D.7 When These Actions Become Effective.

The rule would become effective 60 days after the final rule is published in the *Federal Register*. The requirements for sources greater than or equal to 1/10th of Category 3 nationally tracked sources would be implemented by July 31, 2009. This means that by this date any licensee that possesses a Category 3 or sources greater than or equal to 1/10th of Category 3 must have reported its initial inventory and report thereafter all transactions involving sources greater than or equal to 1/10th of Category 3 to the NSTS.

### III. Discussion of Proposed Amendments by Section

#### § 20.1003 Definitions.

An expanded definition of nationally tracked sources to include Category 3 and 1/10th of Category 3 sources would be added to the regulations.

#### § 20.2207 Reports of transactions involving nationally tracked sources.

A revision to paragraph (h) would require a licensee to report its initial inventory of Category 3 and 1/10th of Category 3 nationally tracked sources by July 31, 2009.

#### Appendix E Nationally Tracked Source Thresholds.

A revision to Appendix E of 10 CFR Part 20 would be made to revise the thresholds for nationally tracked sources to include Category 3 and 1/10th of Category 3 levels. The Terabecquerel (TBq) values listed in the revised Appendix E are the regulatory standard. The curie (Ci) values specified are obtained by converting from the TBq value. The Ci values are provided for reference only and are rounded after conversion. The curie values are not intended to be the regulatory standard.

#### § 32.2 Definitions.

An expanded definition of nationally tracked sources to include Category 3 and 1/10th of Category 3 sources would be added to the regulations.

#### IV. Criminal Penalties

For the purpose of Section 223 of the Atomic Energy Act (AEA), as amended, the Commission is proposing to amend 10 CFR Parts 20 and 32 under one or more of Sections 161b, 161i, or 161o of the AEA. Willful violations of the rule would be subject to criminal enforcement.

#### V. Agreement State Compatibility

Under the “Policy Statement on Adequacy and Compatibility of Agreement State Programs” approved by the Commission on June 30, 1997, and published in the *Federal Register* on September 3, 1997 (62 FR 46517), § 20.2207 of the proposed rule is 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. Agreement State and NRC licensees would report their transactions to the NSTS and the database will be maintained by the NRC.

#### VI. Plain Language

The Presidential Memorandum “Plain Language in Government Writing” published June 10, 1998 (63 FR 31883), directed that the Government’s documents be in clear and accessible language. The NRC requests comments on this proposed rule specifically with respect to the

clarity and effectiveness of the language used. Comments should be sent to the address listed under the “ADDRESSES” heading.

## VII. Voluntary Consensus Standards

The National Technology Transfer Act of 1995 (Pub. L. 104-113) requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this proposed rule, the NRC would require licensees that possess, manufacture, transfer, receive, or dispose of the nationally tracked sources specified in the proposed rule to report the information relating to such transactions to the National Source Tracking System. This action does not constitute the establishment of a standard that contains generally applicable requirements.

## VIII. Environmental Impact: Categorical Exclusion

The NRC has determined that this proposed rule is the type of action described as a categorical exclusion in 10 CFR 51.22(c)(3)(iii). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this proposed rule.

## IX. Paperwork Reduction Act Statement

This proposed rule contains new or amended information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq*). This rule has

been submitted to the Office of Management and Budget (OMB) for review and approval of the information collection requirements.

*Type of submission, new or revision:* Revision.

*The title of the information collection:* 10 CFR Parts 20 and 32, National Source Tracking of Sealed Sources.

*The form number, if applicable:* NRC Form 748

*How often the collection is required:* Initially, at completion of a transaction, and at inventory reconciliation annually.

*Who will be required or asked to report:* Licensees that manufacture, receive, disassemble, transfer, or dispose of nationally tracked sources.

*An estimate of the number of annual responses:* 20,912 (19,746 responses and 1,166 recordkeepers).

*The estimated number of annual respondents:* 3500 (NRC 700; Agreement States 2800)

*An estimate of the total number of hours needed annually to complete the requirement or request:* The total burden increase for this rulemaking is 16,821 hours (10 CFR Part 20: 13,748 hours; 10 CFR Part 32: 600 hours; NRC Form 748: 2,473 hours).

*Abstract:* The NRC is proposing to amend its regulations to expand the NSTS to include Category 3 and 1/10th of Category 3 sealed sources. The proposed amendments would require licensees to report certain transactions involving nationally tracked sources to the NSTS. These transactions would include manufacture, transfer, disassembly, receipt, or disposal of the nationally tracked source. The proposed amendment would require each licensee to provide its initial inventory of nationally tracked sources to the NSTS and to annually verify and reconcile the information in the system with the licensee's actual inventory. The proposed rule would also require manufacturers of nationally tracked sources to assign a unique serial number of each source. This information collection is mandatory and will be used to populate the NSTS.

The NRC is seeking public comment on the potential impact of the information collections contained in this proposed rule and on the following issues:

1. Is the proposed information collection necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility?
2. Is the estimate of burden accurate?
3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection be minimized, including the use of automated collection techniques?

A copy of the OMB clearance package may be viewed free of charge at the NRC Public Document Room, One White Flint North, 11555 Rockville Pike, Room O-1 F21, Rockville, MD 20852. The OMB clearance package and rule are available at the NRC Worldwide Web site: <http://www.nrc.gov/public-involve/doc-comment/omb/index.html> for 60 days after the signature date of this notice.

Send comments on any aspect of these proposed information collections, including suggestions for reducing the burden and on the above issues, by **(INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER)** to the Records and FOIA/Privacy Services Branch (T-5 F52), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet electronic mail to [INFOCOLLECTS@NRC.GOV](mailto:INFOCOLLECTS@NRC.GOV) and to the Desk Officer, Nathan Frey, Office of Information and Regulatory Affairs, NEOB-10202 (3150-0001, 3150-0014, 3150-0202), Office of Management and Budget, Washington, DC 20503. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date. You may also comment by telephone at (202) 395-7345.

## X. Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

## XI. Regulatory Analysis

The Commission has prepared a draft regulatory analysis on this proposed regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission.

The Regulatory Analysis considers costs to licensees that would result from the proposed amendments. The largest burden would likely fall on the manufacturers and distributors of nationally tracked sources because they will have the most transactions to report. The NRC believes that by allowing batch loading of information using a computer readable format, the burden on the high transaction licensees will be lessened. The Regulatory Analysis also considers costs to the NRC and to Agreement States, including initial costs of entering licensees into the NSTS, annual costs of maintenance and operation of the expanded NSTS, costs of inspections, and costs to Agreement States of issuing legally binding requirements.

The Commission requests public comment on the draft regulatory analysis. Comments may be submitted to the NRC as indicated under the **ADDRESSES** heading. The analysis is available for inspection in the NRC Public Document Room (Adams Accession Number ML073521333), 11555 Rockville Pike, Rockville, MD 20852. Single copies of the draft regulatory analysis are available from Michael Williamson, telephone (301) 415-6284, e-mail

mkw1@nrc.gov, of the Office of Federal and State Materials and Environmental Management Programs.

## XII. Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the Commission certifies that this rule would not, if promulgated, have a significant economic impact on a substantial number of small entities. The proposed rule would affect about 700 NRC licensees and an additional 2800 Agreement State licensees possessing Category 3 and 1/10th of Category 3 sources. Affected licensees include laboratories, reactors, universities, colleges, medical clinics, hospitals, irradiators, and radiographers, some of which may qualify as small business entities as defined by 10 CFR 2.810. However, the proposed rule is not expected to have a significant economic impact on these licensees.

The total time required by a licensee to complete each National Source Tracking Transaction report is estimated to be approximately 10 minutes, depending on the number of sources involved in the transaction and the method of reporting. This is time needed to complete the report. No research or compilation is necessary as all information is transcribed from bills of lading, in-house records kept for other purposes, sales agreements, etc. Each licensee would also spend on average 1 hour on the annual reconciliation. Based on the draft regulatory analysis conducted for this action, the annual costs of the proposed amendments for affected licensees are estimated to be \$0.56 M total or on average about \$160 per affected licensee. The NRC believes that the selected alternative reflected in the proposed amendment is the least burdensome, most flexible alternative that would accomplish the NRC's regulatory objective.

Because of the widely differing conditions under which impacted licensees operate, the NRC is specifically requesting public comment from licensees concerning the impact of the proposed regulation. The NRC particularly desires comment from licensees who qualify as small businesses, specifically as to how the proposed regulation will affect them and how the regulation may be tiered or otherwise modified to impose less stringent requirements on small entities while still adequately protecting the public health and safety. Comments on how the regulation could be modified to take into account the differing needs of small entities should specifically discuss:

(1) The size of the business and how the proposed regulation would result in a significant economic burden upon it as compared to a larger organization in the same business community;

(2) How the proposed regulation could be further modified to take into account the business's differing needs or capabilities;

(3) The benefits that would accrue, or the detriments that would be avoided, if the proposed regulation was modified as suggested by the commenter;

(4) How the proposed regulation, as modified, would more closely equalize the impact of NRC regulations as opposed to providing special advantages to any individuals or groups;  
and

(5) How the proposed regulation, as modified, would still adequately protect the public health and safety.

Comments should be submitted as indicated under the **ADDRESSES** heading.

### XIII. Backfit Analysis

The NRC has determined that the backfit rule (§§ 50.109, 70.76, 72.62, or 76.76) does not apply to this proposed rule because this amendment would not involve any provisions that would impose backfits as defined in the backfit rule. Therefore, a backfit analysis is not required.

#### List of Subjects

##### 10 CFR Part 20

Byproduct material, Criminal penalties, Licensed material, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Packaging and containers, Radiation protection, Reporting and recordkeeping requirements, Source material, Special nuclear material, Waste treatment and disposal.

##### 10 CFR Part 32

Byproduct material, Criminal penalties, Labeling, Nuclear materials, Radiation protection, Reporting and recordkeeping requirements.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 553; the NRC is proposing to adopt the following amendments to 10 CFR Parts 20 and 32.

## PART 20 --STANDARDS FOR PROTECTION AGAINST RADIATION

1. The authority citation for Part 20 continues to read as follows:

AUTHORITY: Secs. 53, 63, 65, 81, 103, 104, 161, 182, 186, 68 Stat. 930, 933, 935, 936, 937, 948, 953, 955, as amended, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 2073, 2093, 2095, 2111, 2133, 2134, 2201, 2232, 2236, 2297f), secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); Sec. 651(e), Pub. L. 109-58, 119 Stat. 806 – 810 (42 U.S.C. 2014, 2021, 2021b, 2111).

2. In § 20.1003, the definition *nationally tracked source* is revised to read as follows:

### § 20.1003 Definitions.

\* \* \* \* \*

*Nationally tracked source* is a sealed source containing a quantity equal to or greater than Category 1, Category 2, Category 3, or 1/10th of Category 3 levels of any radioactive material listed in Appendix E of this Part. In this context a sealed source is defined as radioactive material that is sealed in a capsule or closely bonded, in a solid form and which is not exempt from regulatory control. It does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet. Category 1 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 1 threshold. Category 2 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 2 threshold but less than the Category 1 threshold. Category 3 nationally tracked sources are

those containing radioactive material at a quantity equal to or greater than the Category 3 threshold but less than the Category 2 threshold. The 1/10th Category 3 nationally tracked sources are those containing radioactive material at a quantity greater than or equal to 1/10th of Category 3 threshold but less than the Category 3 threshold.

\* \* \* \* \*

3. In § 20.2207, paragraph (h) is revised to read as follows:

**§ 20.2207 Reports of transactions involving nationally tracked sources.**

\* \* \* \* \*

(h) Each licensee that possesses Category 1 nationally tracked sources shall report its initial inventory of Category 1 nationally tracked sources to the National Source Tracking System by January 31, 2009. Each licensee that possesses Category 2 nationally tracked sources shall report its initial inventory of Category 2 nationally tracked sources to the National Source Tracking System by January 31, 2009. Each licensee that possesses Category 3 or 1/10th Category 3 nationally tracked sources shall report its initial inventory of Category 3 or 1/10th Category 3 nationally tracked sources to the National Source Tracking System by July 31 2009. The information may be submitted by using any of the methods identified by paragraphs (f)(1) through (f)(4) of this section. The initial inventory report must include the following information:

(1) The name, address, and license number of the reporting licensee;

- (2) The name of the individual preparing the report;
- (3) The manufacturer, model, and serial number of each nationally tracked source or, if not available, other information to uniquely identify the source;
- (4) The radioactive material in the sealed source;
- (5) The initial or current source strength in becquerels (curies); and
- (6) The date for which the source strength is reported.

4. In Part 20, Appendix E is revised to read as follows:

**Appendix E to Part 20 - Nationally Tracked Source Thresholds**

The Terabecquerel (TBq) values are the regulatory standard as promulgated by the International Atomic Energy Agency for Categories 1-3 of its *Code of Conduct on the Safety and Security of Radioactive Sources*, published in January 2004. The curie (Ci) values specified are obtained by converting the TBq value. The curie values are provided for practical usefulness only.

Radioactive Material	Category 1 (TBq)	Category 1 (Ci)	Category 2 (TBq)	Category 2 (Ci)	Category 3 (TBq)	Category 3 (Ci)	1/10th Category 3 (TBq)	1/10th Category 3 (Ci)
Actinium-227	20	540	0.2	5.4	.02	0.54	0.002	0.054
Americium-241	60	1,600	0.6	16	0.06	1.6	0.006	0.16
Americium-241/Be	60	1,600	0.6	16	0.06	1.6	0.006	0.16
Californium-252	20	540	0.2	5.4	0.02	0.54	0.002	0.054
Cobalt-60	30	810	0.3	8.1	0.03	0.81	0.003	0.081
Curium-244	50	1,400	0.5	14	0.05	1.4	0.005	0.14

Cesium-137	100	2,700	1	27	0.01	2.7	0.001	0.27
Gadolinium-153	1,000	27,000	10	270	1	27	0.1	2.7
Iridium-192	80	2,200	0.8	22	0.08	2.2	0.008	0.22
Plutonium-236	60	1,600	0.6	16	0.06	1.6	0.006	0.16
Plutonium-238	60	1,600	0.6	16	0.06	1.6	0.006	0.16
Plutonium-239	60	1,600	0.6	16	0.06	1.6	0.006	0.16
Plutonium-239/Be	60	1,600	0.6	16	0.06	1.6	0.006	0.16
Plutonium-240	60	1,600	0.6	16	0.06	1.6	0.006	0.16
Polonium-210	60	1,600	0.6	16	0.06	1.6	0.006	0.16
Promethium-147	40,000	1,100,000	400	11,000	40	1100	4	110
Radium-226	40	1,100	0.4	11	0.04	1.1	0.004	0.11
Selenium-75	200	5,400	2	54	0.02	5.4	0.002	0.54
Strontium-90	1,000	27,000	10	270	1	27	0.10	2.7
Thorium-228	20	540	0.2	5.4	0.02	0.54	0.002	0.054
Thorium-229	20	540	0.2	5.4	0.02	0.54	0.002	0.054
Thulium-170	20,000	540,000	200	5,400	20	540	2	54
Ytterbium-169	300	8,100	3	81	0.03	8.1	0.003	0.81

PART 32--SPECIFIC DOMESTIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN  
ITEMS CONTAINING BYPRODUCT MATERIAL

5. The authority citation for Part 32 continues to read as follows:

AUTHORITY: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); sec. 651(e), Pub. L. 109-58, 119 Stat. 806 – 810 (42 U.S.C. 2014, 2021, 2021b, 2111).

6. In § 32.2, the definition *nationally tracked source* is revised to read as follows:

**§ 32.2 Definitions.**

\* \* \* \* \*

*Nationally tracked source* is a sealed source containing a quantity equal to or greater than Category 1, 2, 3, or 1/10th Category 3 levels of any radioactive material listed in Appendix E to 10 CFR Part 20. In this context a sealed source is defined as radioactive material that is permanently sealed in a capsule or closely bonded, in a solid form and which is not exempt from regulatory control. It does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet.

Category 1 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 1 threshold. Category 2 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 2 threshold but less than the Category 1 threshold. Category 3 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 3 threshold but less than the Category 2 threshold. Category 1/10th Category 3 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the 1/10th Category 3 threshold but less than the Category 3 threshold.

\* \* \* \* \*

Dated at Rockville, Maryland, this \_\_\_\_\_ day of \_\_\_\_\_, 2008.

For the Nuclear Regulatory Commission.

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Annette L. Vietti-Cook,  
Secretary for the Commission.



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# **Regulatory Analysis for the Proposed Rule on Expanding the National Source Tracking System – 10 CFR Parts 20 and 32**

Draft Report

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**U.S. Nuclear Regulatory Commission**  
Office of Federal and State Materials and  
Environmental Management Programs

February 2008 Draft

# TABLE OF CONTENTS

1.	Introduction .....	3
1.1	Background .....	3
1.2	Objectives of the Proposed Regulatory Action .....	4
2.	Identification and Preliminary Analysis of Alternative Approaches .....	6
2.1	Option 1: No Action.....	6
2.2	Option 2: Expand NSTS to IAEA Category 3 (or lower) sources .....	6
3.	Analysis of Values and Impacts.....	7
3.1	Identification of Affected Attributes .....	7
3.2	Methodology .....	9
3.2.1	Baseline for Analysis .....	9
3.2.2	Assumptions.....	10
3.2.3	Analysis.....	14
3.3	Results .....	23
4.	Backfit Analysis .....	25
5.	Decision Rationale.....	25
6.	Implementation.....	25

## 1. Introduction

The National Source Tracking System (NSTS) was established in a final rule published in the *Federal Register* on November 8, 2006 (71 FR 65686). Under the NSTS program, certain licensees who possess International Atomic Energy Agency (IAEA) Category 1 and 2 sources are required to report information on the manufacture, transfer, receipt, disassembly, and disposal of nationally tracked sources. The implementation date for the NSTS has been extended to January 31, 2009 (72 FR 59162).

The U.S. Nuclear Regulatory Commission (NRC) is now proposing to amend its regulations to expand the existing NSTS to require additional licensees to report information on manufacture, transfer, receipt, disassembly, and disposal of nationally tracked sources. The licensees being considered for inclusion in the NSTS are those that possess IAEA Category 3 or lower (i.e., a subset of IAEA Category 4 or all of Category 4) sources.

The purpose of this regulatory analysis is to evaluate the quantities of material and impacts associated with regulatory alternatives for expanding the NSTS. The NRC considers the regulatory analysis process an integral part of its statutory mission to ensure adequate protection of public health and safety, and to protect the environment from civilian uses of byproduct, source, and special nuclear materials. This document presents background material, describes the objectives of the proposed regulatory action, outlines the alternatives considered by the NRC, and evaluates the values and impacts of the regulatory alternatives.

### 1.1 Background

As a result of the September 11, 2001 attacks in the U.S., the NRC has undertaken a comprehensive review of nuclear material security requirements, with particular focus on radioactive material of concern. This material, including Cobalt-60, Cesium-137, Iridium-192, and Americium-241, has the potential to be used in a radiological dispersal device (RDD) or a radiological exposure device (RED) in the absence of proper security measures. NRC's review has taken into consideration the changing domestic and international threat environments and related U.S. Government-supported international initiatives in the nuclear security area, particularly activities conducted by the IAEA. The NRC has worked with international agencies in developing international guidance for the safety and security of radioactive materials of concern as embodied in the IAEA *Code of Conduct on the Safety and Security of Radioactive Sources* (Code of Conduct).

The IAEA source categorization scheme contained in the Code of Conduct includes five categories. These categories are based on the potential for sources to cause deterministic health effects to persons exposed to them. Sources in Category 1 are considered to be the most 'dangerous' because they can pose a very high risk to human health if not managed safely and securely. At the lower end of the categorization system, sources in Category 5 are the least dangerous; however, even these sources could give rise to doses in excess of the dose limits if not properly controlled. Based on analysis of potential health effects, each of the IAEA Categories contain radioactive material in sealed sources in quantities that can be characterized as follows: Category 1: greater than or equal to the Category 1 threshold (e.g., for Cobalt-60 (Co- 60): 810 Curies (Ci)); these sources are typically used in practices such as radiothermal generators, irradiators and radiation therapy; Category 2: less than the Category 1 threshold but equal to or greater than the Category 2 threshold (which is 1/100th of

the Category 1 threshold); (e.g., for Co-60: 8.1 Ci); these sources are typically used in practices such as industrial gamma radiography and high and medium dose rate brachytherapy; Category 3: less than the Category 2 threshold but equal to or greater than the Category 3 threshold (which is 1/10th of the Category 2 threshold); (e.g., for Co-60: 0.81 Ci); these sources are typically used in practices such as fixed industrial gauges involving high activity sources; Category 4: less than the Category 3 threshold but equal to or greater than the Category 4 threshold (which is 1/100th of the Category 3 threshold); (e.g., for Co-60: 0.0081 Ci); Category 5: less than the Category 4 threshold down to IAEA exempt quantities.

The scope of IAEA's Code of Conduct is limited to Categories 1-3, i.e., those having the highest potential to cause permanent injury or death when used in a malevolent manner. In particular, the Code of Conduct recommends that each IAEA member State develop a national source registry of radioactive sources that should include Category 1 and 2 radioactive sources as described in Annex 1 of the Code of Conduct. The recommendation covers 16 isotopes that should be included in the source registry.

As a result of these activities, NRC issued a final rule published in the *Federal Register* on November 8, 2006 (71 FR 65856), establishing a national system for source tracking for Category 1 and 2 sources. In that rulemaking, specific rationale was provided for establishing tracking and inventory requirements for Category 1 and 2 sources. It was noted that a DOE/NRC analysis of potential health effects from use of sources in a RDD or a RED identified radionuclide "quantities of concern" to be in a range similar to the IAEA Category 2 threshold values. Therefore, to allow alignment between domestic and international efforts to increase safety and security of radioactive sources, NRC adopted the IAEA Category 2 values and used them as a threshold in its rulemaking decision regarding sources requiring tracking and inventorying in a national source tracking system.

Under the NSTS established by the November 8, 2006, final rule, certain 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. This information is to be used to support the NSTS and will provide the NRC with a life cycle account for nationally tracked sources and, thus, improve accountability and controls over them. The final rule to establish the NSTS reflected those IAEA Code of Conduct recommendations that are consistent with NRC's responsibilities under the Atomic Energy Act, including protection of public health and safety. As noted above, the current implementation date for the NSTS is January 31, 2009.

## **1.2 Objectives of the Proposed Regulatory Action**

In this current rulemaking, NRC has considered the need to enhance the tracking of Category 3 (or lower) sources to improve accountability and control of these sources and to provide additional protection against aggregation of these sources to higher activity levels (Category 1 or Category 2).

At issue in this rulemaking is the extent appropriate for expanding the NSTS beyond IAEA Category 2, i.e., should the NSTS be expanded to include IAEA Category 3 sources or should it be expanded even further to include sources that are in IAEA Category 4, in particular sources at the high end of the Category 4 activity range (specifically, 1/10th of the Category 3 threshold, referred to in the rest of this Regulatory Analysis as "1/10th of Category 3"). Consideration was

also given to expanding the NSTS to include sources in the low end of the Category 4 activity range or in IAEA Category 5. Analyses for expanding the NSTS to include Category 3 sources and to include lower category sources are provided in Sections 2 and 3, which follow.

In determining whether to expand the NSTS to Category 3 (or lower) sources, NRC has considered balancing the secure handling and use of the materials without discouraging their beneficial use in academic, medical, and industrial applications. Radioactive materials provide critical capabilities in the oil and gas, electrical power, construction, and food industries; are used to treat millions of patients each year in diagnostic and therapeutic procedures; are used in a variety of military applications; and are used in technology research and development involving academic, government, and private institutions. These materials are as diverse in geographical location as they are in functional use.

With regard to expanding the NSTS to include IAEA Category 3 sources, there can be concerns regarding the accountability and control of these sources because IAEA defines Category 3 sources (as well as the Category 1 and 2 sources) as "dangerous sources", i.e., a source that could if not under control give rise to exposure sufficient to cause severe deterministic effects, although, as noted above, it left to its individual member States whether it would be necessary to actually set up a tracking system for these sources. In addition, Category 3 sources could be easily aggregated to Category 2 levels, as part of a concerted effort to do so, 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, sources at the high end of the range of activities in Category 3 can be at levels just below the threshold of a Category 2 source, meaning that it would take only a few sources to aggregate to Category 2. The major categories of licensees who possess Category 3 sources include those with fixed industrial gauges (level gauges, conveyor gauges, thickness gauges, blast furnace gauges, dredger, pipe gauges); those who conduct well-logging operations; medical facilities with brachytherapy machines; and some radiographers with relatively low activity sources. Because these sources are thus relatively widespread in use and relatively broadly used in industry, there would be potential for aggregation of sufficient numbers of them to Category 2 levels. Adding these sources to the NSTS with its inventory and tracking requirements would provide for increased accountability and control of these sources because there would be a near real-time knowledge of source whereabouts and an ability to confirm an individual licensee's account of his sources.

With regard to considerations of expanding the NSTS to sources below the Category 3 threshold, a principal rationale for including sources at the high-end of the Category 4 range of activities (i.e., at 1/10th of Category 3) is the potential that a sufficient number of these higher-activity Category 4 sources could be obtained and aggregated to create the equivalent of Category 2 sources. These "high-end" Category 4 sources can be at levels just below the threshold of a Category 3 source, which is about 1/10th of the threshold of a Category 2 source, meaning that it would require about 10-12 of these sources to aggregate to Category 2 quantity. These high-end Category 4 (1/10th of Category 3) sources are possessed by the same licensees noted to have Category 3 sources, namely those with fixed industrial gauges, those who conduct well-logging operations, medical facilities with brachytherapy machines, and few radiographers, and as previously noted, are relatively widespread in use and broadly used in industry, thus allowing for the potential for aggregation of sufficient numbers of them to Category 2 levels.

Expanding the NSTS to additional licensees would include both rulemaking and information technology (IT) development and maintenance activities, as was the case for the original development of the NSTS for Category 1 and 2 sources. Like the current NSTS, the expanded NSTS would be a web-based system that would allow licensees to meet the proposed reporting requirements on-line. This proposed rulemaking would impose requirements on both NRC and Agreement State licensees and would establish the regulatory foundation for expanding the NSTS. The expanded NSTS is being developed and would be implemented under NRC's statutory authority to protect public health and safety.

As described in NRC's Action Plan in SECY-07-0147, August 25, 2007, expanding the existing NSTS is part of a comprehensive radioactive source control program for radioactive materials of concern. Although neither the existing NSTS, nor an expanded NSTS, can ensure the physical protection of sources, they can provide greater source accountability which should foster increased control of sources by licensees.

## **2. Identification and Preliminary Analysis of Alternative Approaches**

This regulatory analysis evaluates the values and impacts of two regulatory alternatives, one of which includes five sub-alternatives. The following subsections describe these alternatives.

### **2.1 Option 1: No Action**

Under Option 1, NRC would not expand the NSTS to additional licensees possessing Category 3 (or lower) sources. Thus, these additional licensees would not be required to report transaction information associated with the manufacture, transfer, receipt, disassembly, and disposal of nationally tracked sources.

### **2.2 Option 2: Expand the NSTS to Include Category 3 (or lower) sources**

Under Option 2, NRC would expand the NSTS to include Category 3 (or lower) sources.

Option 2 has three sub-options depending on what Category the NSTS was expanded to as follows:

- Sub-Option 2a: Expand National Source Tracking System to IAEA Category 3
- Sub-Option 2b: Expand National Source Tracking System to 1/10th of IAEA Category 3
- Sub-Option 2c: Expand National Source Tracking System to IAEA Category 4

Each sub-option would be made up of two alternate approaches:

- (1) require the additional licensees possessing Category 3 (or lower) sources to follow the same requirements as in the existing NSTS, including making initial and annual inventories, tracking transaction reports; and assigning serial numbers to sources;
- (2) require the additional licensees possessing Category 3 (or lower) sources to only follow inventory requirements of the NSTS

Under these sub-option/approaches, a licensee who manufactures, transfers, receives, disassembles, or disposes of nationally tracked source would be required to:

- Report its initial inventory of Category 3 (or lower) nationally tracked sources to the NSTS by July 2009.
- On an annual basis, reconcile and verify the inventory of Category 3 (or lower) nationally tracked sources it possesses against the data in the NSTS
- Complete and submit a National Source Tracking Transaction Report (i.e., NRC Form 748) after each transaction of a Category 3 (or lower) source
- Correct any errors in previously filed National Source Tracking Transaction Reports within five business days of the discovery
- For licensees who manufacture a Category 3 (or lower) nationally tracked source, assign a unique serial number to each nationally tracked source.

### **3. Analysis of Values and Impacts**

The subsections below describe the analysis conducted to identify and evaluate the values and impacts expected to result from the implementation of expanding the NSTS to additional licensees. Subsection 3.1 identifies the attributes that the expanded NSTS is expected to affect. Subsection 3.2 describes the methodology used to analyze the values and impacts associated with expanding the NSTS. Subsection 3.3 discusses the results of the analysis.

#### **3.1 Identification of Affected Attributes**

This subsection identifies the attributes, within the public and private sectors, that the expanded NSTS is expected to affect, using the list of potential attributes provided in Chapter 5 of NUREG/BR-0184, "Regulatory Analysis Technical Evaluation Handbook," dated January 1997, and in Chapter 4 of NUREG/BR-0058, Rev. 5, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," dated September 2004. Each attribute listed in Chapter 5 was evaluated. The basis for selecting those attributes expected to be affected by expanding the NSTS is presented below.

Expanding the NSTS is expected to affect the following attributes:

- *Public Health (Accident/Event)*. Expanding the NSTS would require additional licensees having Category 3 (or lower) sources to report information on the manufacture, transfer, receipt, disassembly, and disposal of nationally tracked sources. This information would provide a life cycle account for these sources. As a result, the proposed regulatory action is expected to improve accountability and controls over them which should have a positive effect on public health.
- *Offsite Property*. As stated above, licensees with Category 3 (or lower) sources would be required to provide a life cycle account for nationally tracked sources. Improvement in the accountability and controls over these sources is expected to avert potential offsite property damage and costs (e.g., long-term relocation, emergency response).

- *Industry Implementation.* The proposed regulatory action would require licensees with Category 3 (or lower) sources to report their initial inventory of Category 3 (or lower) nationally tracked sources to the NSTS. Licensees who reported nationally tracked source information to the One-time Data Collection would need only to verify or update their reported inventory information. Licensees who did not provide nationally tracked source information to the One-time Data Collection would need to report their inventory information by the specified dates. As a result, licensees (i.e., industry) would incur one-time implementation costs under the proposed regulatory action.
- *Industry Operation.* The proposed regulatory action would require licensees with Category 3 (or lower) sources to: (1) complete and submit a National Source Tracking Transaction Report after each transaction; (2) correct any errors in previously filed National Source Tracking Transaction Reports within five business days of the discovery; (3) reconcile and verify the inventories of nationally tracked sources they possess against the data in the NSTS on an annual basis; and (4) assign a unique serial number to each nationally tracked source they manufacture (if applicable). As a result, licensees (i.e., industry) would incur annual operating costs under the proposed regulatory action.
- *NRC Implementation.* To implement the proposed regulatory action, NRC would perform rulemaking and IT development activities to expand the original NSTS. Specifically, NRC would develop a proposed and final rule to implement the expansion of the NSTS to cover additional licensees with Category 3 (or lower) sources and arrange to expand the web-based NSTS, as well as extend the guidance on how to report information on nationally tracked source transactions to the NSTS.<sup>2</sup> As a result, NRC would incur one-time implementation costs under the proposed regulatory action.
- *NRC Operation.* Under the proposed regulatory action, NRC staff would review nationally tracked source information submitted to the expanded NSTS and arrange for operation and maintenance activities on the expanded web-based NSTS. As a result, NRC would incur annual operating costs under the proposed regulatory action.
- *Other Government.* Under the proposed regulatory action, other Federal agencies and State and local governments (e.g., Department of Homeland Security, Agreement States) would have access to and benefit from the information contained in the expanded NSTS. This information may allow them to better monitor the location of nationally tracked sources and focus resources on licensees based on their possession of nationally tracked sources. In addition, the information contained in the expanded NSTS would improve coordination among the various agencies.
- *Improvements in Knowledge.* The proposed regulatory action would require licensees with Category 3 (or lower) sources to report information on the manufacture, transfer, receipt, disassembly, and disposal of nationally tracked sources. This information would allow NRC to better understand the location of nationally tracked sources.

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<sup>2</sup> Consistent with direction in Section 5.7.9 of NUREG/BR-0184, this analysis does not include the pre-decisional costs of developing and issuing the proposed rule.

- *Regulatory Efficiency.* The proposed regulatory action would improve regulatory efficiency by expanding the NSTS to monitor the location of Category 3 (or lower) nationally tracked sources. Consequently, there would be increased accountability among all parties associated with a nationally tracked source transaction. In addition, the proposed regulatory action would improve regulatory efficiency by implementing applicable features of the IAEA's Code of Conduct.
- *Safeguards and Security Considerations.* The proposed regulatory action would require licensees to provide a life cycle account for Category 3 (or lower) nationally tracked sources. This information would allow NRC to better monitor the location of nationally tracked sources and thus, improve accountability and controls over them. Consequently, the proposed regulatory action would enhance NRC's ability to protect public health and safety.
- *Other Considerations.* The proposed regulatory action would require licensees with Category 3 (or lower) sources to provide a life cycle account for nationally tracked sources. This information would allow NRC to better monitor the location of nationally tracked sources. As a result, the proposed regulatory action may increase public confidence in NRC's regulation of inventories of radioactive materials.

Expanding the NSTS to Category 3 (or lower) sources is *not* expected to affect the following attributes:

- Public Health (Routine)
- Occupational Health (Accident)
- Occupational Health (Routine)
- Onsite Property
- General Public
- Antitrust Considerations
- Environmental Considerations

### **3.2 Methodology**

This subsection describes the methodology used to analyze the values and impacts associated with the implementation of the expanded NSTS. The values include any desirable changes in the affected attributes, while the impacts include any undesirable changes in the affected attributes.

This analysis relies on both a quantitative and a qualitative analysis of the affected attributes. The quantitative analysis involves the assessment of values (savings) and impacts (costs) under the expanded NSTS. The qualitative analysis involves a discussion of those attributes that NRC was not able to quantify.

The balance of this subsection describes the most significant analytical data and assumptions used in the quantitative analysis of the affected attributes.

#### **3.2.1 Baseline for Analysis**

The analysis measures the incremental values and impacts of the NSTS relative to a baseline

(Option 1, the no-action alternative), which is how the world would be in the absence of the expanded NSTS.

### **3.2.2 Assumptions**

The following subsections discuss the assumptions used in the analysis.

#### **3.2.2.1 Number of Licensees that Possess Nationally Tracked Sources**

Major categories of specific licensees who possess Category 3 (or lower) sources include:

- fixed industrial gauges (level gauges, conveyor gauges, thickness gauges, blast furnace gauges, dredger gauges, pipe gauges)
- well-logging
- brachytherapy - high/medium range and low dose range
- radiography

NRC is conducting the One-time Data Collection to obtain data on these specific licensees and the devices and sources they possess.

As noted in Section 2.2 above, NRC is considering 5 sub-options under Option 2 (namely expanding the NSTS to licensees with Category 3, 1/10th of Category 3, and lower than 1/10th of Category 3 sources, as well as whether to require licensees with these Category 3 (or lower) sources to follow all requirements of the NSTS or only the inventory requirements). Based on preliminary information from NRC's One-time Data Collection and NRC staff's best judgment, NRC estimates that there are approximately:

- 1000 NRC and Agreement State licensees that may possess Category 3 nationally tracked sources
- 2500 NRC and Agreement licensees that may possess nationally tracked sources at 1/10th of Category 3;

(based on the current total of 34 Agreement States, approximately 80% of these licensees are Agreement State licensees).

The One-time Data Collection is not collecting data on lower than 1/10th of Category 3 sources (i.e., Category 4 or 5). Therefore, quantitative analysis of these sources cannot be undertaken as part of this analysis. The discussion below presents a qualitative analysis of these lower than 1/10th of Category 3 sources.

#### **3.2.2.2 Number of Nationally Tracked Sources**

Based on preliminary information from NRC's One-time Data Collection and NRC staff's best judgment, NRC estimates that, collectively, licensees possess approximately:

- 5,200 Category 3 nationally tracked sources possessed by NRC and Agreement State licensees (as above, approximately 80% of the sources would be in Agreement States);
- 11,500 nationally tracked sources possessed by NRC and Agreement State licensees at 1/10th of Category 3 (approximately 80% would be in Agreement States).

### 3.2.2.3 Number of National Source Tracking Transaction Reports

To determine the number of source transactions (and therefore, the number of source transaction reports) it is first necessary to estimate the nature of the transactions that would be made under the requirements of the expanded NSTS. As input, we considered the Regulatory Analysis prepared in support of the final rule for the NSTS for IAEA Category 1 and 2 sources. In estimating the number of transactions, that Regulatory Analysis made certain assumptions regarding material flow balancing of replacement, manufacturing, transfer and receipt, disassembly, and disposal of sources. The Regulatory Analysis for Category 1 and 2 sources also made certain assumptions regarding the nature of submittal of the transaction reports, including the type of submittal (on-line, computer readable, fax, mail) and the amount of time spent on each transaction report. Although the licensees possessing Category 3 (or lower) sources are different than those with Category 1 and 2 sources, this Regulatory Analysis has used similar assumptions regarding general flow balancing of sources. This Regulatory Analysis has also used similar assumptions regarding the nature of the submittals of the transaction reports based on the general computer literacy and pervasive use of computers in U.S. society for a range of activities. In addition, in estimating the amount of time taken to complete transaction reports, this Regulatory Analysis used values similar to the earlier analysis because as new licensees become more familiar with the system, the times to complete these actions may have a tendency to become equal between licensees with Category 3 (or lower) sources and those with Category 1 and 2 sources.

In reviewing preliminary information from the One-time Data Collection, the principal categories of licensee/source types are fixed industrial gauges (including level gauges, conveyor gauges, blast furnace gauges, dredger gauges, pipe gauges) well logging, brachytherapy for medical use, and radiography. The approach used in estimating the number of source transactions considers the licensee/sources types and the half-life of the radionuclides used in those sources. In general, the longer the half-life of the radionuclide, the less frequently the source is replaced. Also, well-logging sources and fixed gauge sources usually are changed infrequently for reasons other than radionuclide decay based on their general location in a facility and because damage to the source does not generally occur. As a result, it is assumed that fixed gauge sources (which primarily contain Cs-137 and Co-60, with half-lives of 30 and 5 years, respectively) are replaced every ten years; well logging sources (which primarily contain Am-241, with a half-life of 458 years) are replaced every ten years; brachytherapy sources (which primarily contain Ir-192, with a half-life of 74 days) are replaced every four months; and radiography sources (which primarily contain Ir-192) are replaced every four months. Based on the estimated inventory of the number of sources in Section 3.2.2.2 and the estimated frequency of the replacement of sources noted here, NRC estimates that, each year, the licensees annually perform approximately 6,233 Category 3 source replacements and 11,677 of 1/10th of Category 3 source replacements.

As required by the proposed expanded NSTS, transactions must be reported when a source is manufactured, transferred, received, disassembled, or disposed of. In estimating the number of transactions of each type, simplifying assumptions are made that: the number of manufactures is approximately the same as the number of replacements; the number of source transfers and receipts are equal to each other; there is disassembly of sources when no longer serviceable; there is some decay of sources; and there is some disposal of sources at licensed low-level waste burial. Based on these assumptions and the net balance of sources, Tables 1 and 2 estimate the number of major transactions each year.

**Table 1**  
**Estimated Annual Number of Category 3 Source Transactions**

<b>Type of Transaction</b>	<b>Number of Transactions</b>
Manufacture	6,233
Transfer	11,843
Receipt	11,843
Disassemble	5,610
Disposal	312
Total	35,841

**Table 2**  
**Estimated Annual Number of 1/10th of Category 3 Source Transactions**

<b>Type of Transaction</b>	<b>Number of Transactions</b>
Manufacture	11,677
Transfer	22,186
Receipt	22,186
Disassemble	10,510
Disposal	584
Total	67,143

For each of the transactions identified in Tables 1 and 2, licensees would be required to complete and submit a National Source Tracking Transaction Report using on-line forms, computer-readable format files, fax, mail, or telephone with follow-up by fax or mail. NRC is uncertain about the number of National Source Tracking Transaction Reports that would be submitted each year for each type of transaction and submission method. However, NRC anticipates that the majority of the reports would be submitted by manufacturers and distributors. These entities are expected to report their transaction information electronically using computer-readable format files, given the large volume of transactions they perform. For purposes of this analysis, NRC made the following simplifying assumptions:

Manufacture:

- Each year, licensees would perform 6233 Category 3 (11,677 of 1/10th of Category 3) source transactions associated with the manufacture of new nationally tracked sources
- All reports associated with the manufacture of new Category 3 and/or 1/10th of Category 3 nationally tracked sources would be submitted using computer-readable

format files

- The Regulatory Analysis for Category 1 and 2 sources assumed that reports would contain information on 100 transactions; however it is assumed that reports on Category 3 sources would contain 50 transactions as there are fewer transactions.

#### Transfer and receipt

- Each year, licensees would perform 23,686 Category 3 (44,372 of 1/10th of Category 3) transactions associated with the transfer and receipt of nationally tracked sources
- Reports associated with the transfer and receipt of nationally tracked sources would be submitted as follows: about half would be submitted by manufacturers and distributors using computer-readable files, and about half would be submitted by users who use on-line forms. In addition, it is estimated that about 2-3% of the reports would be submitted by fax, mail, or phone with follow-up by fax or mail.
- Reports submitted using computer-readable format files would contain information on the number of transactions in the manner noted above. The Regulatory Analysis for Category 1 and 2 sources assumed that reports using on-line, or other, forms would contain information on three transactions; however it is assumed these reports for Category 3 sources would contain two transactions as there are fewer transactions.
- The number of transfer reports equals the number of receipt reports

#### Disassembly

- Each year, licensees perform an estimated 5610 Category 3 (10510 of 1/10th of Category 3) transactions associated with the disassembly of nationally tracked sources
- All reports associated with the disassembly of nationally tracked sources would be submitted using computer readable format files
- Reports submitted using computer-readable files would contain information on the number of transactions in the manner noted above.

#### Disposal

- Each year, licensees would perform 312 Category 3 (584 of 1/10th of Category 3) transactions associated with the disposal of nationally tracked sources
- All reports associated with the disposal of nationally tracked sources would be submitted using on-line forms
- Each report would contain information in the manner noted above.

These assumptions are reflected in Tables 3 and 4.

**Table 3**  
**Estimated Number of Category 3 National Source Tracking Transaction Reports Submitted Annually, by Type of Transaction and Submission Method**

Type of Transaction	Submission Method					Total
	On-Line Forms	Computer-Readable Format File	Fax	Mail	Telephone with Follow-up by Fax or Mail	
Manufacture	0	125	0	0	0	125
Transfer	2961	118	41	41	5	3166
Receipt	2961	118	41	41	5	3166
Disassemble	0	112	0	0	0	112
Disposal	156	0	0	0	0	156
Total	6078	473	82	82	10	6725

**Table 4**  
**Estimated Number of 1/10th of Category 3 National Source Tracking Transaction Reports Submitted Annually, by Type of Transaction and Submission Method**

Type of Transaction	Submission Method					Total
	On-Line Forms	Computer-Readable Format File	Fax	Mail	Telephone with Follow-up by Fax or Mail	
Manufacture	0	117	0	0	0	117
Transfer	3698	111	78	78	10	3975
Receipt	3698	111	78	78	10	3975
Disassemble	0	105	0	0	0	105
Disposal	195	0	0	0	0	195
Total	7591	444	156	156	20	8367

### 3.2.3 Analysis

This subsection discusses the analyses of the quantifiable impacts (i.e., costs) associated with implementation of the expanded NSTS. For purposes of this analysis, the impacts under the NSTS were categorized as follows:

- Rulemaking and IT development/maintenance activities
- National source tracking system account set-up
- Initial inventory of nationally tracked sources

- Annual inventory reconciliation of nationally tracked sources
- National Source Tracking Transaction Reports
- Correction of previously filed National Source Tracking Transaction Reports
- For manufacturers, assigning nationally tracked source unique serial numbers

The cost assumptions for each of the above impact categories are discussed in the following subsections. Note that all costs presented in this Regulatory Analysis are in 2005 dollars. Year 2005 dollars were used in this Regulatory Analysis to facilitate comparison with the Regulatory Analysis for the NSTS for Category 1 and 2 sources. Results using year 2007 dollars as a base would be comparable as the unit costs of labor (\$93 for year 2007 vs. \$87 for year 2005) are comparable.

### **3.2.3.1 Rulemaking and IT Development/Maintenance Activities**

In implementing the proposed regulatory action, the NRC expects to perform final rulemaking and IT development/maintenance activities for expanding the NSTS to include licensees with Category 3 (or lower) sources.

Significant costs of IT development were already tabulated as part of the preparation of the NSTS rule for licensees with Category 1 and 2 sources. Significant additional IT development costs and resources are not expected for expanding the NSTS to Category 3 (or lower) sources due to the capabilities being incorporated into the NSTS software; however costs would be incurred for adding and certifying additional licensees so that they can access the system to enter or verify data.

The NRC estimates that, between 2008 and 2010, the NRC would incur approximately \$0.6 M to expand the IT requirements for the NSTS to Category 3 (\$1.5 M for 1/10th of Category 3). This estimated cost includes costs for entering new licensees into the NSTS and credentialing new users, including the process of validating users, and providing certificates and hardware tokens. This value represents both NRC staff and contractor time and effort. In addition to initial set-up costs to implement the NSTS, there would also be annual costs to NRC for maintenance and operation of the system. The Regulatory Analysis for the rulemaking for Category 1 and 2 licensees estimated that these annual costs would be approximately \$2.7 M for the 1350 licensees estimated for that system. Based on that analysis, including considerations related to DOE sources, it is estimated that the annual costs for the expanded NSTS, based on the numbers of licensees with Category 3 and 1/10th of Category 3 sources, would be approximately \$2M per year for the addition of Category 3 sources (\$5 M for 1/10th of Category 3 sources) beginning in FY 2010<sup>4</sup> beyond what is already expended on the existing NSTS. This includes NRC and contractor time and effort.

### **3.2.3.2 National Source Tracking System Account Set-Up**

To report nationally tracked source transaction information electronically, a licensee would need to establish an account with the NSTS. Once an account is established, the licensee would be provided with password information that would allow access to the system.

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<sup>4</sup> FY 2010 covers the period between October 1, 2009 and September 30, 2010.

The NRC estimates that, on average, 0.5 hour (30 minutes) of licensee staff time would be required to establish an account with the NSTS. Using an estimated average labor rate of \$87 per hour for licensee staff<sup>5</sup>, the cost for establishing an account is estimated to be \$43.50 per licensee (i.e., 0.5 hour x \$87/hour). NRC anticipates that, of the 1000 Category 3 (2500 of 1/10th of Category 3) licensees, over 90% of Category 3 and 1/10th of Category 3 licensees would report transaction information electronically using on-line forms or computer-readable format files. Thus, industry's total cost for establishing accounts with the NSTS is estimated to be \$42,360 for Category 3 and \$106,575 for 1/10th of Category 3.

Note that, for purposes of this analysis, the NRC made the assumption that all licensees reporting nationally tracked source transaction information electronically would establish their accounts with the NSTS in 2009.

In addition to account set-up, licensees planning to use the computer readable format files would also expend some programming effort to establish the ability to report using this method. Some programming would be necessary to collect the information from current computer files. As noted above, licensees using computer-readable files would primarily include manufacturers and distributors expecting to file larger numbers of reports. The Regulatory Analysis for Category 1 and 2 sources estimated the licensee staff time that would be required to conduct the necessary programming and, since most of the licensees affected by the expansion of the NSTS would also be covered under the existing NSTS, a smaller value of 20 hours for programming is used in this Regulatory Analysis. Using an estimated average labor rate of \$87 per hour for licensee staff, the cost of programming is estimated to be \$1740 per licensee (i.e., 20 hours x \$87/hour). Based on the Regulatory Analysis for Category 1 and 2 sources, it is estimated that industry's total programming cost would be \$87,000. It is assumed that this effort would occur in 2009.

Licensees may also expend some effort on training. Each licensee is assumed to expend 4 hours per person to conduct the training and to train two individuals in use of the system. Using an average labor rate of \$87 per hour for licensee staff, industry's total training cost is estimated to be \$696,000 (i.e., 1000 licensees x 8 hours x \$87/hour) for Category 3 licensees (\$1,700,000 for 1/10th of Category 3 licensees). It is assumed that this effort would occur in 2009.

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<sup>5</sup> The average hourly labor rate of \$87 is based on NRC staff's best judgment. This hourly labor rate includes costs associated with employee benefits (e.g., health plan). However, it does not include costs associated with overhead (e.g., rent, utilities). Note that this approach was taken because, for purposes of this analysis, the NRC is interested in measuring costs associated with incremental workload changes in response to the proposed regulatory action.

### 3.2.3.3 Initial Inventory of Nationally Tracked Sources

Under existing regulations, licensees are required to conduct an inventory of their sealed sources. For example, well loggers must conduct an inventory under 10 CFR 39.37, brachytherapy users must conduct an inventory under 10 CFR 35.67, and radiographers must conduct an inventory under 10 CFR 34.29. The proposed regulatory action would require licensees to report their initial inventory of Category 3 (or lower) nationally tracked sources to the NSTS. Licensees whose nationally tracked source information was reported to the One-time Data Collection would need only to verify or update their inventory information because, to ease the reporting process, information already in the One-time Data Collection system would be downloaded to the NSTS. Licensees whose nationally tracked source information was not reported to the One-time Data Collection System would need to report their initial inventory of Category 3 and/or nationally tracked sources to the NSTS by July 2009.

The NRC estimates that licensees would require, on average, 0.50 hour (30 minutes) to verify/update or report initial inventory information on their nationally tracked sources.<sup>6</sup> Using an estimated average labor rate of \$87 per hour for licensee staff, the labor cost for verifying/updating or initially reporting this information is estimated to be \$43.50 per licensee (i.e., 0.50 hour x \$87/hour). As indicated in Section 3.2.2.1, the NRC estimates that 1000 licensees with Category 3 sources (2500 licensees with 1/10th of Category 3 sources) would verify/update or initially report inventory information for nationally tracked sources. Thus, the labor cost to licensees is estimated to be \$43,500 (i.e., 1000 licensees x \$43.50/licensee) for licensees with Category 3 sources (\$108750 (i.e., 2500 licensees x \$43.50/licensee) for licensees with 1/10th of Category 3 sources.

In addition, the NRC estimates that licensees would incur materials costs, based on the submission method selected. These costs are described below:

- *On-Line Forms and Computer-Readable Format Files.* The NRC considers Internet access to be a standard business practice. Therefore, for purposes of this analysis, the cost associated with the purchase of Internet access services is not considered an incremental cost to licensees.
- *Fax.* The NRC estimates that each of the 48 licensees with Category 3 sources (119 licensees with 1/10th of Category 3 sources) submitting information by fax would incur a materials cost of \$0.15 for faxing the information to the NSTS.<sup>7</sup> Thus, the materials cost to licensees submitting information by fax is estimated to be \$7 for licensees with Category 3 sources (i.e., 48 licensees x \$0.15/licensee) and \$18 for licensees with 1/10th of Category 3 sources (i.e., 119 licensees x \$0.15/licensee).

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<sup>6</sup> Note that some licensees may require more or less time to verify/update or initially report inventory information on their nationally tracked sources. The time required by each licensee would depend on licensee-specific factors (e.g., number of sources, licensee's efficiency).

<sup>7</sup> Based on the cost of a two-minute State-to-State telephone call.

- *Mail.* The NRC estimates that each of the 48 licensees with Category 3 sources (119 licensees with 1/10th of Category 3 sources) submitting information by mail would incur a materials cost of \$3.64 for mailing the information to the NSTS<sup>8</sup>. Thus, the materials cost to licensees submitting information by mail is estimated to be \$173 for licensees with Category 3 sources (i.e., 48 licensees x \$3.64/licensee) and \$432 for licensees with 1/10th of Category 3 sources (i.e., 119 licensees x \$3.64/licensee).

Based on the above, the materials cost to licensees is estimated to be \$180 for licensees with Category 3 sources and \$450 for licensees with 1/10th of Category 3 sources

In summary, the NRC estimates that industry's total one-time cost for verifying/updating or initially reporting nationally tracked source inventory information would be \$43,680 for licensees with Category 3 sources and \$109,200 for licensees with 1/10th of Category 3 sources. For purposes of this analysis, the NRC assumes that 50 percent of this one-time industry implementation cost would be incurred in 2009 and 50 percent would be incurred in 2010.

#### **3.2.3.4 Annual Inventory Reconciliation of Nationally Tracked Sources**

Under existing regulations, licensees are required to conduct inventories of their sealed sources. For example, well loggers must conduct an inventory under 10 CFR 39.37, brachytherapy users must conduct an inventory under 10 CFR 35.67, and radiographers must conduct an inventory under 10 CFR 34.29. The proposed regulatory action would require each licensee to reconcile and verify its inventory of nationally tracked sources against the data in the National Source Tracking System. This verification would be conducted during the month of January each year. As part of the verification process, the licensee would be required to resolve any discrepancies between the NSTS and the actual inventory by filing the necessary National Source Tracking Transaction Report(s).

The NRC estimates that licensees would require, on average, one hour to reconcile and verify inventory information on their nationally tracked sources.<sup>9</sup> Using an estimated average labor rate of \$87 per hour for licensee staff, the labor cost for reconciling and verifying this information is estimated to be \$87 per licensee (i.e., 1 hour x \$87/hour). As indicated in Section 3.2.2.1, the NRC estimates that 1000 licensees with Category 3 sources (2500 licensees with 1/10th of Category 3 sources) would reconcile and verify inventory information for nationally tracked sources. Thus, the labor cost to licensees is estimated to be \$87,000 (i.e., 1000 licensees x \$87/licensee) for licensees with Category 3 sources (\$217,500 (i.e., 2500 licensees x \$87/licensee) for licensees with 1/10th of Category 3 sources).

In addition, the NRC estimates that licensees would incur materials costs, based on the submission method selected. These costs are described below:

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<sup>8</sup> Includes costs associated with mailing a five-ounce package by certified mail in a manila envelope (\$1.29 for postage, \$2.30 for the certified-mail fee, and \$0.05 for a manila envelope).

<sup>9</sup> Note that some licensees may require more or less time to reconcile and verify inventory information on their nationally tracked sources. The time required by each licensee would depend on licensee-specific factors (e.g., number of sources, licensee's efficiency).

- *On-Line Forms and Computer-Readable Format Files.* The NRC considers Internet access to be a standard business practice. Therefore, for purposes of this analysis, the cost associated with the purchase of Internet access services is not considered an incremental cost to licensees.
- *Fax.* The NRC estimates that each of the 48 licensees with Category 3 sources (119 licensees with 1/10th of Category 3 sources) submitting information by fax would incur a materials cost of \$0.15 for faxing the information to the NSTS.<sup>10</sup> Thus, the materials cost to licensees submitting information by fax is estimated to be \$7 for licensees with Category 3 sources (i.e., 48 licensees x \$0.15/licensee) and \$18 for licensees with 1/10th of Category 3 sources (i.e., 119 licensees x \$0.15/licensee).
- *Mail.* The NRC estimates that each of the 48 licensees with Category 3 sources (119 licensees with 1/10th of Category 3 sources) submitting information by mail would incur a materials cost of \$3.64 for mailing the information to the NSTS.<sup>11</sup> Thus, the materials cost to licensees submitting information by mail is estimated to be \$173 for licensees with Category 3 sources (i.e., 48 licensees x \$3.64/licensee) and \$432 for licensees with 1/10th of Category 3 sources (i.e., 119 licensees x \$3.64/licensee).

*Telephone with Follow-up by Fax or Mail.* To be calculated – small

Based on the above, the materials cost to licensees is estimated to be \$180 for licensees with Category 3 sources and \$450 for licensees with 1/10th of Category 3 sources

In summary, the NRC estimates that industry's total annual labor and materials cost for reconciling and verifying its inventory of nationally tracked sources would be \$87,180 for licensees with Category 3 sources (\$217,950 for licensees with 1/10th of Category 3 sources). For purposes of this analysis, the NRC assumes that this annual industry operating cost would be incurred for the first time in 2010.

### **3.2.3.5 National Source Tracking Transaction Reports**

As stated earlier, the proposed regulatory action would require each licensee who manufactures, transfers, receives, or disposes a nationally tracked source to complete and submit a National Source Tracking Transaction Report (i.e., NRC Form 748).

Following is a discussion of the costs that would be incurred by industry in completing and submitting these reports:

<sup>10</sup>Based on the cost of a two-minute State-to-State telephone call.

<sup>11</sup> Includes costs associated with mailing a five-ounce package by certified mail in a manila envelope (\$1.29 for postage, \$2.30 for the certified-mail fee, and \$0.05 for a manila envelope).

- *Reports Submitted Using On-Line Forms.* The NRC estimates that, on average, 10 minutes of licensee staff time would be required to complete and submit a National Source Tracking Transaction Report on-line. Using an estimated average labor rate of \$87 per hour for licensee staff, the cost for conducting these activities is estimated to be \$14.50 per report [i.e., (10 minutes/60 minutes) x \$87/hour].<sup>12</sup>

As shown in Table 3, the NRC estimates that, each year, licensees with Category 3 sources would complete and submit 6078 reports on-line (licensees with 1/10th of Category 3 sources would complete/submit 7591 reports on-line). Thus, the industry's total annual cost for completing and submitting National Source Tracking Transaction Reports on-line is estimated to be \$88,131 for licensees with Category 3 sources (i.e., 6078 reports x \$14.50/report) (\$110,069 for licensees with 1/10th of Category 3 sources (i.e., 7591 reports x \$14.50/report).

- *Reports Submitted Using a Computer-Readable Format File.* The NRC estimates that, on average, five minutes of licensee staff time would be required to complete and submit a National Source Tracking Transaction Report electronically using a computer-readable format file. Using an estimated average labor rate of \$87 per hour for licensee staff, the cost for conducting these activities is estimated to be \$7.25 per report (i.e., (5 minutes/60 minutes) x \$87/hour).<sup>13</sup>

As shown in Tables 3 and 4, the NRC estimates that, each year, licensees with Category 3 sources would complete and submit 473 reports (licensees with 1/10th of Category 3 sources would complete/submit 444 reports using computer-readable format files). Thus, the industry's total annual cost for completing and submitting National Source Tracking Transaction Reports electronically using computer-readable format files is estimated to be \$3429 for licensees with Category 3 sources (i.e., 473 reports x \$7.25/report) (\$3219 for licensees with 1/10th of Category 3 sources (i.e., 444 reports x \$7.25/report).

- *Reports Submitted by Fax.* The NRC estimates that, on average, 0.25 hour (15 minutes) of licensee staff time would be required to complete and submit a National Source Tracking Transaction Report by fax. Using an estimated average labor rate of \$87 per hour for licensee staff, the labor cost for conducting these activities is estimated to be \$21.75 (i.e., 0.25 hours x \$87/hour). In addition, the NRC estimates that, on average, licensees would incur a materials cost of \$0.15 for each report they fax to the NSTS.<sup>14</sup> Thus, the total cost for completing and submitting a report is estimated to be \$21.90 (i.e., \$21.75 + \$0.15).

<sup>12</sup> The NRC considers Internet access to be a standard business practice. Therefore, for purposes of this analysis, the cost associated with the purchase of Internet access services is not considered an incremental cost to licensees.

<sup>13</sup> The NRC considers Internet access to be a standard business practice. Therefore, for purposes of this analysis, the cost associated with the purchase of Internet access services is not considered an incremental cost to licensees.

<sup>14</sup> Based on the cost of a two-minute State-to-State telephone call.

The NRC further estimates that, each year, licensees with Category 3 sources would complete and submit 82 reports by fax (licensees with 1/10th of Category 3 sources would complete/submit 156 reports by fax). Thus, the industry's total annual cost for completing and submitting National Source Tracking Transaction Reports by fax is estimated to be \$1796 for licensees with Category 3 sources (i.e., 82 reports x \$21.90/report) (\$3416 for licensees with 1/10th of Category 3 sources (i.e., 156 reports x \$21.90/report)).

- *Reports Submitted by Mail.* The NRC estimates that, on average, 0.25 hour (15 minutes) of licensee staff time would be required to complete and submit a National Source Tracking Transaction Report by mail. Using an estimated average labor rate of \$87 per hour for licensee staff, the labor cost for conducting these activities is estimated to be \$21.75 (i.e., 0.25 hours x \$87/hour). In addition, the NRC estimates that, on average, licensees would incur a materials cost of \$3.64 for each report they mail to the National Source Tracking System.<sup>15</sup> Thus, the total cost for completing and submitting a report is estimated to be \$25.39 (i.e., \$21.75 + \$3.64).

The NRC further estimates that, each year, licensees with Category 3 sources would complete and submit 82 reports by mail (licensees with 1/10<sup>th</sup> of Category 3 sources would complete/submit 156 reports by mail). Thus, the industry's total annual cost for completing and submitting National Source Tracking Transaction Reports by mail is estimated to be \$2082 for licensees with Category 3 sources (i.e., 82 reports x \$25.39/report) (\$3960 for licensees with 1/10<sup>th</sup> of Category 3 sources (i.e., 156 reports x \$25.39/report)).

### 3.2.3.6 Correction of Previously Filed National Source Tracking Transaction Reports

The proposed regulatory action would require licensees to correct any errors in previously filed National Source Tracking Transaction Reports within five business days of the discovery. The NRC anticipates that all reports would be corrected and re-submitted using on-line forms.

The NRC estimates that, on average, 0.05 hour (3 minutes) of licensee staff time would be required to correct and re-submit a previously filed National Source Tracking Transaction Report on-line. Using an estimated average labor rate of \$87 per hour for licensee staff, the cost for conducting these activities is estimated to be \$4.35 per report (i.e., 0.05 hour x \$87/hour).<sup>16</sup> As shown in Tables 3 and 4, the NRC estimates that, each year, licensees with Category 3 sources would submit 6725 National Source Tracking Transaction Reports (licensees with 1/10th of Category 3 sources would submit 8367 such reports). Based on best judgment, the NRC estimates that licensees would correct and re-submit one percent of these reports, (i.e., 6725 x 0.01 = 67 reports for Category 3 licensees)(i.e., 8367 x 0.01 = 84 reports for 1/10<sup>th</sup> Category 3 licensees). Thus, the industry's total annual cost for correcting and re-submitting previously filed National Source Tracking Transaction Reports is estimated to be \$291 (i.e., 67 reports x \$4.35/report)(\$365.00 for licensees with 1/10<sup>th</sup> Category 3 sources [i.e., 84 reports x \$4.35/report]).

<sup>15</sup> Includes costs associated with mailing a five-ounce package by certified mail in a manila envelope (\$1.29 for postage, \$2.30 for the certified-mail fee, and \$0.05 for a manila envelope).

<sup>16</sup> The NRC considers Internet access to be a standard business practice. Therefore, for purposes of this analysis, the cost associated with the purchase of Internet access services is not considered an incremental cost to licensees.

Note that, for purposes of this analysis, the NRC assumes that this annual industry operating cost would be incurred for the first time in 2009.

### **3.2.3.7 Nationally Tracked Source Unique Serial Numbers**

The proposed regulatory action would require each licensee who manufactures a nationally tracked source after the effective date of the rule to assign a unique serial number to each nationally tracked source.<sup>17</sup> Serial numbers may be composed only of alpha-numeric characters.

The NRC estimates that, on average, two minutes of licensee staff time would be required to assign a unique serial number to a nationally tracked source. Using an estimated average labor rate of \$87 per hour for licensee staff, the cost for assigning a serial number is estimated to be \$2.90 per source (i.e., [2 minutes/60 minutes] x \$87/hour). In Tables 1 and 2, NRC estimates that 6233 Category 3 (11,677 of 1/10th of Category 3) nationally tracked sources are manufactured each year. Thus, the industry's total annual cost for assigning unique serial numbers to Category 3 nationally tracked sources is estimated to be \$18,076 (i.e., 6233 sources x \$2.90/source) (\$33,863 for 1/10th of Category 3 sources [11,677 sources x \$2.90/source]).

### **3.2.3.8 Inspection Costs**

NRC and Agreement States would conduct inspections of the NSTS reporting requirements. These inspections would be included as part of routine inspections. NRC estimates between one half to one hour would be needed to conduct the inspection for NSTS requirements. Thus, the total effort would be \$17,400 for NRC (i.e., \$87 per hour x 1 hour per licensee x 200 NRC licensees) and \$69,600 for Agreement States (i.e., \$87 per hour x 1 hour per licensee x 800 Agreement State licensees) for 2010. In later years, the inspection effort would be based on reporting discrepancies; therefore, beginning in 2011, the cost would be \$5,742 for NRC and \$22,970 for Agreement States for Category 3 licensees (\$14,355 and \$57,420, respectively for 1/10th of Category 3 licensees)

### **3.2.3.9 Agreement State Costs**

Agreement States would need to issue legally binding requirements to their licensees to require the licensees to report to the expanded NSTS. This could be done through promulgating a comparable rule, issuing orders, or adding and revising individual license conditions. It may involve more than one activity. The proposed rule is Compatibility Category "B"; therefore, an Agreement State should adopt program elements essentially identical to those of NRC. The NRC program elements in this category are those that apply to activities that have direct and significant transboundary implications. The expanded NSTS is a national system and everyone must begin reporting at the same time and using the same requirements for the system to be

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<sup>17</sup> The existing NSTS rule requires such serialization; the proposed rule would expand the requirement to IAEA Category 3 sources (or 1/10th of IAEA Category 3 sources).

useful. Since each of the 34 Agreement States may choose different implementation mechanisms and have different numbers of licensees, it is difficult to estimate the costs for each Agreement State. Since legally binding requirements need to be essentially word-for-word compatible, the process should be relatively simple, especially as a follow-on to the establishment of the NSTS for Category 1 and 2 sources. NRC estimates that on the average, each Agreement State would expend 0.15 FTE at \$76,000/FTE for each State. At this time, there are 34 Agreement States; therefore, the total cost for all Agreement States would be approximately \$384,000.

### **3.2.3.10 Costs of Annual Inventory Only for the Approach of Only Requiring Licensees to Follow Inventory Requirements of the NSTS**

As noted in Section 2.2, each Sub-option considered in this Regulatory Analysis includes an approach of only requiring licensees to follow the inventory requirements of the NSTS. Under this approach licensees would not track transactions or file transaction reports. They would also not perform annual reconciliations of their inventory with the transaction reports. However, they would still conduct, and report on, the initial inventory and an annual inventory. It is assumed for the purposes of estimating costs in this Regulatory Analysis that the costs of the annual inventory would be similar to the costs of the initial inventory.

Thus, the NRC estimates that under the requirements of an inventory-only expansion of the NSTS, industry's annual cost would include conducting and reporting the inventory of nationally tracked sources; account set-up and training in use of the NSTS; and assigning of serial numbers. In addition, there would also be costs of NRC credentialing of users, inspection costs, although reduced; NRC monitoring costs, although substantially reduced; and Agreement State implementation costs. For purposes of this analysis, the NRC assumes that this *annual* industry operating cost would be incurred for the first time in 2010.

## **3.3 Results**

As discussed in Section 2.2, the NRC considered Options 2a, 2b, and 2c in this Regulatory Analysis. As noted in Section 3.2.2.1, the One-time Data Collection is not collecting data on lower than 1/10th of Category 3 sources (i.e., Category 4 or 5) and, therefore, quantitative analysis of Option 2c (Expanding the NSTS to IAEA Category 4) was not undertaken as part of this analysis. Expansion of the NSTS to include all of Category 4 sources (and/or Category 5) was considered. However in both cases it was decided that, because of the magnitude of the thresholds of each of these categories and the lower likelihood that sources at the lower range of Category 4 or in Category 5 could be aggregated to the higher category levels, it would not be reasonable to incur the additional Option 2c burden of including these sources in the NSTS.

Under the NSTS alternative for each of the two sub-options that can be quantified (Sub-options 2a and 2b), the NRC would require licensees with sources at or above the Category 3 threshold and/or at or above 1/10th of the Category 3 threshold to report information as follows:

Sub-Option 2a: Expand National Source Tracking System to IAEA Category 3

- (1) require these additional licensees to follow the same requirements as in the existing NSTS, including: making and reporting initial and annual inventories; tracking transaction reports; and assigning serial numbers to sources; and

- (2) require the additional licensees possessing these sources to only follow the inventory requirements of the NSTS.

Sub-Option 2b: Expand National Source Tracking System to 1/10th of IAEA Category 3

- (1) require these additional licensees to follow the same requirements as in the existing NSTS, including: making and reporting initial and annual inventories; tracking transaction reports; and assigning serial numbers to sources; and
- (2) require the additional licensees possessing these sources to only follow the inventory requirements of the NSTS.

In estimating the costs for following the inventory requirements of the NSTS, it is assumed that licensees would be required to:

- set up an account with the NSTS and conduct necessary training;
- conduct and report an initial inventory;
- conduct and report an annual inventory;
- for manufacturers, mark a unique serial number on the source.

As can be seen in Sections 3.2.3.1 through 3.2.3.10 of this document, NRC staff used the cost assumptions in Section 3.2 to estimate one-time and annual incremental costs to industry and the NRC under Options 2a and 2b. As noted in Section 3.2.3, all one-time and annual costs were calculated in 2005 dollars to facilitate comparison with the Regulatory Analysis for the NSTS for Category 1 and 2 sources. These one-time and annual costs were then estimated over a three-year period, in a manner similar to that done for the OMB burden analysis, using discount rates of 7 and 3 percent. These results are presented in Tables 5 through 8 located at the end of this analysis.

NRC staff believes that expected qualitative values contribute substantially to the benefits of the NSTS. These qualitative values include:

- *Improved Control of These Additional Nationally Tracked Sources.* The expanded NSTS is expected to result in improved accountability of nationally tracked sources and provide additional protection against aggregation of lower activity sources. This is expected to improve public health (accident/event) and avert potential offsite property damage and costs.
- *Improved Regulatory Efficiency.* The expansion of the NSTS to monitor the location of Category 3 (or lower) nationally tracked sources would improve regulatory efficiency by increasing accountability among all parties associated with a nationally tracked source transaction.
- *Increased Public Confidence.* Information contained in the expanded NSTS would allow the NRC to better monitor the location of nationally tracked sources. This is expected to result in increased public confidence in NRC's regulation of inventories of radioactive materials.

- *Enhanced NRC's Ability to Protect Public Health and Safety.* Information contained in the expanded NSTS would allow the NRC to better monitor the location of nationally tracked sources and, thus, improve accountability of them. Consequently, the NSTS should enhance NRC's ability to protect the public health and safety.

#### **4. Backfit Analysis**

The proposed regulatory action includes new reporting requirements and does not impose any backfits on systems, structures, or components of a facility. That is, the proposed regulatory action does not contain any provisions involving backfitting, as defined at 10 CFR 50.109, 70.76, 72.62, and 76.76. Therefore, a backfit analysis is not required.

#### **5. Decision Rationale**

For the regulatory alternatives identified, the values and impacts have been considered. Option 2b (expanding the NSTS to 1/10th of Category 3 sources) was determined to be the preferred option because it is expected to: (1) improved accountability and control of nationally tracked sources and thereby enhance NRC's ability to protect public health and safety; (2) improve regulatory efficiency (by increasing accountability among all parties associated with a nationally tracked source transaction); and (3) increase public confidence. NRC believes that the incremental costs to licensees and the NRC under Option 2b are justified based on these considerations and because the Energy Policy Act of 2005 requires NRC to issue regulations for a source tracking system.

#### **6. Implementation**

The proposed regulatory action would be enacted through a Proposed Rule, public comments, and a Final Rule, with promulgation of the Final Rule by April 2009. No impediments to implementation of the recommended alternative have been identified.

The proposed regulatory action would require licensees who manufacture, transfer, receive, disassemble, or dispose of a nationally tracked source to: (1) report their initial inventory of nationally tracked sources greater than or equal to 1/10th of the IAEA Category 3 threshold to the NSTS; (2) complete and submit a National Source Tracking Transaction Report after each transaction; (3) correct any errors in previously filed National Source Tracking Transaction Reports within five business days of the discovery; and (4) reconcile and verify the inventories of nationally tracked sources they possess against the data in the NSTS on an annual basis. In addition, licensees who manufacture nationally tracked sources after the effective date of the rule would be required to assign a unique serial number to each nationally tracked source.

The NRC is currently in the process of expanding the NSTS and expects to finalize its development by January 2009. When completely operational, the expanded NSTS would be a web-based system that would allow licensees to meet the proposed reporting requirements.

Table 5

## Regulatory Analysis for Extending NSTS to IAEA Category 3 Sources

Category	3% Discount Rate				7% Discount Rate			
	Industry	NRC	AS	Total	Industry	NRC	AS	Total
Inventory Requirements	210,496	0	0	210,496	201,303	0	0	201,303
Transaction Reports	182,686	0	0	182,686	172,618	0	0	172,618
Manufacturers' Costs	34,587	0	0	34,587	32,681	0	0	32,681
Licensee Account Set-up	826,500	0	0	826,500	826,500	0	0	826,500
Implementation By Regulators	0	600,000	387,600	987,600	0	600,000	387,600	987,600
Operations by Regulators	0	3,873,059	184,480	4,057,540	0	3,661,533	42,785	3,704,318
Total	1,254,269	4,473,059	572,080	6,299,409	1,233,102	4,261,533	430,385	5,925,020

Table 6

Regulatory Analysis for Extending NSTS to 1/10<sup>th</sup> of IAEA Category 3 Sources

Category	3% Discount Rate				7% Discount Rate			
	Industry	NRC	AS	Total	Industry	NRC	AS	Total
Inventory Requirements	526,241	0	0	526,241	503,258	0	0	503,258
Transaction Reports	226,113	0	0	226,113	213,652	0	0	213,652
Manufacturers' Costs	64,796	0	0	64,796	61,225	0	0	61,225
Licensee Account Set-up	1,935,750	0	0	1,935,750	1,935,750	0	0	1,935,750
Implementation By Regulators	0	1,500,000	387,000	1,887,000	0	1,500,000	387,600	1,887,600
Operations by Regulators	0	9,682,648	461,201	10,143,849	0	9,153,831	106,962	9,260,794
Total	2,752,900	11,182,648	848,201	14,784,349	2,713,885	10,653,831	494,562	13,862,279

Table 7

## Regulatory Analysis for Extending NSTS to IAEA Category 3 Sources

## Inventory Requirements Only

Category	3% Discount Rate				7% Discount Rate			
	Industry	NRC	AS	Total	Industry	NRC	AS	Total
Inventory Requirements	127,260	0	0	127,260	122,654	0	0	122,654
Transaction Reports	0	0	0	0	0	0	0	0
Manufacturers' Costs	34,587	0	0	34,587	32,681	0	0	32,681
Licensee Account Set-up	739,500	0	0	739,500	739,500	0	0	739,500
Implementation By Regulators	0	600,000	387,600	987,600	0	600,000	387,600	987,600
Operations by Regulators	0	405,754	92,240	497,994	0	384,352	21,392	405,744
Total	901,347	1,005,754	479,840	2,386,941	894,835	984,352	408,992	2,288,179

Table 8

Regulatory Analysis for Extending NSTS to 1/10<sup>th</sup> of IAEA Category 3 Sources

## Inventory Requirements Only

Category	3% Discount Rate				7% Discount Rate			
	Industry	NRC	AS	Total	Industry	NRC	AS	Total
Inventory Requirements	318,151	0	0	318,151	306,636	0	0	306,636
Transaction Reports	0	0	0	0	0	0	0	0
Manufacturers' Costs	64,796	0	0	64,796	61,225	0	0	61,225
Licensee Account Set-up	1,848,750	0	0	1,848,750	1,848,750	0	0	1,848,750
Implementation by Regulators	0	1,500,000	387,000	1,887,000	0	1,500,000	387,600	1,887,600
Operations by Regulators	0	1,014,385	230,600	1,244,985	0	960,879	53,481	1,014,361
Total	2,231,697	2,514,385	617,600	5,364,282	2,216,611	2,460,879	441,081	5,118,572