

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 20 and 32

RIN 3150-AI29

Expansion of the National Source Tracking System

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is amending its regulations to expand the current National Source Tracking System (NSTS) to include Category 3 sealed sources. The amendments will require specific licensees to report transfers of control involving these sealed sources to the NSTS. The transactions include the manufacture, transfer, receipt, disassembly, or disposal of the nationally tracked source. The amendments will also require each licensee to report its initial inventory of nationally tracked sources into the NSTS and annually verify and reconcile the information in the system with the licensee's actual inventory. In addition, the amendments will require manufacturers to assign a unique serial number to each nationally tracked source. This final rule will provide additional accountability of Category 3 sources consistent with NRC's responsibility to protect public health and safety.

DATES: *Effective Date:* This final rule is effective on **[INSERT DATE 90 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]**.

Compliance Date: Compliance with the reporting provisions in 10 CFR 20.2207(h) for Category 3 sources is required by November 30, 2012.

ADDRESSES: You can access publicly available documents related to this document using the following methods:

Federal e-Rulemaking Portal: Go to <http://www.regulations.gov> and search for documents filed under Docket ID NRC-2008-0200. Address questions about NRC dockets to Carol Gallagher at 301-492-3668; e-mail Carol.Gallagher@nrc.gov.

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I. Background

As a result of the September 11, 2001, attacks in the U.S., the NRC has undertaken a comprehensive review of radioactive 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. The NRC's review has taken into consideration the changing domestic and international threat environments and related U.S. Government-supported international initiatives in the radioactive materials security area, particularly activities conducted by the International Atomic Energy Agency (IAEA). The NRC 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). In particular, the Code of Conduct recommends that each IAEA Member State establish a national register of radioactive sources that should include, as a minimum, Category 1 and Category 2 radioactive sources as described in Annex 1 of the Code of Conduct. The recommendation covers 16 radionuclides that should be included in the source registry.

Subsequently, the NRC published a final rule in the *Federal Register* on November 8, 2006 (71 FR 65686), establishing the NSTS. The principal purpose of the NSTS is to provide additional accountability of radioactive materials sufficient to constitute quantities which should be of concern regarding the construction of a RDD or a RED. Under this program, certain licensees who possess IAEA Category 1 and Category 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 these sources and, thus, improve accountability. 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 was January 31, 2009 (72 FR 59162).

In the 2006 rulemaking, the Commission specifically invited comments on whether Category 3 sources should be included in the NSTS (71 FR 65692; November 8, 2006). 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, the NRC is amending its regulations to expand the NSTS to require specific licensees who possess IAEA Category 3 sources to report information on the manufacture, transfer, receipt, disassembly, and disposal of those sources.

In determining whether to expand the NSTS to include additional sources, the NRC has considered the need to balance requirements to ensure the secure handling and use of the materials with the need to allow 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 medical 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.

Although neither the current 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 and in conjunction with other related activities (e.g., web-based licensing and pre-

licensing site visits), improve the control of radioactive sources and protect public health and safety.

Section II of this document 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).

A. Rationale for expanding the NSTS to include additional source categories.

A.1 Congressional concerns and GAO investigation.

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

A.2 Recent NRC actions.

In light of the issues noted, 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 accountability of

Category 3 sources. In response to that paper, the Commission provided direction to the NRC staff in a Staff Requirements Memorandum (SRM) for 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 to include Category 3 data in the NSTS.

Subsequently, in response to concerns raised by members of Congress and the GAO, NRC staff provided the Commission with an Action Plan in SECY-07-0147, dated August 25, 2007. 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 in the SRM for SECY-07-0147, dated September 18, 2007. Specifically, the SRM noted that the staff should submit a proposed rule to include 1/10th of Category 3 data in the NSTS. That proposed rule (SECY-08-0031) was published in the *Federal Register* on April 11, 2008 (73 FR 19749).

A.3. Considerations regarding the need for expanding the NSTS and the extent to which the NSTS should be expanded to include additional categories (or sub-groups of categories) of sources.

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. 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 have the greatest potential 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 have the least potential; 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));

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);

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);

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 through 3 (i.e., those having the highest potential to cause permanent injury or death when misused).

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

In the rulemaking establishing the NSTS for Category 1 and Category 2 sources (71 FR 65686; November 8, 2006), specific rationale was provided for establishing tracking and inventory requirements for these sources. In that rulemaking, it was noted that the analysis by

the U.S. Department of Energy (DOE) and the NRC of potential health effects due to misuse 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, the NRC adopted the IAEA Category 2 values and used them as a threshold in its rulemaking decision regarding sources requiring tracking and inventory management 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 (71 FR 65692; November 8, 2006) 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. 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 through a one-time survey of licensees who possess sources at a level of 1/10th of Category 3. The Commission then noted that 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 will be done through subsequent rulemaking. This rule is a result of the subsequent rulemaking which concluded to expand the NSTS to include Category 3 sources.

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

In preparing this final rule, NRC 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 (Category 1 or Category 2). The NRC considered the appropriate extent for expanding the NSTS beyond Category 2. One approach would expand NSTS to include IAEA Category 3 sources, as directed in the June 9, 2006 SRM. A second approach would expand NSTS to include sources that are 1/10th of the Category 3 threshold, which is actually a subgroup of high-end Category 4 sources, as directed in the SRM in the August 25, 2007 GAO Action Plan. A third approach would expand NSTS to include sources in the low end of Category 4 or in Category 5. The rationale for expanding the NSTS to include Category 3 sources is provided in Sub-Sections A.3.4.1 of this document.

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

The Commission believes that there is a need to enhance the accountability of Category 3 sources through improved tracking of these sources. The following items form the rationale to include Category 3 sources in the NSTS:

a) The potential exists to aggregate Category 3 sources to a Category 2 level:

Category 3 sources could be aggregated to Category 2 levels, as they represent sources with activity levels that range from just below the Category 2 threshold down

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

- b) The additional burden to track Category 3 sources is justified given the benefit in improved source accountability: Adding Category 3 sources to the NSTS results in increased burden to the NRC, Agreement States, and to the licensed industry for implementation and maintenance of the expanded NSTS. The existing NSTS has approximately 1,300 NRC and Agreement State licensees and an expanded NSTS under this final rule to include Category 3 sources adds approximately 1,000 licensees. The regulatory analysis supporting this final rule estimates total cost of about \$14 million over a 10-year analysis period, at 3 percent discount rate, assuming the large majority of licensees fax their Category 3 transaction reports to the NRC for input into the NSTS. The regulatory analysis cites a sensitivity analysis performed by staff, showing an 18 percent reduction in total cost over ten years, if instead 50 percent of those licensees use the on-line NSTS and the remaining licensees submit a computer readable batch file to the NRC for input of the data into

the NSTS. Staff believes that the additional cost of this final rule is justified, given the additional improvement in accountability of these sources and the potential risks that they pose if they are misused.

- c) Category 3 sources are defined as dangerous by IAEA: The IAEA defines Category 3 sources (as well as the Category 1 and Category 2 sources) as dangerous sources because these sources could, if not under control, give rise to exposure sufficient to cause severe deterministic effects.
- d) The NSTS design can accommodate additional sources: As noted in Section II.C.1 of this document, the NSTS was designed to accommodate Category 3 sources and licensee information, and this feature can be implemented at a reasonable cost. If the appropriate resources are applied, the inclusion of Category 3 sources in an expanded NSTS will not detract from the performance of tracking higher-risk Category 1 and Category 2 sources.

Based on the considerations noted of the definition of Category 3 as dangerous and the potential for aggregation to Category 2, the Commission has determined 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 provides for Category 3 sources the same single point of reference to enhance source safety as has been collected for Category 1 and Category 2 sources. Although separate NRC and Agreement State systems contain information about specific licensees who possess Category 3 sources and the maximum amounts of materials they are authorized to possess, those systems do not record actual sources or their movements.

In arriving at an informed and professional judgment of what should constitute radioactive materials of concern, the NRC staff has not performed a detailed analysis of the potential vulnerabilities for possible theft or diversion of these radioactive materials. The GAO stated that NRC should regulate Category 3 sources more stringently and the Senate PSI recommended that NRC should consider including Category 3 sources in the NSTS. The NRC staff has considered such matters in reaching its judgment that the aggregation of Category 3 sources through illicit and malevolent acts presents a threat to public health and safety that can be lessened by including the Category 3 sources in the existing NSTS regulatory requirements.

Thus, to improve sealed source accountability, the NRC is expanding the NSTS to include Category 3 sources. Tracking specific transactions of Category 3 sources will help prevent an adversary from aggregating these sources into larger and 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 evaluated 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 a Category 2 source. 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 will require about 10 to 12 of these sources to aggregate to Category 2. These high-end Category 4 (1/10th Category 3) sources are possessed by the same licensees noted, namely those with fixed industrial gauges, those who conduct well-logging operations, medical facilities with brachytherapy machines, and a few radiographers. As with Category 3 sources, these sources are relatively widespread in use by industry and there is a potential that aggregation could occur to Category 2 levels. The NRC staff analyzed the net impacts of expanding the NSTS to 1/10th of Category 3 levels. As noted in the regulatory analysis to this final rule, an expanded NSTS to include 1/10th Category 3 sources would add approximately 3,500 licensees with a resultant overall cost to industry, Agreement States, and to the NRC of about \$33 million over a 10-year analysis period.

The NRC staff also considered including all of Category 4 and Category 5 source data in the NSTS; however, in both cases the staff considered it a low likelihood that these sources would be aggregated in such large numbers to attain a Category 2 threshold. Thus, the NRC staff has not included Category 4 and Category 5 sources in the final rule.

Licensee reporting of source inventory data, at year-end on an annual basis, was also evaluated for control of Category 3, and 1/10th of Category 3, sources. The total costs of these regulatory alternatives are on the order of \$5 million and \$13 million, respectively, over a 10-year analysis period. However, these alternatives would not provide knowledge of source transactions in a timely manner to protect public health and safety and would not provide a confirmatory cross-check of transactions from which to guard against the misuse of these sources.

Based on these considerations, the NRC has decided to not include sources below the Category 3 threshold in the NSTS.

B. Enhanced accountability provided by these amendments.

The NSTS for Category 1 and Category 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, licensees, and disposal sites for IAEA Category 1 and Category 2 sources.

This final rule to expand the NSTS to Category 3 sources will improve NRC oversight to track aggregation of these sources and will alert the NRC to discrepancies between transaction reports of manufacturing and distribution licensees and of the persons to whom the shipment of sources is being made. Also, the NRC plans to use data from the NSTS with other data management systems, such as web-based licensing, to provide for better source accountability.

C. Other considerations.

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

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 Category 2 sources. The NSTS expansion does not compromise the information technology (IT) aspects of the NSTS because those capabilities have for the most part already been incorporated into the NSTS software. The NRC staff working with the current version of the NSTS maintain that the IT design and software is flexible and expandable such that it can accommodate the extra

1,000 specific licensees and the tracking of their sources with no detrimental effects on the tracking of Category 1 and Category 2 sources.

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

Another consideration is the public comments received on the proposed rule for establishing the NSTS for IAEA Category 1 and Category 2 sources. In the proposed rulemaking, the Commission specifically invited public comment. The public comments received on this subject were discussed in the November 8, 2006 final rule *Federal Register* notice (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 as Category 2 sources; 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 Category 2 sources. Commenters opposing inclusion of Category 3 sources in the NSTS generally cited the increased burden that will be imposed on licensees and the NRC. Most of these commenters did not provide specific numbers, but indicated that inclusion of Category 3 sources will 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 Category 2. These commenters were concerned that inclusion of Category 3 sources will bog down the NSTS and suggested that a better approach will be to require inventory reporting rather than source transactions.

The NRC staff considered these comments in making its recommendation to include Category 3 sources in the NSTS.

D. What action is the NRC taking?

Based on the considerations of Sections II.A through II.C of this document, the NRC is expanding the NSTS by requiring licensees with Category 3 sources to report information to the NSTS on the manufacture, transfer, receipt, disassembly, and disposal of the Category 3 sources. The expanded NSTS remains 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 Category 3 sources added to the NSTS are the same as those for Category 1 and Category 2 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 Category 2 sources (71 FR 65686, November 8, 2006). This section is intended to provide licensees new to the NSTS, with Category 3 sources, with information similar to that provided in the FRN for the final rule for the establishment of the NSTS for IAEA Category 1 and Category 2 sources.

D.1 Definition of a Nationally Tracked Source.

A sealed source consists of radioactive material that is 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. In this final rule, the definition of a nationally tracked source is revised to include sealed sources containing a quantity of radioactive material equal to or greater than the Category 3 threshold values listed in the amended Appendix E to 10 CFR Part 20. A nationally tracked source may be either a Category 1 source, a Category 2 source, or a 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 is not covered by the rule. However, if a nationally tracked source is placed in a matrix material, the sealed source is still covered by the rule.

The specific radioactive material and activity levels covered by this rule are listed in the revised Appendix E to 10 CFR Part 20. The IAEA Code of Conduct recommends that at a minimum the radionuclides and the threshold values for Category 1 and Category 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 Code of Conduct states that every nation should define its domestic threat, and assess its vulnerability with respect to this threat for the variety of sources used

within its territory, based on the potential for loss of control and malicious acts involving one or more radioactive sources. The GAO has stated its concern that aggregation of low activity sources could occur. The NRC agrees with this concern as it applies to Category 3 sources. The Code of Conduct also states that Category 3 sources, if not safely managed or securely protected, could cause permanent injury to a person who handled them, or were otherwise in contact with them, for some hours.

The Terabecquerel (TBq) values listed in 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.

D.2. Who is affected by this action?

This final rule applies to any person (entity or individual) with a specific license to possess or manufacture a Category 3 source.

D.3 How is information reported to the NSTS?

Licensees have several methods for providing the required information under the existing NSTS. Under the expanded NSTS, these methods continue to include on-line, computer-readable format files, paper, fax, and telephone as described below:

- Reporting information on-line: The NRC estimates that none of the source manufacture transactions and about 15 percent of transfer, receipt, disassembly, and disposal

transactions will be done using the on-line NSTS. 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 needs to establish an account with the NSTS. Once an account is established, the licensee is provided with password information and a smart card and reader that allow access to the on-line system. A licensee has access only to information regarding its own material or facility; a licensee does not have access to information concerning other licensees or facilities. When logged on, the licensee types the necessary information onto the on-line forms. Once a source is in the system, the licensee is able to click on the source and report a transfer or other transaction. The identifying information does not need to be typed in a second time because information such as license number, facility name, and address will pop up automatically.

- Computer-readable format file: The NRC estimates that about 25 percent of the source manufacture transactions and about 10 percent of transfer, receipt, disassembly, and disposal transactions will be done using a computer-readable file submitted by the licensee to the NRC for direct input into the NSTS. Licensees that use a computer-readable format file typically conduct a large number of transactions, especially manufacturing and distribution licensees, and already have an internal system to manage sealed source information. The NSTS is able to accept batch load information using a computer-readable format. The licensee should be able to send electronically to the NRC a batch file that can be executed to add the licensee's source transactions that occurred that day into the NSTS.

- Paper submittals by mail, fax, or telephone: The NRC estimates that about 75 percent of the source manufacture, transfer, receipt, disassembly, and disposal transactions will be done by licensees sending a facsimile (i.e., fax) of the transaction data to the NRC. The basis for this estimate is the experience to date with licensees entering Category 1 and Category 2 source data into the NSTS. The NRC plans to work with licensees who decide to fax their information to improve the efficiency of the tracking system for all concerned. Licensees can also complete a paper version of the National Source Tracking Transaction form and submit the form by over-night mail, or provide transaction information by telephone and then follow-up with a paper copy sent to the NRC.

D.4 Specific information that licensee will report under the expanded NSTS.

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

- Report their initial inventory of sources greater than or equal to Category 3 nationally tracked sources to NSTS;
- On an annual basis, reconcile and verify the inventory of sources greater than or equal to 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 source;
- Correct any errors in previously filed National Source Tracking Transaction Reports within 5 business days of the discovery; and

- For licensees who manufacture a Category 3 nationally tracked source, assign a unique serial number to each source.

How licensees will 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 with Category 3 sources are required to report their initial (i.e., current) inventory of such sources to the NSTS by November 30, 2012.

The NRC staff has estimated in the regulatory analysis the significant effort for the NRC and Agreement States to implement the requirements of this final rule by November 30, 2012. The NRC will incur most of the costs in its work to support implementation and operating and maintenance of the NSTS for Category 3 sources. Implementation costs include NRC preparing a standard license condition for use by Agreement States, as needed, to assist the States in defining consistent requirements among all Agreement State and NRC licensees.

The NRC staff is prepared to assist licensees with their reporting of initial inventories and to assist Agreement States with their use of NSTS report generation programs to ease the implementation of the initial reporting into the NSTS. Licensees will need to report the information on their Category 3 source inventory by the date specified above. Disposal facilities will 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 are required to reconcile their on-site inventory of nationally tracked sources with the information previously reported to the NSTS. This reconciliation occurs during the month of January of each year. This reconciliation is necessary to maintain the accuracy and reliability of the National Source Tracking database. The licensee is able to print a copy of the inventory information from the NSTS. Licensees without on-line access can receive a paper copy of the information in the NSTS. The licensee can 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 does 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 is required to reconcile any differences by reporting the appropriate transaction(s) or corrections to the NSTS. The licensee is required to verify by the end of January of each year that the inventory in the NSTS is correct. For Category 3 sources, the first reconciliation must occur by January 31, 2014. Licensees will continue to verify by the end of January of each year that the inventory information in NSTS for Category 1 or Category 2 sources they possess is correct.

D.4.3 Reporting transaction information to the NSTS.

Timely updating of the NSTS is necessary for it to be useful and accurate. In order to capture information as soon as possible, licensees are required to report information on nationally tracked source transactions by the close of the next business day after the transaction. Specific transaction information that is 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 is 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 and facility name, as well as the name of the individual that prepared the report.

Recycled or Reconfigured Sources: Some sources are recycled or reconfigured. For example, a source that has decayed below its usefulness may be returned to the manufacturer for reconfiguration. The decayed source may be placed in a reactor and reactivated. 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 is required to report the information on 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 will be considered the source origin unless the source had been previously possessed in the United States. The licensee must 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 also needs to 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 will also need to provide information on the facility (name and address) that sent the source and the import license number if applicable. Only Category 1 and Category 2 sources, and multiple sources that aggregate on a per shipment basis to a Category 2 level or higher, are required to have a specific NRC import license.

D.4.3.2 Reporting information on source transfer.

Transfers of sources: Each time a licensee transfers control of a nationally tracked source, the transferring licensee is 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 will 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 also has to report the waste manifest number and the container identification number for the container with the nationally tracked source.

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

requested by DOE impose no additional requirements, and is not a substantive modification. The change has been added to the final rule text.

Transfers where the source stays within the licensee's possession: NSTS reporting requirements are triggered by the transfer of control between different licensees and/or authorized facilities (e.g., DOE sites, Agreement State, NRC, or a foreign entity). A licensee does not have to report the transfer of the source to a temporary job site. The licensee does not have to report this transfer because the nationally tracked source remains under the control of the licensee. For example, a radiographer conducting business does not need to report the movement of sources 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. In the medical community, an example would be when a source is being used in a brachytherapy procedure. The licensee remains responsible for control of the source during the procedure.

Export of sources: The export of sources is 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. In the case of exports, the NRC export license number is reported as the license number of the receiving facility in the foreign country. Only Category 1 and Category 2 sources, and multiple sources that aggregate on a per shipment basis to a Category 2 level or higher, are required to have a specific NRC export license. Most Category 3 sources are 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 will 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 must also report the source activity and associated activity date. The import license number is 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 are not 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 treat the transaction as a transfer (see Section E.4.3.2), and 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 is 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 is the decay of a source is automatically calculated so a licensee does not need to report an endpoint of decay. Once a source has decayed below Category 3, it is no longer considered a nationally tracked source, and the source is automatically removed from a licensee's active inventory in the NSTS. The licensee receives 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, is 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 enters 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 are to be captured by the NSTS. These events are already reported to either NRC or to the Agreement States. Licensees are not required to report this information a second time to the NSTS. Agreement State licensees will continue to report to the Agreement State. NRC staff will 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, particularly by the large number of transactions reported by fax. 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, reporting of device data instead of source data, or incorrect typing of the serial number.

Each licensee is 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 can 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 rule requires manufacturers of Category 3 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 its use.

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

The expanded NSTS is used for a variety of purposes. This standardized, centralized information helps 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 Category 2 sources only, or those possessing sources greater than or equal to Category 3, are of a similar nature. The NSTS rule reporting requirements include reporting by licensees of an initial inventory, source transactions, and periodic reconciliation of source inventory. The implementation process includes 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 has been prepared for the implementation of the NSTS for Category 1 and Category 2 licensees; similar guidance is being developed for sources greater than or equal to Category 3 licensees. Regarding enforcement action, in a manner similar to that for Category 1 and 2 licensees, NRC and the Agreement States will first identify licensees who have not reported the required inventory and transaction information, based on knowledge of the licensee population of interest, which is determined by using the License Tracking System for NRC licensees or equivalent Agreement State systems,

and eventually by the Web Based Licensing (WBL) system, when operational. Agreement States have their own systems for determining the licensee population of interest.

D.7 When do these actions become effective?

This final rule is effective 90 days after publication in the *Federal Register*. The reporting requirements in 10 CFR 20.2207(h) for Category 3 sources must be implemented by November 30, 2012. This means that by November 30, 2012, any specific licensee who possesses a Category 3 source must have reported its initial inventory and report thereafter to the NSTS all transactions involving Category 3 sources. The Agreement States are expected to adopt the NSTS expansion final rule requirements by August 30, 2012.

III. Analysis of Public Comments on the Proposed Rule

The proposed rule to expand the NSTS was published on April 11, 2008 (73 FR 19749). The NRC received 19 public comment letters on the proposed rule. Comments on the proposed rule were received from States, licensees and industry organizations. Copies of the public comments are available for review in the NRC Public Document Room, 11555 Rockville Pike, Rockville, MD., or from <http://www.regulations.gov> under Docket ID NRC-2008-0200.

The comments and responses are grouped into six areas. The NRC specifically sought comments on two topical areas: (1) whether NSTS should be expanded to include 1/10th of Category 3 sources; and (2) whether specific requirements for tracking should be included in 10 CFR Part 110 for imported sources. The comments received are summarized under B.2 and D.1 respectively. The six topical areas of comment and response are: (A) the rule is

premature and should be delayed; (B) there is not sufficient justification provided for expanding the NSTS; (C) the burden estimate in the regulatory analysis and OMB packages are inaccurate; (D) the guidance is incomplete and is needed; (E) suggested approaches; and (F) miscellaneous comments. To the extent possible, all the comments on a particular subject are grouped together. A discussion of the comments and the NRC staff's responses follow.

A. RULE IS PREMATURE AND SHOULD BE DELAYED.

Comment A.1: Several commenters state that the NSTS was not currently functional to use as a model. The commenters assert that licensees affected by the expanded NSTS would have little or no knowledge of how the system will actually work. The commenters also assert that a fully operational NSTS should be successfully tracking Category 1 and Category 2 sources before Category 3 is added, especially considering that expansion will add 1,000 licensees to the system which currently has 1,300 licensees who possess Category 1 and Category 2 sources. The commenters state that without a history of NSTS use, one cannot assess how administering the NSTS will affect internal operations, staff workloads, and resources of the NRC and States.

Response: The NRC disagrees with this comment. The NRC is expanding the NSTS to Category 3 sources to improve accountability of these sources and to provide additional protection against aggregation of these sources to higher activity levels. Based on preliminary information from NRC's One-time Data Collection and NRC staff's best judgment, the NRC estimates that 1,000 NRC and Agreement State licensees may possess Category 3 nationally tracked sources. Additionally, the NSTS is now operational and licensees have been reporting information into the system since January 31, 2009. The NRC staff has considered this

operational information in preparing this Regulatory Analysis for the final rule, and the staff has used this data to revise burden estimates. The input assumptions in the Regulatory Analysis for this final rule are fully documented and supported by the operating information of the NSTS to date and comments received during the NSTS expansion proposed rule public comment period.

Comment A.2: One commenter states that the States put forth a large effort to obtain information for the Category 1 and Category 2 NSTS rule. The commenter also states that the economic burden to the States could not have been properly evaluated for expansion of a system that is not currently functioning consistent with its design objectives.

Response: The NRC acknowledges the effort and success of implementing NSTS by licensees and States. The NRC also acknowledges that the expansion of the NSTS results in increased burden to licensees to implement and then maintain source transaction reporting. In the regulatory analysis, the NRC analyzed the net impacts of expanding the NSTS to Category 3. There is additional burden to licensees and Agreement States, but the NRC believes this additional burden is a reasonable amount given the additional improvement in accountability for these sources.

The NRC is reducing the burden by adopting public comments on the following two issues: 1) we extended the implementation date to 2012, and 2) we eliminated sources between Category 3 and 1/10th of Category 3 from the final rule.

Comment A.3: Two commenters request clarification on the required resources needed by licensees/States to add Category 3 sources to the NSTS.

Response: The NRC acknowledges that the expansion of NSTS imposes additional burden on licensees required to report transactions to the system, and on States to verify and inspect the accuracy of information reported into NSTS. The amount of additional burden depends on the method of submittal chosen by the licensee. These methods range from using the on-line NSTS to submitting a fax of the required information to the NRC. The burden estimates are documented in the regulatory analysis for this final rule, for both licensees and Agreement States. If the large majority of licensees decide to fax their Category 3 transaction reports to the NRC for input into the NSTS, as assumed in the regulatory analysis, the total cost of the final rule is about \$14 million over ten years. If, instead, based on a sensitivity analysis cited in the regulatory analysis, 50 percent of those licensees use the on-line NSTS and the remaining licensees submit a computer readable batch file to the NRC for their NSTS input data, the total cost of the final rule is about \$11 million. The NRC is taking measures to improve the efficiency of the NSTS reporting process. Licensees will not be required to invest in any additional equipment to make their reports. Most licensees already have computers and internet access. If licensees do not have this equipment, they can use mail to submit reports.

Comment A.4: One commenter states that the existing NSTS cannot accommodate added sources, especially given the problems it has experienced that have significantly delayed its implementation. The commenter further states that clarification is needed on whether and how the current system would be ready to handle additional sources, and questioned whether the expanded system would work. The commenter also questions whether NRC resources would be diverted from tracking Category 1 and Category 2 sources.

Response: The NRC disagrees with the comment. The NSTS can be used with few minor maintenance changes to manage the individual source and accumulated inventory data. Some user interface functionality would need to be enhanced slightly to address the needs arising from an inventory reporting requirement for other than Category 1 and Category 2 sources. A new database would not have to be built. The NRC believes that the existing NSTS system can accommodate additional licensees and sources based on the expandability and flexibility of the system. With the NRC applying the appropriate resources, the monitoring of the expanded NSTS would not divert attention from the monitoring of higher-risk Category 1 and Category 2 sources.

Comment A.5: Several commenters state that the NSTS should not be expanded until the handling of general licenses (GLs) is resolved as this decision could significantly affect the number of sources and licensees subject to the NSTS and associated costs. The commenters state that the considerations of a GL vs. specific license (SL) regulatory framework and/or a GL rule should be well underway, if not completed, before making a decision on expanding the NSTS. One commenter states that the existing GL program is robust and active and adequately tracks and accounts for these materials.

Response: The NRC disagrees with the comment. The NRC developed a proposed rule (RIN 3150-A133) that would require certain general licenses above a specified level (1/10th of IAEA Category 3) to be reclassified as specific licenses. The GLs that would be converted to SLs would have to follow all of the regulatory requirements for a SL, including implementation of the NSTS. The draft regulatory analysis prepared in support of that rulemaking provided estimates of the additional burden associated with converting GLs to SLs, including the burden

associated with implementing the NSTS for those licensees. That regulatory analysis cites an additional 1,400 NRC and Agreement State licensees, who possess sources greater than or equal to 1/10th of Category 3, would need to report source information to the NRC. That rulemaking and its regulatory analysis preceded this final rule which limits NSTS reporting to a smaller set of licensees, those who possess Category 3 sources. Based on the current schedule, that rulemaking (RIN 3150-AI33) is expected to be published as a final rule in February 2010 with an effective date in April 2010 and an implementation date in July 2010 (150 days after publication of the final rule), more than two years before the November 30, 2012, implementation date of the NSTS expansion final rule.

Comment A.6: One commenter states that the rule is premature, unnecessary, and can not be justified under the Paperwork Reduction Act.

Response: The NRC disagrees with the comment. The NRC has determined that the need exists to enhance the tracking of lower activity sources to improve accountability of these sources consistent with NRC's responsibility to protect public health and safety. The Paperwork Reduction Act requires the government to collect information with a minimum burden to the public and at minimum cost to the Government. One of the purposes of both the 1980 and the 1995 acts was to minimize the paperwork burden for individuals, small businesses, and others resulting from the collection of information by or for the Federal government. Information collection is one way in which the NRC carries out its mission to license and regulate the Nation's civilian use of byproduct, source, and special nuclear materials to ensure adequate protection of public health and safety. The NRC believes that the agency has justified the collection of information from the public by establishing the need and intended use of the

information, estimating the burden that the collection imposes, and showing that the collection is the least burdensome way to gather the information.

B. THERE IS NOT SUFFICIENT JUSTIFICATION PROVIDED FOR EXPANDING THE NSTS.

Comment B.1: One commenter states that the aggregation rationale was not justified in any detail and was a misapplication of the IAEA Code of Conduct. The commenter also states that aggregation alone did not result in a single source of concern due to self shielding, physical geometry, etc. The commenter points out that consideration should be given to new categories (Categories A, B, C) related to dispersal. The new categories of source terms that when used in a device, the material will be dispersed such that a fatal or even significant exposure is possible (Category A), those produced contamination levels result in a necessary quarantine of the area affected (Category B), or contamination levels would result in restricted activity until decontamination can be affected in the area (Category C).

Response: The NRC disagrees with the comment. The NRC and Agreement States have required enhanced security measures for the protection of IAEA Category 2 quantities of material including aggregation of smaller sources to the Category 2 levels regardless of the activity level of the individual sources. Aggregation can result in the equivalent of a single source that can be used as a RED or incorporated in a RDD. The NRC believes that expanding the NSTS to include aggregation of sources would be in alignment with the current enhanced security strategies for Category 2 sources. In addition, the NRC disagrees that the aggregation was a misapplication of the Code of Conduct. The Code states “In addition to these categories, Member States should give appropriate attention to radioactive sources considered by them to

have the potential to cause unacceptable consequences if employed for malicious purposes, and to aggregations of lower activity sources (as defined by IAEA Safety Guide No. RS-G-1.9, “Categorization of Radioactive Sources”) which require management under the principles of this Code.” Section 3.5 of Safety Guide No. RS-G-1.9 specifies a standard for aggregation of sources, noting that “There will be situations in which radioactive sources are in close proximity to each other (e.g., during manufacturing and storage). In such circumstances, the regulatory body may wish to aggregate the activity in the sources to determine a situation specific categorization for the purpose of implementing regulatory control measures.” With regards to the comments on new dispersal categories, the NRC does not believe that new categories need to be developed. In Safety Guide No. RS-G-1.9, “Categorization of Radioactive Sources,” the IAEA provides statements regarding the risk from the dispersal of Category 1, 2, and 3 sources. For example, IAEA states that the risk from an event involving a Category 3 source that is dispersed by fire or explosion “.... could possibly, although it would be extremely unlikely, permanently injure or be life threatening to persons in the immediate vicinity. There would be little or no risk of immediate health effects to persons beyond a few meters away, but contaminated areas would need to be cleaned up in accordance with international standards. The area to be cleaned up would probably not exceed a small fraction of a square kilometer.”

Comment B.2: Several commenters assert that the rulemaking did not demonstrate that sources greater than 1/10th Category 3 poses a significant risk and do not pose the same relative risks as Category 1 and Category 2. The commenters pointed out that they were not currently seeing a loss or theft of material in transit or know of any public attempts to steal and/or accumulate Category 3 sources. The commenters solicited the NRC to identify a threat basis upon which to expand the NSTS. The commenters requested the completion of a risk-

based assessment or vulnerability assessment (including bases; balancing of risks and benefits; specific risk estimates for accumulation of Category 3 and 1/10th Category 3 sources to Category 2 levels based on past data or reports of theft or loss, violations, orphan source recovery; etc.), and/or additional IAEA documentation regarding feasibility of aggregate RDD devices and potential doses to the public in this type of scenario, were needed before the expansion of the NSTS would be considered.

Response: The NRC agrees that no specific threat exists for the use of radioactive material in an RDD or RED. However, the NRC recognized that a general threat exists for terrorist organizations to use radioactive materials in an RDD or RED. The NRC also recognized that the IAEA defined sources in Categories 1, 2, and 3 as dangerous sources. By tracking Category 3 sources, the NRC is not implying that these sources pose the same relative risks as Category 1 and Category 2 sources. The purpose of tracking Category 3 sources is to monitor transactions of sources that could be aggregated into activity equivalent to that of a Category 2 source. Tracking specific transactions of sources greater than or equal to Category 3 enhances accountability and allows the NRC and Agreement States to detect situations in which a licensee's aggregate sources would create larger and possibly more dangerous quantities. The NRC agrees with the commenters regarding the relative risk of 1/10th Category 3 sources and has removed these lower level sources from the final rule.

Comment B.3: One commenter states that aggregation of sources would be physically difficult because sealed sources are incorporated within secured, often heavyweight, radiological shields that form an integral part of the nucleonic device. In addition, the commenter states that the most likely place for aggregation would be on the premises of

manufacturers, however these licensees operate under enhanced security conditions.

Response: In general, the NRC agrees that the task of aggregating of numerous small sources may be difficult and time consuming. However, the September 11, 2001 terrorist attacks demonstrated that individuals were patient and willing to expend considerable time and effort in order to achieve certain objectives.

Comment B.4: Several commenters state that the existing NRC licensing system, with its recent improvements and initiatives (background investigations; increased inspections; additional license review; pre-licensing verification and site visits; transfer of sources under existing security orders to verify new users; flagging of significant changes in ordering patterns; the fact that accumulation of 100 sources would attract interest of distributors; licensing of end-users; 6-month leakage test requirements; requirements in 10 CFR Part 30.41 requiring licensees to verify that a recipient is authorized to receive material; presence of existing Increased Control Orders for licensees possessing quantities of material that in the aggregate exceed Category 2 levels; etc.) would be more beneficial to address security of sources. The commenters also state that the expansion of the NSTS would not significantly improve current source accountability or aid in preventing aggregation for malevolent use. Hence, the commenters assert that the resources should be spent on existing and planned licensing, inspection, and enforcement programs to ensure licensee compliance with these systems.

Response: The NRC disagrees with the comment. The NRC improved the materials licensing process to reduce the likelihood of a license being issued to individuals interested in conducting a terrorist act with radioactive materials. However, the NRC recognizes that the

changes to the process will not prevent individuals from modifying their license or individuals from producing a counterfeit license. The verification requirements in the enhanced security Orders do not apply to Category 3 quantities of radioactive materials. Also, leak test records are only checked during inspections and may not be an indication of the true number of sources at a facility. Moreover, 10 CFR Part 30.41 does not require licensees to contact a regulator to verify the recipient is authorized to possess radioactive materials. The recipient can send a fax of a license that may be a counterfeit or a modified license. Increased controls (ICs) are intended to enhance security of Category 1 and Category 2 quantities of radioactive materials and not to prevent the unauthorized aggregation of smaller sources. The aggregation of 100 sources should attract attention of a distributor. However, the sources could be obtained from multiple distributors and over an extended period of time giving the individual radioactive materials orders the appearance of being legitimate. The NRC believes that the expansion of the NSTS adds a layer of security that will enhance the NRC's ability to detect the unauthorized aggregation of radioactive materials. The NRC recognizes that the NSTS alone will not prevent the aggregation of sources for malevolent use. The data collected by the NSTS can be readily examined for anomalies in source transfers which may have led, or be leading to, a potential malevolent act.

Comment B.5: One commenter requests clarification on how NRC would be able to monitor all the large amount of data collected or how the NRC would be able to monitor the data to identify potentially nefarious practices in a timely manner.

Response: The NSTS functional specification provides the capability for queries and automated reports to alert NRC of any discrepancies in reports on sources. The data integrity

for the NSTS is extremely important. The NRC expects licensees to provide correct information to the NSTS and to double check the accuracy of their information before submission. To maintain the accuracy, currency, and reliability of the National Source Tracking database, licensees are required by this rule to correct any mistakes in their inventory information and annually verify the accuracy of their data. If licensees accurately report their transactions in a timely manner, the NRC is confident that the NSTS would contain correct, up-to-date information. However, the NRC recognizes that some transactions may be missed and that errors may be introduced into the system over time. The NRC also recognizes that discrepancies may result from licensees' failure to report the receipt of a source or failure to report the transfer of a source to another licensee. The NRC acknowledges that inaccuracies can result from errors in the initial inventory report, selection of the wrong model number, or incorrectly typing the serial number. As stated in 10 CFR 20.2207(g), the NRC requires each licensee to correct any errors or missed transactions that it becomes aware of within 5 business days of the discovery, and in that same paragraph, each licensee is required to reconcile its on-site inventory of nationally tracked sources with the information previously reported to the NSTS. This reconciliation must be completed by January 31 of each year, except that for Category 3 sources, the NRC is extending the initial reconciliation for these sources until January 31, 2014, in amended 10 CFR 20.2207(h). The reason for this extension is that little change is expected in the NSTS information for Category 3 sources from November 30, 2012, the date by which licensees must first report their inventory information, to January 31, 2013, when the first reconciliation would be required and the reconciliation report during this short period would provide only a small benefit for the increased reporting burden.

Comment B.6: One commenter states that too many licensees and Agreement State

resources would be needed. The comment also states that resources are scarce and no clear public health and safety basis exist to justify the expense of the proposed rule for these lower risk sources. The commenter further expresses that the costs to the NRC are too high for the small benefit that would be realized from the rule and resources would be more effectively spent on existing licensing, inspection, and enforcement programs which would increase public confidence.

Response: The NRC disagrees with the comment. The cost of the final rule was estimated in the regulatory analysis to be about \$13.7 million over a 10 year analysis period, with over one-half that cost borne by the NRC. The cost to licensees was estimated to be \$5.2 million over a 10 year analysis period. The societal cost of misuse of Category 3 sources, either individually or in aggregated form, are higher than the cost to implement the rule. At this time, the NRC acknowledges that no specific threat exists for the use of radioactive materials in a RDD or RED. However, the NRC recognizes the existence of a general threat for terrorist organizations to use radioactive materials in a RDD or RED. The Agency believes that the expansion of the NSTS adds a layer of accountability that will enhance the NRC's ability to detect the unauthorized aggregation of radioactive material. The response to the comments in Section C below, notes the cost burden for implementing the proposed requirements and that, based on the risk, the cost burden for expanding the NSTS is considered appropriate.

Comment B.7: Several commenters state that the rule improperly deviated from IAEA guidelines in the sub-division of categories in which IAEA says are not that precise. The commenters state that the proposed expansion would make NRC requirements inconsistent with all other countries, resulting in added burden to U.S. licensees and putting them at a

competitive disadvantage. The commenters state that if NRC was going to deviate from the IAEA guidelines, then the D-values derived for dispersed/dispersible material should be used and not the D-values derived for external exposure scenarios for which aggregation has little meaning (about half of the nuclides in Appendix E have D-values based on external exposure scenarios).

Response: The NRC disagrees that the proposed rule deviated from IAEA guidelines for using the term “1/10th IAEA Category 3.” The NRC has decided not to track sources at the 1/10th of Category 3 level at this time. If conditions warrant it at a later date, the Agency will reconsider the tracking of these sources. The NRC believes that the increased burden and expense to track sources at the 1/10th of Category 3 level is not reasonable at this time. Much of the attention is given to source categorization and security issues pertains to individual sources; however, one must be mindful of the potential for aggregation of a number of lower category sources to form a dangerous source as noted by the IAEA in Safety Guide No. RS-G-1.9, “Categorization of Radioactive Sources,” Section 3.5, regarding source aggregation: “There will be situations in which radioactive sources are in close proximity to each other, such as in manufacturing processes (e.g., in the same room or building) or in storage facilities (e.g., in the same enclosure). In such circumstances, the regulatory body may wish to aggregate the activity in the sources to determine a situation specific categorization for the purposes of implementing regulatory control measures.”

In regards to the IAEA derived D-values for dispersion and for external exposure to radioactive material, the smaller of the two D-values is listed in the Code of Conduct. The NRC is not deviating from the Category 3 quantities listed in the Code. NRC and Agreement States have required enhanced security measures for the protection of IAEA Category 1 and

Category 2 quantities of radioactive material including aggregation of smaller sources to the Category 2 levels regardless of the activity level of the individual sources. Aggregation can result in the equivalent of a single source that can be used as an RED or an RDD. Therefore, it is appropriate to consider scenarios for dispersal of material as well as contained sources such as exposure devices, i.e., both internal and external exposure scenarios need to be included.

Lastly, the requirements are not necessarily inconsistent with other countries. The IAEA notes the following in Paragraph 11 of the Code of Conduct: "Every State (IAEA Member State) should establish a national register of radioactive sources. The NSTS implements the U.S. government commitment to the IAEA in this area. This register should, as a minimum, include Category 1 and Category 2 radioactive sources."

Comment B.8: One commenter states that real-time tracking is not needed because legitimate, highly scrutinized licensees will be aware of source movement.

Response: The NRC agrees that "real-time tracking" is not needed. The NSTS does not provide for such tracking; rather, the system provides information regarding source transactions in a timely manner, i.e., by the end of the next business day. Individual licensees should be aware of source movement within their facilities, as well as transfers that were made. However, NSTS serves to provide regulators with a much-needed bigger picture of source movement. In addition, the NRC believes that while the aggregation of an unusual number of sources should attract attention of a distributor, the NRC does identify that sources could be obtained from multiple distributors and over an extended period of time giving the individual orders the appearance of being legitimate. The NRC believes that the expansion of the NSTS adds an additional layer of security that enhances the NRC's ability to detect the unauthorized

aggregation of radioactive materials.

Comment B.9: Three commenters stated that the rule would affect patients' access to care (e.g., brachytherapy implant patients).

Response: The NRC is concerned about patient care and efficient procedures used at hospitals for handling radionuclides for medical use. The NRC believes that the rule does not affect patients' access to care because the radionuclides that are used in permanent implants (Iodine-125, Palladium-103) are not on the list of concern identified by the NRC. Hospitals do not have to track the procedures using Iodine-125 and Palladium-103 because these procedures do not transfer sources. Since Cesium-137 (Cs-137) and Iridium-192 (Ir-192) are used in temporary implants, licensees keeping these sources internally do not have to enter tracking information into NSTS until the sources are transferred or disposed.

C. THE BURDEN ESTIMATES IN THE REGULATORY ANALYSIS AND OMB PACKAGES ARE INACCURATE

Comment C.1: Several commenters request clarification on the source of data used by the NRC for the regulatory analysis. The commenters state that the input assumptions used in the regulatory analysis on which the burden estimates were based were not properly documented and therefore were not understood. The commenters also state that the estimates of time needed for NSTS support activities were not accurate and that the NRC did not understand how many licensees would be affected by the rule. The commenters further state that without knowledge of how the NSTS database works, they are unable to estimate the

amount of time needed to use the database for both initial start-up and day-to-day usage.

Response: In developing the estimates of net impacts of the proposed rule in the draft regulatory analysis, the NRC staff used input assumptions from the regulatory analysis for the NSTS final rule (71 FR 65856) for tracking Category 1 and Category 2 sources when there was no better data. The NRC used data from an internal Interim Database to estimate the number of licensees and sources below Category 2 down to the lower threshold of 1/10th of Category 3, and used experience and knowledge of NRC regional office staff to review the reasonableness of input assumptions. As noted in the draft regulatory analysis, the NRC identified three broad components that were used in developing the regulatory burden and cost associated with the proposed rule. These components were: (1) number of licensees and sources that would be affected; (2) the resultant number of source transactions and transaction reports prepared by licensees; and (3) estimated unit costs of actions taken by licensees to comply with the requirements. These components and cost bases were described in the draft regulatory analysis and summarized here.

(1) Number of licensees and sources that would be affected. The draft regulatory analysis for the proposed rule used information collected from an internal one-time data collection from an Interim Database to estimate a total of 1,000 licensees possessing IAEA Category 3 sources and 2,500 licensees possessing sources with activity level below Category 3 down to a lower threshold of 1/10th of Category 3. Thus, the total number of new licensees that would be affected by the NSTS expansion rule would either be an additional 1,000 if the lower threshold was Category 3 or 3500 if the lower threshold was 1/10th of Category 3. This information was reviewed in tandem with the IAEA Safety Guide RS-G-1.9 and information from NRC's License

Tracking System with respect to the principal categories of licensee functions and the types of sources used in those functions. The primary applications of these sources included fixed industrial gauges, well logging, brachytherapy for medical use, and radiography. Following the review of public comments on the proposed rule, the NRC staff believes it has an accurate representation of the number of licensees affected by the rule and the type of source application of these licensees. Based on public comment on the proposed rule, the NRC has increased the number of Category 3 replacement sources in circulation each year from 6,233 to 8,000. The basis for this increase is described in the regulatory analysis supporting the final rule.

(2) Resultant number of transactions. The draft regulatory analysis for the proposed rule used information from the NSTS final rule (71 FR 65856) regulatory analysis to represent the estimated number of source transaction reports per year. As discussed above, the NRC has increased the number of Category 3 replacement sources each year. This increases the number of source transaction reports. Based on public comment on the proposed rule and considering experience with implementation of the NSTS since publication of the NSTS expansion proposed rule, the NRC staff has also revised the input assumptions for the source transaction reports. Those revised assumptions are documented in the regulatory analysis for the final rule. At Category 3, the total number of source transaction reports has been increased from about 36,000 per year in the proposed rule to about 46,000 per year in the final rule.

(3) Unit costs of actions to comply with requirements. The draft regulatory analysis for the proposed rule used many of the unit costs supporting the NSTS final rule (71 FR 65856). The unit costs have been updated to support the NSTS expansion final rule to reflect more current

unit costs estimates, using 2008 dollars.

In summary, the NRC believes the regulatory analysis supporting the NSTS expansion final rule is an accurate estimate of the net impacts considered in this final rule.

Comment C.2: Several commenters state that data on the IAEA Category 1 and Category 2 sources was not available from an operating NSTS, so the estimates in the regulatory analysis for the NSTS expansion have no basis and their source is unclear. The commenters also state that a period of 2 years of operating the Category 1 and Category 2 sources on the NSTS is needed to collect data and/or a pilot program or test programs from which to estimate the scope of efforts to support an expansion of the NSTS. One commenter is willing to survey its members to ascertain the number of sources that would be included in an expanded NSTS.

Response: The NRC agrees that at the proposed rule public comment period, the NRC had no experience or operating data on NSTS. However, the NSTS is now operational and licensees have been reporting information into the system since January 31, 2009. The NRC staff has considered this operational information in preparing this regulatory analysis for the final rule, and the staff has used this data to revise burden estimates. The input assumptions in the regulatory analysis for this final rule are fully documented and supported by the operating information of the NSTS to date and comments received during the NSTS expansion proposed rule public comment period.

Comment C.3: One commenter states that requiring manufacturers to keep records of

initial source manufacture and any source transfer adds 30 percent to the total number of transactions and is unneeded (and an unnecessary burden) given the secure environment at manufacturers facilities.

Response: The NRC disagrees with this comment and supports the need to track sources below Category 2 down to Category 3. The same requirements of manufacturers of Category 1 and Category 2 sources have been determined to be necessary for the manufacturers of Category 3 sources. Tracking sources from manufacture to disposal provides NRC source accountability during the complete life-cycle of individual sources.

Comment C.4: One commenter states that the amount of time needed to reconcile discrepancies is greatly underestimated and could take hours.

Response: Licensees are currently required to perform an evaluation of end-of-year source inventory as part of their requirements to maintain control of radioactive material under their possession license. The process during the year of recording transfers-in and transfers-out should not further complicate that effort, no more than monthly ledger accounting of financial transactions would complicate the preparation of end-of-year financial statements. The NRC staff is of the opinion that the regular reporting of source transfers, both in and out of the firm, is an activity necessary to confirm end-of-year balances. As a result, the labor effort assumption for licensees to reconcile and verify annual inventory information that was used in the proposed rule is unchanged in the regulatory analysis for the NSTS expansion final rule. That assumption is that each licensee uses 1 additional hour in its end-of-year inventory reconciliation as a result of implementation of the NSTS as a required tracking system.

The NRC acknowledges that the time needed and costs for reconciling end-of-year inventory discrepancies may initially be larger in the first few years following the effective date of the final rule but would diminish over time as licensees grow more accustomed to the system and its process. Thus, the cost indicated in the regulatory analysis is considered reasonable in considering the burden to licensees over the 10-year analysis period used in the regulatory analysis.

Comment C.5: One commenter states that the estimate of the number of transactions is too low. The commenter estimates that the number of sources manufactured and put into the system each year could be 4,000 from one manufacturer, giving a total number of transactions much higher than what NRC assumed in the regulatory analysis. This large number of entries into the system has the potential for discrepancies to occur which would have to be resolved using up licensee and NRC resources.

Response: The NRC agrees with this comment and has increased the number of annual source transactions, as described in the response to Comment C.1.

Comment C.6: One commenter states that the impact would be greater if NRC expands the list of nuclides beyond those listed in Appendix E to Part 20.

Response: The NRC is not expanding the list of nuclides beyond those listed in Appendix E to Part 20. The nuclides for tracked sources with radioactive materials greater than or equal to the IAEA Category 3 threshold values are consistent with those that will be tracked

in the NSTS for IAEA Category 1 and Category 2 sources and consistent with the IAEA categorization system. The NRC at this time does not plan to expand the list of radionuclides tracked using the NSTS.

D. GUIDANCE IS INCOMPLETE AND IS NEEDED.

Comment D.1: Two commenters state that no information was provided on certain specifics such as import/export (i.e., reporting the export of less than Category 2 sources).

Response: Since import and export of sources are considered source transactions, the sources are reported to the system in the same way for all categories of sources covered by the system.

Comment D.2: One commenter states that guidance related to implementing the system is incomplete and additional guidance is needed and no guidance or training has been provided to potential participants. In particular, issues that should be addressed include: identification of licensees needing to be part of system; possession limits or actual material possessed; how to identify individual sources or aggregate of sources; sources that are collocated; sealed sources used in permanent brachytherapy procedures.

Response: The NRC will provide extensive user support and training for use of the system. This will pertain to both the Category 1 and Category 2 sources included initially and the Category 3 sources added by this rulemaking. Additionally, the NRC will provide guidance related to implementation of the system before initial inventories of Category 3 sources are

required to be reported. Licensees have been identified through license information and responses to surveys for the Interim Database. The NSTS will not track aggregated quantities of radioactive materials. The system will only track individual sources. Sealed sources used in permanent brachytherapy procedures will not be tracked in the NSTS.

Comment D.3: One commenter states that the NRC needed to ensure user-friendliness and efficiency of the expanded NSTS, especially regarding the medical community, otherwise hospital administrators may not use the system and there could be impaired patient access to health care services. The commenter argues that the NSTS must be compatible with licensees' existing technological capabilities, there should be free and accessible training, and there should be flexibility at NRC to suspend and improve the NSTS if it proves problematic for licensees to use.

Response: In developing the NSTS, the NRC solicited extensive user involvement in the requirements definition and interface reviews were sought to ensure user friendliness of the actual software. The NRC will include in its guidance documents for implementation of Category 3 requirements those process and procedure issues identified by the commenters.

Comment D.4: One commenter suggests that the NRC needs to define the term "transfer." The commenter also requests the NRC to clarify whether the movement of a source from one building to another within the licensee's facility is considered a "transfer."

Response: In the original NSTS rulemaking for Category 1 and Category 2 sources, the NRC defines a transfer as moving the source material from one authorized licensee to another.

The movement from one building to another is not considered a transfer if it is still in the same authorized licensee's possession. The NRC will provide future guidance that will discuss the definition of "transfer" in more detail.

Comment D.5: One commenter states that "Credentialing" was discussed in the proposed rule FRN but no information was given as to how this would be done.

Response: In Section 3.2.3.1 of the regulatory analysis supporting the NSTS expansion proposed rule, the NRC states that credentialing includes the process of validating users, and providing certificates and hardware tokens for access to the on-line NSTS. Credentialing is discussed in the regulatory analysis for this final rule and licensee costs to complete the credentialing process have been increased compared to those in the proposed rule. The NRC will provide future guidance on the process of credentialing for licensees with Category 3 sources.

E. SUGGESTED APPROACHES.

Comment E.1: Two commenters state that the rule should only require updating of inventory on an annual basis (such as done for the interim inventory), and not real-time input or tracking.

Response: The NSTS requires reporting of transactions, not real-time tracking. The NRC considered the alternative of inventory reporting in the regulatory analysis. However, in the regulatory analysis and FRN (73 FR 19749), it was indicated that this alternative would not

provide the necessary near real-time knowledge of source transactions in order to conduct timely follow-up actions relative to those that appear suspicious. In addition, lack of transaction data from other licensees would not facilitate a cross-check for accurate reporting of inventories. In addition, there would still be significant costs incurred as a result of a rule that only required source inventories to be reported at a given frequency; costs of this inventory-only approach would include 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. Therefore, the NRC did not adopt the option requiring only updating of the inventory on an annual basis.

Comment E.2: Several commenters suggest that the rule should be delayed at least 1-2 years while experience is gained with Category 1 and Category 2 sources providing information on the ability of licensees to participate in the NSTS and sufficient data on which to base the rule. The commenters state that during the delayed period, the NRC could solicit further public comments and conduct meetings with stakeholders and plan other outreach, such as forming users groups. Workshops should be held so that licensees are able to fully understand the impact of the rulemaking and, in particular, to ensure that the reporting mechanisms are user-friendly and do not cause problems in the practice of medicine. The commenters suggest that a pilot program using information gained from tracking Category 1 and Category 2 sources should be undertaken to inform any rulemaking on expansion of the NSTS.

Response: The NRC agrees in part with the comment. The NSTS has been operational since December 30, 2008, and licensees were required to report to the system by January 31, 2009. The NRC has acquired several months of operational data from the system

and does not believe that the rulemaking should be delayed. Thus a pilot study or a delay of the rule is not warranted. However, the NRC plans to modify the proposed final rule to require that implementation of the expanded NSTS for IAEA Category 3 sources not take place until November 31, 2012. This will allow additional time for the preparation of detailed guidance and information dissemination for licensees possessing these additional sources affected by expansion of the NSTS.

Comment E.3: One commenter suggests the NRC consolidate the NSTS with the Web Based License (WBL) to encourage a single system for tracking.

Response: The NRC recognizes a complementary relationship between the NSTS and NRC licensing systems such as the current License Tracking System (LTS) and planned WBL. However, these systems have different purposes so are optimally maintainable as separate systems. As a result, the NRC is developing the License Verification System (LVS) that will link the NSTS and the WBL.

Comment E.4: One commenter from the metals industry supports the rule as written (primarily due to their concerns over orphan sources winding up in their metal supply to steel mills) and suggests that the NSTS be expanded to include Category 4 and 5 sources.

Response: The NRC agrees with the comment regarding the impact of orphan sources; however, the NRC does not agree that Category 4 and Category 5 source should be included in the scope of the NSTS. The NRC considered including all of Category 4 and/or Category 5 sources in the NSTS, however the NRC decided that, because of the magnitude of the

thresholds of each of these categories and the lower likelihood that sources at the Category 4 or Category 5 level could easily be aggregated to the higher category levels, that they would not be included in the expansion of the NSTS.

Comment E.5: One commenter states that the primary aims of the NSTS would be better served by allocation of funds to provisions of ensured disposal sites for secured disposal of sealed sources; this is an important issue due to the loss of Barnwell for disposal of Category 3 and below sources.

Response: The NRC considers the primary aim of the NSTS is to provide greater source accountability, which should foster increased control by licensees. Moreover, the NRC has no authority to allocate funds for the disposal of radioactive material. The opening of a disposal site is an issue relegated to the compacts defined in the Low-Level Radioactive Waste Policy Act (passed in 1980, amended in 1985).

Comment E.6: One commenter indicated that expansion of the NSTS should not include sources below Category 3 and that this rule should be delayed until experience is gained with Category 1 and Category 2 sources.

Response: The NRC 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. However, based on public comments, the cost and burden to licensees, Agreement States and the NRC, the NSTS will be expanded to include sources greater than, or equal to, IAEA Category 3. In reference to

delaying the rulemaking, the NRC feels that this rule is necessary and will continue on its current path to promulgate the rulemaking. However, the NRC plans to modify the proposed final rule to require that implementation of the expanded NSTS for IAEA Category 3 sources not take place until November 2012.

F. MISCELLANEOUS.

Comment F.1: One commenter inquires whether the expanded NSTS would include other nuclides such as Americium-241 (Am-241), Cadmium-109 (Cd-109), and/or Iron-55 (Fe-55).

Response: The NSTS currently tracks Am-241 as listed in Appendix E of 10 CFR Part 20. At this time, the NRC does not have any plans to add Cd-109 and Fe-55 to the tracked sealed sources.

Comment F.2: One commenter recognizes a math error regarding the value of Cs-137.

Response: The NRC agrees with the discovery of a math error. The math error was in the Category 3 TBq values for Cs-137, Selenium-75 (Se-75), and Ytterbium-169 (Yb-169). The error involved the relationship between the Category 2 and 3 values. The Category 3 values should have been 10 percent of the Category 2 values, instead of the 1 percent ratio for those three radionuclides. The TBq threshold values for all Category 3 radionuclides have been corrected in the final rule.

Comment F.3: One commenter agrees with the proposed approach to limit sources tracked to only those sealed sources listed in Appendix E; tracking other materials including unsealed sources is unnecessary and extremely difficult. The commenter indicates that the text of the rule should state “sealed sources” whenever the word “sources” appears.

Response: The NRC disagrees with the comment. The use of the word “source” in the rule text is understood to mean the word “sealed sources” because the rule refers to sources listed under the different categories which are nationally tracked sources. In 10 CFR Part 20, a sealed source is defined under nationally tracked source. The NRC will revise the definition of nationally tracked source to include Category 3 sources in this final rule.

Comment F.4: One commenter states that the NRC said that it is “proceeding with the proposed rule for expansion” (73 FR 19754) at the same time that the NRC was requesting input on three specific questions to gather additional information. The commenter believes that the NRC requesting information from the public appears internally inconsistent and raises questions as to the basis for the decision to proceed with the expansion. The commenter also states that the inconsistency is compounded by the fact that 12 of 18 previous commenters opposed expanding the NSTS and these comments have not been resolved satisfactorily.

Response: The NRC posed the three questions in order to confirm the data used in the draft regulatory analysis. NRC’s intent in asking the questions during the public comment period was to gather burden and cost information to support the regulatory decision for the final rule.

Comment F.5: One commenter states that NRC should consider access to the database, as currently the NSTS limits access only to those licensees regulated by the “home jurisdiction.”

Response: The NRC assumes that the commenter is stating that access to the database should be controlled in a manner which maintains information security. The information recorded in the NSTS is considered sensitive to homeland security, and will be designated for “Official Use Only.” Concerning materials and facility, each licensee will have access to their own data. Agreement State officials will have access to data on licensees within their own State. DOE officials will have access to data on DOE sites. Some NRC staff will have access to all of the data in the system. Other agencies will only have limited access to the data on a need to know basis. The NRC will establish a procedure for handling requests from groups/agencies for data access.

Comment F.6: One commenter notes that States without electronic database systems will have to manually review records to identify licensees required to participate.

Response: The NRC will work with all of the Agreement States to identify and address implementation issues as they arise. The NRC will use an approach similar to the one used with the increased controls, e.g., routine calls, electronic communications, formation of an NRC-State working group. Through these interactions, the NRC will continue to coordinate with the states to understand any issues with the impact of expanding of the NSTS implementation on state resources.

Comment F.7: One commenter states that the NRC should coordinate the rulemaking with other activities and focus on the high-risk activities.

Response: The NRC manages its rulemaking priorities based on rules that are planned and in process and the development of technical bases supporting anticipated requests for new rulemaking activities. The NRC believes that tracking specific transactions of Category 3 sources (defined by the IAEA as dangerous) will enhance accountability for more sources, and will detect situations where a licensee's aggregate sources would create larger and possibly more dangerous quantities. In addition, an expanded NSTS will alert the NRC to discrepancies between transaction reports of manufacturing and distribution licensees and the persons to whom the sources were shipped. The NRC will use the data from the NSTS in conjunction with other data management systems to provide for better source accountability. Moreover, the NRC believes that expanding the NSTS is part of a comprehensive radioactive source control program. In conclusion, the NRC believes that the rule is consistent with NRC's strategic objectives and performance goals.

Comment F.8: One commenter states that the expansion of NSTS does not address lifecycle accountability.

Response: The NSTS will track Category 1 through Category 3 sources from production to disposal. However, if a source decays below the Category 3 level, it is no longer considered a nationally tracked source and is no longer tracked.

Comment F.9: One commenter states that State regulators should have access to NSTS data of licensees in other States.

Response: The NRC disagrees with this comment. The NSTS allows State regulators to view information of source transactions and source inventory of licensees who possess a license issued by their State. If a State has reason to inquire about a nationally tracked source held by a person whose license was issued in another State, those States have procedures and acceptable practices currently in place to obtain that information.

IV. Summary of Final Revisions

§ 20.1003 Definitions.

An expanded definition of nationally tracked source to include Category 3 sources is added to the regulations. Also, the definition of nationally tracked source was simplified as a result of public comments.

§ 20.2207 Reports of transactions involving nationally tracked sources.

A revision to paragraph (b) is made to clarify that licensees who transfer control of a nationally tracked source are required to report the transfer in the NSTS. NRC has determined that the change imposes no additional requirements, and is not a substantive modification. The change has been added to the final rule text.

A revision to paragraph (h) requires a licensee to report its initial inventory of Category 3 nationally tracked sources by November 30, 2012, and requires a licensee to perform inventory

reconciliation, pursuant to § 20.2207(g), the first time for Category 3 sources by January 31, 2014. Licensees will continue to perform reconciliation of Category 1 or Category 2 source inventories by the end of January of each year.

Appendix E Nationally Tracked Source Thresholds.

An amendment to Appendix E of 10 CFR Part 20 revises the thresholds for nationally tracked sources to include 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 source to include Category 3 sources is added to the regulations.

V. Criminal Penalties

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

VI. 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 final 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. The database would be maintained by NRC. The Agreement States are expected to adopt legally binding requirements by August 30, 2012 on their licensees such that all licensees, both NRC and Agreement States, will begin reporting at the same time.

The following table lists the Parts and Sections that are revised and their corresponding categorization under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs."

Compatibility Table for Final Rule

Section	Change	Subject	Compatibility	
			Existing	New
Part 20				
20.1003	Amend	Definitions	B	B
Part 20				
20.2207	Amend	Reports of transactions involving nationally tracked sources	B	B
Part 20				
Appendix E	Amend	Nationally tracked source thresholds	B	B
Part 32				
32.2	Amend	Definitions	B	B

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 final rule, the NRC will require licensees that possess, manufacture, transfer, receive, disassemble, or dispose of the nationally tracked sources specified in the rule to report the information relating to such transactions to the NSTS. 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 final 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 rule.

IX. Paperwork Reduction Act Statement

This final rule contains amended information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq*). These requirements were approved by the Office of Management and Budget (OMB), approval numbers 3150-0014 and 3150-0001.

The burden to the public for these information collections is estimated to average 0.7 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. Send comments on any aspect of these information collections, including suggestions for reducing the burden, to the Records and FOIA/Privacy Services Branch (T-5 F52), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to INFOCOLLECTS.RESOURCE@NRC.GOV and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202 (3150-0014), Office of Management and Budget, Washington, DC 20503, or by e-mail to Christine.Kymn@omb.eop.gov at telephone number (202) 395-4638.

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.

X. Regulatory Analysis

The NRC staff has prepared a regulatory analysis on this regulation. The analysis examines the costs and benefits of the final rule and alternatives for this rulemaking.

About 50 percent of the total cost of this final rule will be incurred by the NRC in its implementation and annual operating and maintenance (O&M) expense associated with an expanded scope NSTS for Category 3 sources. This is equal to about \$6.6 million over 10 years, due to the \$1.3 million one-time implementation cost and \$5.3 million over 10 years for annual O&M costs. About 40 percent of the total cost of the final rule will be incurred by

licensees, equal to about \$5.2 million over 10 years. Annual operating costs are the bulk of the increase to Industry, equal to \$4.4 million over 10 years. One-time implementation cost for Industry is estimated to be \$870,000. For the 100 licensees that are assumed to set-up accounts on the expanded NSTS, this represents \$8,700 per licensee. The estimated cost of this final rule to Agreement States is \$1.8 million over 10 years. About 70 percent of these costs are due to one-time costs to implement the final rule in State regulations.

The analysis is available for inspection in the NRC Public Document Room, 11555 Rockville Pike, Rockville, MD 20852. Single copies of the regulatory analysis are available from Kevin O'Sullivan, telephone (301) 415-8112, e-mail Kevin.OSullivan@nrc.gov, of the Office of Federal and State Materials and Environmental Management Programs.

XI. Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the Commission certifies that this rule does not have a significant economic impact on a substantial number of small entities. The final rule affects about 200 NRC licensees and an additional 800 Agreement State licensees possessing 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 final rule does not have a significant economic impact on these licensees.

XII. Backfit Analysis

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

XIII. Congressional Review Act

In accordance with the Congressional Review Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

List of Subject Terms

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. 552 and 553; the NRC is adopting 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 means a sealed source containing a quantity equal to or greater than the Category 3 threshold 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.

* * * * *

3. In § 20.2207, the introductory text to paragraphs (b) and (h) are revised to read as follows:

§ 20.2207 Reports of transactions involving nationally tracked sources.

* * * * *

(b) Each licensee that transfers control of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

* * * * *

(h) Each licensee that possesses one or more 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 one or more 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 one or more Category 3 nationally tracked sources shall report its initial inventory of Category 3 nationally tracked sources to the National Source Tracking System by November 30, 2012, and conduct the inventory reconciliation required by paragraph (g) of this section no later than January 31, 2014, for Category 3 nationally tracked sources. The information may be submitted by using any of the methods identified in paragraphs (f)(1) through (f)(4) of this section. The initial inventory report must include the following information:

* * * * *

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

Appendix E to Part 20 - Nationally Tracked Source Thresholds

* * * * *

Radioactive Material	Category 1 (TBq)	Category 1 (Ci)	Category 2 (TBq)	Category 2 (Ci)	Category 3 (TBq)	Category 3 (Ci)
Actinium-227	20	540	0.2	5.4	0.02	0.54
Americium-241	60	1,600	0.6	16	0.06	1.6
Americium-241/Be	60	1,600	0.6	16	0.06	1.6
Californium-252	20	540	0.2	5.4	0.02	0.54
Cobalt-60	30	810	0.3	8.1	0.03	0.81
Curium-244	50	1,400	0.5	14	0.05	1.4
Cesium-137	100	2,700	1	27	0.1	2.7
Gadolinium-153	1,000	27,000	10	270	1	27
Iridium-192	80	2,200	0.8	22	0.08	2.2
Plutonium-238	60	1,600	0.6	16	0.06	1.6
Plutonium-239/Be	60	1,600	0.6	16	0.06	1.6
Polonium-210	60	1,600	0.6	16	0.06	1.6
Promethium-147	40,000	1,100,000	400	11,000	40	1100
Radium-226	40	1,100	0.4	11	0.04	1.1
Selenium-75	200	5,400	2	54	0.2	5.4
Strontium-90	1,000	27,000	10	270	1	27
Thorium-228	20	540	0.2	5.4	0.02	0.54
Thorium-229	20	540	0.2	5.4	0.02	0.54
Thulium-170	20,000	540,000	200	5,400	20	540
Ytterbium-169	300	8,100	3	81	0.3	8.1

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 means a sealed source containing a quantity equal to or greater than the Category 3 threshold of any radioactive material listed in Appendix E to Part 20 of this chapter. 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.

* * * * *

Dated at Rockville, Maryland, this _____ day of _____, 2009.

For the Nuclear Regulatory Commission.

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