RULEMAKING ISSUE
AFFIRMATION

April 6, 2006 SECY-06-0080

FOR: The Commissioners

FROM: Luis A. Reyes
Executive Director for Operations

SUBJECT: Final Rule: National Source Tracking of Sealed Sources (Rin 3150-ah48)

PURPOSE:

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

SUMMARY:

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

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

BACKGROUND:

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

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

As part of the effort to improve the security of radioactive sources, NRC initiated development of a national tracking system for radioactive sources of concern. It formed the National Source Tracking Working Group in November 2003, the SafeSource[1] Steering Committee in December 2003, and the Interagency Coordinating Committee in February 2004, to aid in the development of the National Source Tracking System.

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

[1]SafeSource is the name for the overall project that includes the web-based licensing project, the interim database project, and the national source tracking project.

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

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

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

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

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

DISCUSSION:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

AGREEMENT STATE ISSUES:

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

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

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

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

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

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

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

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

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

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

COMMITMENTS:

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

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

RECOMMENDATIONS:

That the Commission:

1. Approve for publication in the *Federal Register* the attached notice of the basis change (Enclosure 4).

2. Approve for publication in the *Federal Register* the attached notice of final rulemaking (Enclosure 2). If substantive comments are received on the basis change, the staff will resubmit the final rule package to the Commission for approval. If no substantive comments are received, the staff will submit the final rule to the Office of the Secretary for signature.

3. To satisfy the requirement of the Regulatory Flexibility Act, 5 U.S.C. 605 (b), certify that this rule, if promulgated, will not have significant impact on a substantial number of small entities. This certification is included in the attached Federal Register notice.

4. Note:

   a. The Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification and the reasons for it, as required by the Regulatory Flexibility Act, 5 U.S.C. 605(b);

   b. A final Regulatory Analysis has been prepared for this rulemaking (Enclosure 3);

   c. The staff has determined that this action is not a "major rule," as defined in the Congressional Review Act (CRA) of 1996 [5 U.S.C 804(2)]] and has confirmed this determination with the Office of Management and Budget (OMB). The appropriate Congressional and Government Accountability Office contacts will be informed (Enclosure 7);

   d. The appropriate Congressional committees will be informed;

   e. A press release will be issued by the Office of Public Affairs when the final rulemaking is filed with the Office of the Federal Register; and

   f. The final rule contains amended information collection requirements subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, et seq.) that must be submitted to the OMB for its review and approval before publication of the final rule in the *Federal Register*.

RESOURCES:

To complete the rulemaking, 0.1 full-time equivalent positions will be required. These resources are included in the current budget.

COORDINATION:

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

/RA/

Luis A. Reyes,
Executive Director
for Operations

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

Basis Change Rationale for the National Source Tracking Rule

Background

The basis provided in the proposed rule on national source tracking was promulgation under the Commission's authority to promote common defense and security. During the Agreement State review period, several Agreement States opined that the basis for the rulemaking should be under protection of the public health and safety for consistency with the framework established for issuance of the increased controls, which was developed after the approval of the source tracking proposed rule. Comments on the basis for the rule were also received during the public comment period.

As a result of these continued interactions, and the Commission direction in the Staff Requirements Memorandum for COMSECY-05-0028, the SafeSource Steering Committee convened to further discuss the basis for the national source tracking rule. The Steering Committee has carefully considered this issue, including the advantages and disadvantages discussed below, and recommends that the basis of the rulemaking be changed to protection of the public health and safety, with an immediate mandatory Compatibility Category B designation. The time-frame for implementation under a public health and safety approach would need to be consistent with the scheduled roll-out of the National Source Tracking System (NSTS).

Discussion

The National Source Tracking System should improve source accountability and foster greater control over radioactive sources. However, the rule does not impose any controls on use of the sources, it imposes data reporting requirements related to source transactions. The actual security and control of the sources is provided by measures imposed under public health and safety for the majority of licensees possessing Category 1 and 2 sources. The security and control for Category 1 and 2 sources possessed by irradiator licensees and manufacturer and distributor licensees is imposed under both common defense and security (NRC Orders) and public health and safety (20.1801 and 20.1802 and Agreement State equivalents). While the system would not increase actual security and control, the system would be part of the overall security program. The system should provide better accountability of the sources and will provide information to the government that was not previously readily available. Inspectors had access to the information only during inspections of licensees. This information can be used as a tool to enhance both the overall security and safety programs. As a practical matter, safety and security are intertwined in the industrial, medical, and academic uses of materials, and the goal in both safety and security is to prevent the loss of control of material.

The decision to issue the rule under common defense and security was based primarily on a concern over timeliness. All licensees needed to begin reporting at the same time; Agreement States may not have had time to issue regulations to cover their licensees.

Under the common defense and security basis, Agreement States would have the option to perform inspections for and on behalf of NRC by entering into Section 274i Agreements. NRC would retain implementation responsibility for Agreement State licensees in States which do not sign Section 274i Agreements. In addition, NRC would retain broad oversight and implementation responsibility for Agreement State licensees in States signing Section 274i

Agreements. This includes, for example, issuance of final inspection reports, issuance of enforcement actions, inspection accompaniment of State inspectors, and contractual oversight.

Advantages of Common Defense and Security Basis

- Consistent with Commission direction for the Orders to Irradiators and Manufacturers and Distributors.

- The existing Section 274i Agreements could potentially be expanded to include the inspections for the National Source Tracking System.

- Ensures national consistency in implementation because it would be fully implemented by NRC.

- Provides a directly enforceable method for implementing the National Source Tracking System.

Disadvantages of Common Defense and Security Basis

- Need for expansion and indefinite commitment of NRC resources for inspection and enforcement of Agreement State licensees against the national source tracking requirements. These resources would be needed to fund those States that sign the Section 274i Agreements, and NRC inspection and follow-up actions in States not signing Section 274i Agreements.

- NRC would have continued need to maintain administrative and oversight costs for Section 274i Agreements.

- Based on NRC's experience in related program areas, it is not clear that Agreement States would be willing to enter into 274i Agreements.

- Could be perceived as dual regulation, especially by small licensees, where the State currently performs inspections of its requirements, and NRC would perform new National Source Tracking System inspections.

- If a future decision is made to lower the threshold for source tracking (i.e., include Category 3 or lower sources), it will likely be harder to justify under a common defense and security basis using a cost benefit analysis.

There are benefits to allowing the Agreement States to implement the National Source Tracking System in their states. Experience with the interim database demonstrated that State licensees responded more promptly when contacted by Agreement State officials with whom they were familiar than when contacted by NRC officials with whom they had no history. A similar effect could be expected with the National Source Tracking System. The Agreement States have demonstrated that they can issue legally binding requirements in both a timely and consistent manner with the recent implementation of the increased controls. The lead time for the National Source Tracking System requirements will be about 6 months from the date of publication of the final rule. The requirements are already laid out in the rule; and it should be a

relatively straight forward matter to develop the legally binding requirements. The majority of the Agreement States support the change in basis.

Advantages of Public Health and Safety Basis

- Agreement State implementation is consistent with the conventional division of responsibilities with NRC overseeing NRC licensees and Agreement States overseeing Agreement State licensees, in protecting public health and safety relating to the possession and use of certain Atomic Energy Act materials.

- Consistent with the framework established for the increased controls for sources containing quantities of concern.

- Enable safety and National Source Tracking System requirements to be inspected during the same inspection, maximizing efficiency of inspection resources and reducing travel costs. Actual inspection time is expected to be about 60 minutes.

- Anticipated resource savings for the NRC (e.g., Agreement States would have oversight of Agreement State licensees.)

- Consistent with the Agency's strategic goal of integrating safety, security, and emergency preparedness.

Disadvantages of Public Health Safety Basis

- The possibility exists that not all Agreement States will adopt timely and adequate legally binding requirements in a manner consistent with Commission direction. However, States have recently demonstrated their ability to issue timely and consistent increased control requirements for these same sources.

Resources

The original intent of the staff was to add the inspections for the National Source Tracking System to the existing infrastructure. For NRC licensees, inspections would be conducted during routine security and/or safety inspections. It is anticipated that on average about 1 hour of inspection effort would be necessary for the National Source Tracking System. The only pre-inspection effort would be to print the inventory/transaction report on the licensee from the National Source Tracking System database. This additional inspection effort is covered by the existing budget. For Agreement State licensees, the staff expected to use the same infrastructure that was in place to inspect against the Orders to Agreement State licensees. The additional inspection effort would have been minimal. However, with the shift in the framework for the increased controls, the infrastructure that staff planned to use is not in place. If the rule is promulgated under public health and safety, the Agreement States will be responsible for inspection and enforcement for their licensees, and there will be no additional NRC resources necessary. If the rule is promulgated under common defense and security, resources will need to be reprogrammed to address the inspection and enforcement effort for the Agreement State licensees. Some Agreement States may choose to expand the current Section 274i Agreements to include National Source Tracking System inspections and some

States may decide to enter into new 274i Agreements. It is estimated that there will be about 1,000 Agreement State licensees impacted by the National Source Tracking System requirements. The approximate NRC resources needed to support inspection and enforcement effort is $750,000 and 20 FTE for the first year and $250,000 and 7 FTE for later years. It is anticipated that in the first year all licensees should be inspected to make sure they have reported their entire inventory of Category 1 and 2 sources. In later years, the inspection effort would be based on reporting discrepancies.

Conclusion

Although timely and adequate implementation of the National Source Tracking System can be accomplished under either basis, both the Steering Committee and the staff recommend proceeding under public health and safety. A public health and safety basis is consistent with the framework for the increased controls established by the Commission. It would send a mixed message to licensees and the public to impose actual security controls under public health and safety and impose transaction reporting requirements under common defense and security. The Agreement States have demonstrated that they can issue legally binding requirements in a timely and consistent manner. Under either basis, NRC would maintain the database and Agreement States would only have access to information on licensees located within their State.

If the Commission approves the change in basis of the rule to protection of the public health and safety, the staff will work with the Agreement States to ensure that the legally binding requirements are issued in a timely manner such that both NRC and Agreement State licensees all begin reporting at the same time.

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 20 and 32

RIN: 3150-AH48

National Source Tracking of Sealed Sources

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations to implement a National Source Tracking System for certain sealed sources. The amendments require licensees to report certain transactions involving these sealed sources to the National Source Tracking System. These transactions include manufacture, transfer, receipt, disassembly, or disposal of nationally tracked sources. The amendments also require each licensee to provide its initial inventory of nationally tracked sources to the National Source Tracking System and annually reconcile the information in the system with the licensee's actual inventory. In addition, the amendments require manufacturers to assign a unique serial number to each nationally tracked source.

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

Compliance Dates: Compliance with the reporting provisions in 10 CFR 20.2207 is required by March 15, 2007, for Category 1 sources and March 30, 2007, for Category 2 sources.

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SUPPLEMENTARY INFORMATION:

I. Background

After the terrorist attacks in the United States on September 11, 2001, the NRC conducted a comprehensive review of nuclear material security requirements, with particular focus on radioactive material of concern. This radioactive material (which includes Cobalt-60, Cesium-137, Iridium-192 (Ir-192), and Americium-241, as well as other radionuclides) has the potential to be used in a radiological dispersal device (RDD) or a radiological exposure device

(RED) in the absence of proper security and control measures. The NRC's review took into consideration the changing domestic and international threat environments and related U.S. Government-supported international initiatives in the nuclear security area, particularly activities conducted by the International Atomic Energy Agency (IAEA).

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

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

Category 2 radioactive sources as described in Annex 1 of the Code of Conduct. The source registry recommendation addressed 16 radionuclides.

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

The U.S. Government has formally notified the Director General of the IAEA of its strong support for the current Code of Conduct. Although the Code of Conduct does not have the stature of an international treaty and its provisions are non-binding on IAEA Member States, the U.S. Government has endorsed the Code of Conduct and is working toward implementation of its various provisions. This rulemaking reflects those Code of Conduct recommendations related to the source registry and which are consistent with NRC responsibilities under the Atomic Energy Act.

Efforts to improve controls over sealed sources face significant challenges, especially balancing the need to secure the materials without discouraging their beneficial use in

academic, medical, and industrial applications. Radioactive materials provide critical capabilities in the oil and gas, electrical power, construction, and food industries; are used to treat millions of patients each year in diagnostic and therapeutic procedures; are used in a variety of military applications; and are used in technology research and development by academic, government, and private institutions. These materials are as diverse in geographical location as they are in functional use.

NRC considers national source tracking to be part of a comprehensive radioactive source control program for radioactive materials of greatest concern. Although a national source tracking system can not ensure the physical protection of sources, it can provide greater source accountability, which should foster increased control by licensees. A national source tracking system in conjunction with controls such as those imposed by Orders on irradiator licensees, manufacturer and distributor licensees, and other material licensees will result in improved security and control for radioactive sources. It will also result in improved public health and safety.

To inform the development of the National Source Tracking System, the NRC established an Interagency Coordinating Committee to provide guidance regarding interagency issues associated with the development, coordination, and implementation of the system and to prevent licensees from receiving similar requests from more than one agency. The Committee consists of representatives from various Federal Agencies with an interest in source security and a representative from the Agreement States. The views of the Committee were included in the development of the requirements for the National Source Tracking System and this rulemaking. NRC will be the database manager of the National Source Tracking System, however, the other agencies may become users of the system and have limited access. DOE

will have greater access as they will be responsible for entering data on sources for DOE facilities.

Development of the National Source Tracking System is a two-part activity that includes both a rulemaking and an information technology development component. When completely operational, the National Source Tracking System will be a web-based system that will allow licensees to meet the proposed reporting requirements on-line. The system will contain information on NRC licensees, Agreement State licensees, and DOE facilities.

This final rulemaking establishes the regulatory foundation for the National Source Tracking System recommended in the DOE/NRC report and expands on implementation of the Code of Conduct recommendation to develop a national source registry.

There is clearly broad U.S. Government and international interest in tracking radioactive sources to improve accountability and control. There is no single U.S. source of information to verify the licensed users, locations, quantities and movement of these materials. Separate NRC and Agreement State systems contain information on licensees and the maximum amounts of materials they are authorized to possess, but these systems do not record actual sources or their movements.

To address this lack of information on such issues as actual material possessed, the NRC, in cooperation with the Agreement States, began working on an interim database of sources of concern. In November 2003, both NRC and Agreement State licensees were contacted and requested to voluntarily provide some basic information on the sealed sources located at their facilities. Of the approximately 2600 licensees contacted, over half of the licensees reported possessing Category 1 or Category 2 sealed sources. The interim database was updated in 2005 and will continue to be updated until the National Source Tracking System

is operational. The interim database will ultimately be replaced by the National Source Tracking System. While the interim database provides a snapshot in time, the National Source Tracking System will provide information on an ongoing basis.

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

This final rule on National Source Tracking meets the requirements enumerated above, which were imposed by the Energy Policy Act of 2005 and applicable to source tracking. The rule requires the reporting of transfers and receipts of sources by the close of the next business day, which meets the requirement for reporting within 7 days of any change of possession. The information to be reported includes the serial number of the source, which addresses

identification of each source by serial number. On-line reporting is one of the methods by which licensees may report; this meets the requirement to allow reporting through a secure internet connection. Current NRC and Agreement State regulations require licensees to immediately report, after its occurrence becomes known to the licensee, any lost, stolen, or missing licensed material at the Category 1 or 2 level. Therefore, this final rule does not include provisions for reporting loss of control of, or accountability for, a radiation source.

II. Discussion

A. *What Action is the NRC Taking?*

The NRC is issuing a rule that implements a new program called the National Source Tracking System. The final rule requires licensees to report information on the manufacture, transfer, receipt, disassembly, and disposal of nationally tracked sources. This information captures the origin of each nationally tracked source (manufacture or import), all transfers to other licensees, all receipts of nationally tracked sources, and endpoints of each nationally tracked source (disassembly, disposal, decay, or export). Ultimately, the National Source Tracking System will be able to provide a domestic life history account of all nationally tracked sources.

A system of this type needs prompt updating to be useful and accurate. In order to capture information as soon as possible, this rule requires licensees to report information on nationally tracked source transactions by the close of the next business day. Although the Energy Policy Act of 2005 provides for reporting within 7 days, the rule requires reporting by the close of the next business day. After discussions within the Interagency Coordinating

Committee, NRC determined that 7 days was too long a time period. NRC has determined that the close of the next business day is the appropriate timeframe for reporting.

To ease the burden on licensees, the NRC is establishing a secure Internet-based interface to the National Source Tracking System. While on-line access should be fast, accurate, and convenient for licensees, the NRC will also allow licensees the option of completing and mailing or faxing paper forms. In addition, licensees will also be able to provide batch information using a computer-readable format file. The format will be specified in a guidance document on implementation of the National Source Tracking System.

B. What is a Nationally Tracked Source?

A sealed source consists of radioactive material that is sealed in a capsule or is 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. A nationally tracked source is a sealed source containing a quantity of radioactive material equal to or greater than the Category 2 levels listed in the new Appendix E to 10 CFR Part 20. A nationally tracked source may be either a Category 1 source or a Category 2 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 were to be placed in a matrix material, the sealed source would still be covered by the rule.

Category 1 nationally tracked sources are those containing a quantity equal to or greater than the Category 1 threshold. Category 2 nationally tracked sources are those containing a quantity equal to or greater than the Category 2 threshold but less than the Category 1 threshold. The definition of nationally tracked source is based on the IAEA Code of Conduct and is consistent with the definition of sealed sources in other parts of the NRC regulations and with definitions contained in Agreement State regulations.

The specific radioactive material and amounts covered by this rule are listed in Appendix E to Part 20. The radionuclides and thresholds of 16 of the radionuclides are identical to the Table I values from the Code of Conduct. The IAEA Code of Conduct includes a recommendation that these radionuclides and thresholds be included in a national source registry. The U.S. Government has formally endorsed these values. The NRC has adopted the Category 2 values to allow alignment between domestic and international efforts to increase the safety and security of radioactive sources. The Energy Policy Act of 2005 states that Category 1 and Category 2 sources are to be included in the National Source Tracking System.

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 practical usefulness only and are rounded after conversion. The curie values are not intended to be the regulatory standard.

Table I of the IAEA Code of Conduct lists 16 radionuclides that should be included in a national source registry. Included in this listing is radium (Ra)-226. Before the Energy Policy Act of 2005 was signed into law, the NRC did not have the authority to regulate Ra-226;

therefore it was not included in the proposed rule for national source tracking. Section 651(e) of the Energy Policy Act of 2005 amends section 11e. of the Atomic Energy Act to give NRC authority over discrete sources of Ra-226 and other radioactive materials if they are produced, extracted, or converted after extraction for use in commercial, medical, or research activities. Therefore, NRC is adding Ra-226 to Appendix E in this final rule. Ra-226 sealed sources will now be included in the National Source Tracking System. The term 'discrete source' will be defined in a separate rulemaking to implement section 651(e) of the Energy Policy Act of 2005. That final rule is to be issued by February 7, 2007.

In the proposed rule, the Commission expanded the National Source Tracking System list of radionuclides to include 6 radionuclides that are not on the Code of Conduct list and one radionuclide that is listed in the Code of Conduct but is not included in the source registry recommendation. The 7 additional radionuclides included in the proposed rule were actinium (Ac)-227, plutonium (Pu)-236, Pu-239, Pu-240, polonium-210, thorium (Th)-228, and Th-229. The DOE/NRC RDD report recommendation for a National Source Tracking System included these 7 radionuclides. The thresholds for these radionuclides were developed using the same methodology as those listed in the Code of Conduct. These radionuclides are also included in the interim database. Based on information from the interim database, NRC and Agreement State licensees do not possess large numbers of nationally tracked sources containing these radionuclides. Because this is a national system, it needs to include information from DOE facilities. DOE facilities are more likely to possess these radionuclides, and DOE agreed that these radionuclides should be included in the National Source Tracking System. Therefore, the Commission included them in the proposed rule. The source tracking system NRC is required to establish under the Energy Policy Act of 2005 covers "radiation sources" as defined in the

Act (Category 1 and Category 2 sources and any other material as determined by the Commission other than spent nuclear fuel and special nuclear materials). Three plutonium (Pu) isotopes (Pu-236, Pu-239, Pu-240) are being removed from Appendix E because these isotopes are not "radiation sources" within the meaning of the Act. Two other Pu isotopes (Pu-238 and Pu-239/Be) are being retained in Appendix E because they are listed in the Code of Conduct.

C. *Who Does This Action Affect?*

The final rule applies to any person (entity or individual) in possession of a Category 1 or Category 2 source. It applies to all NRC licensees; including, for example:

Manufacturers and distributors of Category 1 and Category 2 sources;

Medical facilities, radiographers, irradiators, reactors, and any other licensees that are the end users of nationally tracked sources; and

Disposal facilities and waste brokers.

Agreement States will impose legally binding requirements on their licensees such that all licensees, both NRC and Agreement State, will begin reporting at the same time.

The final rule applies whether the source is actively used or in long-term storage.

Nationally tracked sources are possessed by all types of licensees, but primarily by byproduct material licensees. Nationally tracked sources are used in the oil and gas, electrical power, construction, medical, and food industries. They are used in a variety of military applications and in technology research and development. Nationally tracked sources are classified either Category 1 or 2 based on the activity level of the radioactive material of concern. Category 1 sources are typically used in devices such as radiothermal generators and

irradiators, and in practices such as radiation teletherapy. Category 2 sources are typically used in industrial gamma radiography, blood irradiators, and some well logging.

D. *How Will Information Be Reported to the National Source Tracking System?*

Licensees have several options for reporting transaction information to the National Source Tracking System. These reporting methods include on-line, computer-readable format files, paper, fax, and telephone. For most licensees, the most convenient, least burdensome method will be to report the information on-line (e.g. through the internet). To report information on-line, a licensee will need to establish an account with the National Source Tracking System. Once an account is established, the licensee will be provided with password information that will allow access to the on-line system. A licensee will have access only to information regarding its own material or facility; a licensee will not have access to information concerning other licensees or facilities. When logged on, the licensee will be able to type the necessary information onto the on-line forms. Once a source is in the system, the licensee will be able to click on the source and report a transfer or other transaction. Identifying information such as license number, facility name, address, manufacturer, model number, serial number, etc. will not need to be typed in a second time.

Many licensees conduct a large number of transactions, especially manufacturing and distribution licensees. We recognize that most licensees have a system for maintaining their information on sources. The National Source Tracking System will be able to accept batch load information from licensees systems using a computer-readable format. This will ease the reporting burden for a licensee with a large number of transactions. The licensee will be able to electronically send a batch load using a computer-readable format file that contains all of the

transactions that occurred that day. Licensees can also use this format to report their initial inventory.

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

Additional guidance on submitting information will be provided before the effective date of the reporting requirements. The guidance will contain mailing addresses and telephone and fax numbers for providing information to the National Source Tracking System, as well as information on the computer-readable format to be used. The NRC plans to hold several workshops on reporting information to the National Source Tracking System which will include hands-on training. The workshops will be held before the effective date of the reporting requirements. Licensees (both NRC and Agreement State) will receive information on when and where the workshops will be held.

E. *Will a Licensee Need to Report Its Current Inventory to The System?*

Yes, licensees are required to report their current inventory of nationally tracked sources by a specified date. There are separate reporting dates for Category 1 and Category 2 nationally tracked sources. Licensees are required to report all Category 1 sources to the National Source Tracking System by March 15, 2007, and all Category 2 sources by March 30, 2007.

To ease the reporting process, information already in the interim database will be downloaded to the National Source Tracking System. Each licensee that reported information to the interim database will be provided a copy of its information and asked to either verify the information or provide updated information. NRC staff and the company that will operate the

National Source Tracking System will work with licensees to make sure the initial inventory information is correct. Licensees that did not provide information to the interim database must provide the information on their nationally tracked source inventory by the specified dates. Disposal facilities do not need to report sources that have already been buried or otherwise disposed.

For sources that are stored in a device, the licensee must report the serial number of the source within the device. Licensees are not required to report the device number. Sources are usually not placed permanently in the device, but are removed from the device at the end of the source's useful life. Because some licensees track their sources by device number, the National Source Tracking System contains an optional reporting field for reporting the device serial number. Licensees will be able to search their data by device number. For licensees reporting by the paper form, the device number can be added to the comment field.

F. *What Information Will Be Collected on Source Origin?*

Each time a nationally tracked source is manufactured in the United States, the licensee must report the source information to the National Source Tracking System. The information must be reported by the close of the next business day. The licensee must report the manufacturer (make), model number, serial number, radioactive material, activity at manufacture, and manufacture date for each source. The licensee must also provide its license number, facility name, address, and the name of the individual that prepared the report. Manufacturers may make one report that includes both the manufacture and transfer of sources, as long as the transfer occurs within the reporting timeframe of the manufacture. The information required for both transactions will need to be included in the report.

Some sources are recycled or reconfigured. For example, a source that has decayed below its usefulness is sometimes 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 date must be reported to the National Source Tracking System.

For every nationally tracked source that is imported, the facility obtaining the source must report the source information to the National Source Tracking System by the close of the next business day after receipt of the imported source at the site. For the purposes of the National Source Tracking System, this is 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 must also provide its license number, facility name, address, and the name of the individual that prepared the report and the date of receipt. The licensee must also provide information on the facility (name and address) that sent the source and the import license number.

Under separate regulations on import/export of radioactive material, licensees are required to notify the NRC of imports of radioactive material at Category 2 levels or above (70 FR 37985; July 1, 2005). This notification includes source identification information, if available. Initially, NRC staff will enter the notification information into the National Source Tracking System, but eventually, import/export licensees will be able to make the notifications to the NRC using the on-line reporting mechanism of the National Source Tracking System. For example, if the notification includes the detailed source information, a licensee that is receiving an imported nationally tracked source will be able to report the transaction as a simple receipt using the on-

line method. Much of the source information will already be in the National Source Tracking System; the licensee will be able to click on the pending import and then click on the source to indicate that the source had been received at the site.

G. *What Information Will Be Collected on Source Transfer?*

Each time a nationally tracked source is transferred to another authorized facility, the licensee must report the transfer to the National Source Tracking System by the close of the next business day. The licensee must report the recipient name (facility the source is being transferred to), address, and license number, the shipping date, the estimated arrival date, and the identifying source information (manufacturer, model number, serial number, and radioactive material). If the source is being exported, the export license number is reported for the recipient's license number. The licensee also must 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 must also report the waste manifest number and the container identification number for the container with the nationally tracked source.

Source transfer transactions are transfers between different licensees and transfers from a licensee to another authorized facility, such as a DOE site or a foreign entity. A source transfer transaction does not include transfers to a temporary domestic job site. Domestic transactions in which the nationally tracked source remains in the possession of the licensee do not require a report to the National Source Tracking System. For example, a radiographer conducting business does not need to report transfers between temporary job sites, even if the temporary job site is located in another state or if the work is conducted under a reciprocity agreement.

H. *What Information Will Be Reported for Receipt of Sources?*

A licensee must 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 must include its facility name, address, and license number and the name of the individual that prepared the report. The licensee must also provide the name, address, and license number of the facility that sent the source because this information is necessary to match the transactions. If the source is an import, the licensee must report the source activity and associated activity date. The import license number is reported as the license number of the sending facility. 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. To avoid unnecessary exposure, these licensees are not expected to open the waste container to verify the presence of the nationally tracked source; they may rely on the information from the licensee who shipped the source.

I. *What Information Will Be Reported on Source Endpoints?*

Endpoints for a source include export, disassembly, disposal, decay, loss or theft, and destruction of the source. Some of the endpoints are reversible (export, loss, theft) and some are permanent (disassembly, disposal, destruction). Exports are treated as a transfer. (See Section G for more information on source transfer.) An export is considered a reversible endpoint because the source can be imported back into the country. The export license number is reported as the license number of the receiving facility.

Some licensees disassemble sources for possible recycle. The source is taken apart, the radioactive material is removed, and the material may be used for manufacture of new sources or sent for disposal. This is not the same as reconfiguration where the source is not destroyed. The licensee must report the disassembly of any nationally tracked source to the National Source Tracking System by the close of the next business day. Once a source has been disassembled, it is no longer tracked. This is a permanent endpoint. Licensees that report a disassembly transaction must include the source information (manufacturer, model number, serial number, and radioactive material), license information (name, address, license number, name of person making the report), and the date of the disassembly.

Disposal of a source is reported by the licensee conducting the actual burial in a low-level disposal facility or other authorized disposal mechanism. Licensees sending a source to a low-level burial ground for disposal treat the transaction as a transfer. The licensee must include the waste manifest number and the container identification number. The disposal facility is not expected to open the waste container to verify the contents, and may report the information from the licensee who sent the waste for disposal. The disposal facility must report to the National Source Tracking System 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 who prepared the report. The report must be made by the close of the next business day.

The National Source Tracking System automatically calculates the decay of a source so licensees do not need to report an endpoint of decay. Once a source has decayed below Category 2 levels, it is no longer considered to be a nationally tracked source. The source will

be automatically removed from a licensee's active inventory in the National Source Tracking System. The licensee will receive a notification that the source has decayed below the tracking level and that transactions for this source no longer need to be reported. The data on the source will, however, be retained in the system.

Licensees must continue to report accidental destruction of sources to the NRC Operations Center or to their Agreement State. The Agreement States provide the information to the NRC Operations Center. NRC staff will enter the information from the event report into the National Source Tracking System. Because sealed sources are designed to be robust, accidental destruction is rare. Examples of accidental destruction include sources destroyed during attempts to remove them from devices, and well logging sources that become disconnected downhole and destroyed during retrieval attempts.

Other endpoints that will be captured by the National Source Tracking System include the loss or theft of a source or the abandonment of a source in a well. 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 National Source Tracking System. Agreement State licensees must continue to report to their 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 National Source Tracking System. Agreement State staff may also enter the information into the system. Loss and theft of a source are considered to be reversible endpoints and source abandonment in a well is considered a permanent endpoint.

J. *How Will the National Source Tracking System Information Be Kept Current?*

Data integrity for the National Source Tracking System is extremely important. Licensees are expected to provide correct information to the National Source Tracking System

and to double-check the accuracy of their information before submission. However, 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 National Source Tracking System will contain correct, up-to-date information. However, we recognize that some transactions may be missed and that errors may be introduced into the system over time. Discrepancies might result from the failure to report the receipt of a source or failure to report the transfer of a source to another licensee. Inaccuracies can result from errors in the initial inventory report, selection of the wrong model number, or incorrectly typing the serial number. Each licensee is required to correct any errors or missed transactions that it becomes aware of within 5 business days of the discovery.

In addition, each licensee is required to reconcile its on-site inventory of nationally tracked sources with the information previously reported to the National Source Tracking System. This reconciliation occurs during the month of January each year. Each licensee will be able to print a copy of its inventory information from the National Source Tracking System. Licensees without on-line access will receive a paper copy from the NRC of their information in the National Source Tracking System. Each licensee must compare the information contained in the system to the its own inventory, 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. The NRC's regulations already require licensees to conduct physical inventories either annually, semi-annually, or quarterly, depending on the type of license. Each licensee must reconcile any differences by reporting the appropriate transaction(s) or

corrections to the National Source Tracking System. The reconciliation must be completed by January 31 of each year.

In addition, each licensee must report to the National Source Tracking System that their data in the National Source Tracking System is correct. Licensees reporting their reconciliation using non-electronic methods will have to use a hard copy form, which will be provided with the paper copy of the information contained in the National Source Tracking System. The first reconciliation will occur in January 2008.

K. How Will Incorrect Information Be Changed in the National Source Tracking System?

Licensees will be able to correct errors in the National Source Tracking System at any time, either online or through any other permitted reporting mechanism. Each licensee is responsible for correcting any errors in its inventory information in the National Source Tracking System, regardless of the source of the error, within 5 business days of the discovery.

L. *Some Licensees Now Must Report Similar Information to the Nuclear Materials Management Safeguards System. Will This Rule Result in a Duplication in Reporting?*

Yes, some information on plutonium (Pu) and thorium (Th) is collected by both the Nuclear Materials Management Safeguards System (NMMSS) and the National Source Tracking System. The current regulations require reporting transfers, receipts, and inventories to NMMSS of one gram or more of Pu and any Th that has foreign obligations. However, NMMSS does not collect information at the source level; therefore, the detailed information (make, model, serial number) on sealed sources cannot be extracted from NMMSS to provide input into the National Source Tracking System. The National Source Tracking System will only have information on sealed sources and will not contain information on sources that are not considered sealed or on any bulk material that a licensee may possess. The thresholds are

also different for the two systems. Therefore, NRC will not be able to extract information from the National Source Tracking System to support NMMSS. Neither system is able to collect the needed information for the other system without modifications to the databases and additional changes to the regulations. The two systems also have different purposes.

In practice, NRC finds that these Pu and Th sources are typically held by licensees for long time periods and are not routinely transferred to other licensees, so incidences of double-reporting are expected to be rare. Only 10 licensees reported possessing Pu Category 1 or Category 2 sources and no licensee reported Th sources to the interim database. The NRC does not believe that the limited number of licensees and transactions likely to be affected by this dual reporting requirement imposes an unnecessary burden. The NMMSS and the National Source Tracking System collect information on these radionuclides for different purposes and in different formats and with different levels of detail and thresholds as needed by each system. Therefore, the Commission believes that NMMSS and the National Source Tracking System should remain separate.

M. *Are the Actions Consistent with International Obligations*?

Yes, the National Source Tracking System is consistent with international obligations. The system is intended to respond to the recommendation in the IAEA Code of Conduct for development of a national source registry. In addition, attendance at international meetings provides the NRC staff with information on the actions of other countries to implement Code of Conduct recommendations. To the extent feasible, NRC will utilize data formats compatible with those of other countries.

N. *When Do These Actions Become Effective?*

The requirements for Category 1 nationally tracked sources will be implemented by March 15, 2007. This means that by this date any licensee that possesses a Category 1 level source must have reported its initial inventory and must begin reporting all transactions involving Category 1 sources to the National Source Tracking System. The requirements for Category 2 nationally tracked sources will be implemented by March 30, 2007. By this date, all licensees must have reported their initial inventory of nationally tracked sources and begin reporting all transactions to the National Source Tracking System. For all other provisions, the final rule is effective 90 days after publication in the *Federal Register*.

O. Who Will Have Access to the Information and What Will It be Used For?

Information in the National Source Tracking System is considered Official Use Only - Security-Related Information; the information is not considered to be Safeguards Information or Safeguards Information - Modified Handling. A licensee will be able to view its own data, but not data for other licensees. NRC, as the database manager, will have access to all of the information. Agreement State staff will be able to view information on the licensees in their state, but will not be able to view information on licensees in other states. The one exception is information related to lost or stolen sources. Agreement State staff will be able to view the information on lost or stolen sources for all licensees. This will enable better coordination of recovery efforts. Other Federal and State agencies will also be able to view the information on lost or stolen sources and other information on a need-to-know basis.

The National Source Tracking System will be used for a variety of purposes. This standardized, centralized information will help NRC and Agreement States to monitor the location and use of nationally tracked sources; conduct inspections and investigations;

communicate nationally tracked source information to other government agencies; verify legitimate ownership and use of nationally tracked sources; and further analyze hazards attributable to the possession and use of these sources.

P. What Other Things Are Required by This Action?

The final rule also requires manufacturers of nationally tracked sources to use a unique serial number for each source. The combination of manufacturer, model, and serial number will be used in the National Source Tracking System to track the history of each source.

III. Analysis of Public Comments on the Proposed Rule

The proposed rule on National Source Tracking was published on July 28, 2005 (70 FR 43646). The comment period ended on October 11, 2005. The NRC received 33 comment letters on the proposed rule. The NRC also held two public meetings on the proposed rule during the comment period. The first meeting was held in Rockville, Maryland on August 29, 2005, and the second meeting was held in Houston, Texas on September 20, 2005. Approximately 90 people attended the two meetings, with 17 individuals providing comments. The overall commenter mix on the proposed rule included federal agencies, states, licensees, industry organizations, and individuals. Copies of the public comments and the public meeting transcripts are available for review in the NRC Public Document Room, 11555 Rockville Pike, Rockville, MD or on the NRC's rulemaking web site located at http://ruleforum.llnl.gov. NRC also invited comment on the basis change of the rule from common defense and security to

public health and safety. The notice inviting comment on the basis change was published May ??, 2006 (71 FR xxxx) for a 20-day public comment period.

The comments and responses have been grouped into 12 areas. NRC specifically sought comments on the first six areas: (1) inclusion of Category 3 Sources; (2) inclusion of Ra-226; (3) inclusion of transfers between temporary job sites; (4) inspection of waste shipments; (5) data quality assurance; and (6) data protection. The other six comment areas are: (1) general; (2) rule language; (3) regulatory analysis; (4) implementation; (5) system aspects; and (6) miscellaneous. To the extent possible, all of the comments on a particular subject are grouped together. A discussion of the comments and the NRC staff's responses follow.

A. Category 3 Sources

In the proposed rule, NRC specifically invited comment on whether Category 3 sources should be included in the National Source Tracking System. Category 3 sources are those containing a quantity equal to or greater than the Category 3 threshold (1/10th of the Category 2 threshold) but less than the Category 2 threshold. Although the NRC did not plan to include Category 3 sources in this rulemaking, Category 3 sources could be included in the National Source Tracking System in the future. The potential issue was that a licensee possessing a large number of Category 3 sources could present a security concern. Therefore, NRC sought information on the number of additional licensees that would be impacted, the number of Category 3 sources possessed by licensees, and how often those sources changed hands.

Twenty-four commenters addressed the issue of Category 3 sources, including three Agreement States. The majority of commenters on this issue were opposed to including

Category 3 sources in the National Source Tracking System; only six commenters supported the inclusion, including two Agreement States and one non-Agreement State. Reasons for inclusion varied. According to one commenter, the higher activity Category 3 sources may pose a threat nearly comparable to the threat posed by Category 2 sources and should be tracked aggressively. Some commenters thought that Category 3 sources should be included because an accumulation of sources could possibly threaten national security. Others stated that any level of any radioactive material used in an RDD or RED would cause panic among the population. One commenter noted that the IAEA has indicated that Category 3 sources carry a potential risk of harm that warrants inclusion in a tracking system, but Member States did not want to include the Category 3 sources in the national registry recommendation because the large number of such sources and the economic cost for tracking them could be overly burdensome. The commenter stated that Category 3 sources should be included unless it can be shown that to do so is unreasonably burdensome (due to the large number of sources and the economic cost of tracking them). The commenter noted that, by IAEA definition, Category 3 sources are dangerous and could result in permanent injury, as well as cause serious social and economic impact, if not managed or securely protected.

Commenters argued that the Category 3 sources should be tracked to help prevent their possible entry into the scrap metal industry, pointing out that the Category 3 sources were more likely to be introduced into the recycle stream. Commenters stated that the Category 3 sources present a danger to the metals-recycling industry, its employees, and their communities. Two commenters provided data on clean-up costs for contaminated steel mills. Commenters stated that public health and safety concerns, as well as security concerns, support the inclusion of Category 3 sources at this time. One commenter stated that with modest additional investment,

NRC has the ability to track Category 3 sources and that the failure to do so will foreclose an opportunity to advance a rule which would be truly protective of public safety and the environment. Another commenter stated that additional data needs to be collected on the inclusion of Category 3 sources, but noted that any study should not be done in such a way that would disrupt the current implementation schedule for Category 1 and Category 2 source tracking. One commenter argued that the data from the inclusion of Category 3 sources would enable the government to more effectively manage the protection of the public health and safety and the economic vitality of the United States scrap metal industry and that the data could be used to monitor market trends, establish projections for low-level waste disposal, and allocate resources for programs to identify and develop alternate technologies.

Most of the commenters opposed to the inclusion of Category 3 sources cited the increased burden that would be imposed on licensees and the NRC. One commenter noted that the inclusion of Category 3 sources would require over 7,000 additional transaction reports every year for his company; most commenters did not provide specific numbers, but indicated that there would be a significant increase in the transaction reports from thousands to tens of thousands.

According to one commenter, inclusion of Category 3 sources would significantly increase the number of impacted licensees and all medical facilities that perform radiation therapy procedures would be impacted. One commenter noted that most of the sources are used in teletherapy or gamma sterotactic radiosurgery units and that once the sources are placed in the machines, tampering or stealing the sources becomes very difficult. A couple of commenters pointed out that many of these sources are used extensively in generally licensed gauges at fixed facilities and that most of the individuals possessing these materials do not

even realize that they have an NRC or Agreement State license. The commenters felt that these individuals would be unlikely to understand the tracking system and would need additional education to understand their responsibilities under the tracking system. Commenters stated that including Category 3 sources in the tracking system would unduly burden manufacturers and licensees due to the large number of Category 3 sources that are in common use throughout the United States. Other commenters pointed out that licensees are required to maintain inventory records and that this should be sufficient. Some of the commenters suggested inventory reporting instead of source transactions.

Commenters pointed out that many of the Category 3 sources are lower risk and do not pose a significant terrorist threat in comparison to Category 1 and 2 sources. One commenter stated that including Category 3 sources would go beyond the IAEA Code of Conduct recommendation and that to maintain consistency with the Code of Conduct, NRC should not include Category 3 sources. One commenter opposed the inclusion of Category 3 sources now and in the future because implementing standards more stringent than the IAEA code of conduct will generate confusion and not integrate the United States plan with international efforts in this regard. One Agreement State stated that inclusion of Category 3 sources does not fall within the security requirements and should not be included. The State noted that if a licensee possessed enough sources in the aggregate it would be under increased security control requirements.

Several commenters expressed concern that inclusion of Category 3 sources would bog down the system development process, hinder the timely implementation of the system, and potentially degrade the quality of the information in the database. Commenters noted that there will be a breaking-in period while both the regulated and regulators learn to complete, report,

and maintain the necessary reports. Commenters noted that inclusion of Category 3 sources would dramatically increase the number of records and would diminish the effectiveness of the rule (by increasing the likelihood of data entry error, impacting timeliness, and through sheer volume). Several commenters noted that the issue could be revisited after the National Source Tracking System has been implemented and is running smoothly. Two commenters suggested that before including Category 3 sources, the NRC should conduct a roundtable discussion with stakeholders to fully understand the impact of the rulemaking on the medical community and to ensure that final regulations do not impose unintended problems in the practice of medicine.

Response: As part of the proposed rulemaking on the National Source Tracking System, NRC requested the views of potentially impacted stakeholders on the inclusion of Category 3 sources in the National Source Tracking System. The comments received expressed strong views on this topic. It was not NRC's intent to include Category 3 sources in the tracking system at this time. Rather, NRC intended to gather information for future consideration. At this point NRC staff does not have adequate information to support inclusion of Category 3 sources. There are also issues related to possession of Category 3 sources under a general license that need to be addressed before a final decision can be made. In addition, the Radiation Source Protection and Security Task Force, established by the Energy Policy Act of 2005, will be reviewing whether changes to the National Source Tracking System are necessary, including whether Category 3 sources should be included.

At this time, NRC is not including Category 3 sources in the National Source Tracking System. The development and implementation of the National Source Tracking System should be completed before adding another tier of sources and licensees. The NRC staff will continue to evaluate adding Category 3 sources to the tracking system. If a decision is made to include

Category 3 sources, a separate rulemaking would be conducted with an opportunity for public comment.

B. Ra-226

At the time the proposed rule was published, NRC did not have authority over Ra-226. Because the IAEA Code of Conduct included Ra-226 in its recommendation for a source registry, NRC specifically invited comment on whether States would be willing to develop regulations that would require their licensees to report Ra-226 to either the State or to the National Source Tracking System. NRC received input from six commenters, including four States. The commenters all supported the inclusion of Ra-226 in the tracking system.

The Energy Policy Act of 2005 brought discrete sources of Ra-226 that are produced, extracted, or converted after extraction, for use in a medical, research, or commercial activity, under the regulatory authority of the NRC. Because the NRC now has authority over Ra-226 sealed sources, Ra-226 has been added to Appendix E in this final rule. The NRC is currently developing a rulemaking that will, among other things, define discrete sources of Ra-226. NRC intends to issue final regulations by February 7, 2007, which will provide licensees adequate time to become familiar with new Ra-226 requirements before the implementation of the National Source Tracking System.

C. Temporary Job Sites

As drafted, the proposed rule only covered source transfers between different licensees and/or authorized facilities such as a DOE site or an export. It did not include transfer to a temporary job site. Therefore, transactions in which the nationally tracked source remained in

the possession of the licensee would not have required a report to the National Source Tracking System. NRC specifically invited comment on whether licensees should be required to report as a transaction the use of a nationally tracked source at temporary job sites, whether in the same state or a different state, and if temporary job site transactions were included in the System, how much additional burden would be involved and what the reporting timeframe should be. Twenty-four commenters addressed this issue, including two Agreement States. The overwhelming majority of commenters were opposed to reporting transactions for source use at temporary job sites. One state supported the inclusion of transfers to temporary job sites arguing that security at temporary job sites could easily be compromised and reporting would provide information on what sources are on the state highways. Two Agreement States stated that while reporting use at temporary job sites would be useful, it should only be required when licensees perform temporary jobs across state lines. The information could then be compared to existing reciprocity reports if the host state was allowed access to the necessary information. The commenters stated that host states should be allowed access to the data to confirm what sources are within their borders.

Commenters opposed to the inclusion of reporting transactions at temporary job sites indicated that this would impose a large burden, the information reported would not add any value, and in fact would be out of date by the time it was reported. Commenters stated that many licensees can work at several job sites per day, noting that crews could conceivably go to eight different jobs each day. The commenters stated that reporting these movements would not add anything to the physical security of the sources, a point the NRC acknowledged in the Statement of Considerations for the proposed rule. Commenters also pointed out that these sources are used at tens of thousands of temporary job-sites annually and that their inclusion in

the System would increase the already burdensome proposal by factors of hundreds or thousands. One commenter estimated that his company would amass an additional 41,250 reports annually if temporary job site transfers were included. Other commenters noted that it would require additional staff to make the reports; the estimates provided ranged from a quarter person-year to an additional full-time person. One commenter estimated that it would cost $41,600 annually to report source use at temporary job sites. Commenters also noted that due to the transitory nature of the temporary job sites, there may be no easy means of providing the information (i.e., no computer, no internet, fax, etc. at the remote locations). Commenters indicated that by the time the information was reported, it would no longer be valid as the source would already be at a new location. Commenters also pointed out that radiographers are required to maintain a utilization log for each source and that the logs are available for review by NRC or Agreement State inspectors.

Commenters stated that as long as the source remains in the possession of the licensee, there would be an appropriate level of security. Several commenters noted that they are under an immediate detection assessment and response order; therefore, they already need to know where their sources are, and are required to respond to and report any problem to the NRC. They indicated that reporting temporary job site transfers would not improve incident response time. Several commenters stated that the volume of reports generated on temporary job sites would inundate the system and would likely require more manpower at the NRC. Another commenter noted that the risk of error would be increased due to the amount of movement of the sources on a daily basis. One commenter stated that the meaningless information would compromise the integrity of the entire database. Lastly, several commenters

suggested that instead of reporting transactions involving temporary job sites, a shorter (monthly or quarterly) source inventory verification period should be imposed.

Response: NRC has carefully considered the information provided by the commenters and has determined that temporary job site transactions should not be reported to the National Source Tracking System. Requiring reporting of temporary job site transfers would impose a large additional burden on licensees without a corresponding benefit. The information would not be beneficial as it would likely be out of date by the time it was reported to the tracking system. Thus, States would not be able to use the information for checking what sources are within their borders because the sources would likely have been relocated before the data could be entered. As for requiring a more frequent reconciliation period instead of temporary job site reporting, the purpose of temporary job site reporting, if required, was not to provide verification that a licensee is still in possession of a source. A more frequent inventory reconciliation would impose a large burden without a corresponding benefit. NRC is not requiring the reporting of sources being transferred to temporary job sites to the National Source Tracking System.

D. Inspection of Waste Shipments

Waste brokers and disposal facilities are examples of licensees that might receive a nationally tracked source as part of a waste shipment. Because opening waste containers can result in unnecessary exposure for workers, these licensees typically do not open the containers to check contents, although a waste broker may open containers in order to consolidate shipments. After acceptance of a waste shipment, disposal facilities routinely move the container to the disposal area. The proposed rule did not require disposal facilities and waste brokers to verify the presence of the nationally tracked source in a waste container; they

may rely on the verification of the licensee who shipped the source. Because there was to be no verification by the recipient that the source was in the waste container, NRC specifically invited comment on whether the waste broker or disposal facility should be required, at a minimum, to investigate the container for any indication of tampering. The inspection for tampering would provide additional assurance that the source was still in the container.

Six commenters provided input on this question, including two Agreement States. The comments on this issue were mixed. One commenter stated that one cannot assume the material is present and that verification of the presence of the source in the disposal container is necessary for an efficient tracking system. The commenter noted problems at several sites with trying to go back and determine exactly what happened to the material to be disposed. Two commenters supported some sort of verification but suggested the use of a tamper-proof seal for a visual indication of possible tampering with a container. Two commenters stated that the current system is adequate and that waste broker and disposal facilities should not be required to open the containers because it would subject workers to additional radiation exposure. The commenters also noted that the tamper proof seals currently required on transport containers provide sufficient indication that the source is still in the container. One commenter stated that due to ALARA considerations, content verification should be performed only once, with subsequent reliance on container tamper seals. The commenter suggested that two signatures be obtained to verify contents of the package before the seal is applied and that this would be the responsibility of the original licensee packaging the source.

Response: NRC has determined that no additional requirements are necessary for verifying waste shipments. NRC agrees that due to ALARA considerations waste brokers and disposal facilities should not open a container to verify the presence of a source. Licensees

must incorporate a feature, such as a seal, that is not readily breakable and that, while intact, would be evidence that the package has not been opened by unauthorized persons. Licensees generally verify that the seal is intact before handling the container, and NRC does not believe that it is necessary to require such a practice. If this becomes a problem, NRC would consider imposing additional requirements.

E. Quality Assurance

The quality of the information reported to the National Source Tracking System is extremely important. While the proposed rule did contain a provision to correct errors within five days of discovery, there were no required pre-submission data quality checks. To address data quality assurance concerns, NRC specifically invited comment on a proposal to require licensees to double-check the accuracy of the data by using two independent checkers before submission of the transaction report. NRC sought information concerning whether the proposed quality assurance requirement was the appropriate requirement for quality assurance and if not, suggestions for appropriate requirements, and what additional burden a quality assurance requirement would impose on licensees.

Twelve commenters, including three Agreement States, addressed quality assurance in their comments. Two of the commenters were in favor of quality assurance requirements. One commenter stated that inclusion of a quality assurance provision on data submission would be a good idea if it could be managed electronically, but was opposed to a counter signature approach. The other commenter supported a quality assurance provision if the verification was limited to comparison with manufacturer-supplied data or manifests and confirmation of tamper seal integrity.

Ten commenters opposed adding additional quality assurance requirements. Several of the commenters stated that annual reconciliation should be adequate to ensure quality assurance. Several commenters stated that there is no reason to believe that the information provided by the shipper would not be accurate and that the validity of the information could be checked during inspection. Commenters also noted that some data quality assurance would occur when two parties are involved in a transaction; the recipient of a source verifies the data when acknowledging receipt of a source. One commenter stated that mandating a second review is too prescriptive. The commenter noted that most companies have a quality assurance program and should be able to make the decision internally whether a second review is required. The commenter was not aware of any other regulation that specifically requires a quality assurance check prior to submission of data to the NRC.

Most of the commenters stated that requiring an independent check before data submission or any other requirement would impose a large financial burden on licensees, particularly smaller licensees. Commenters stated that for many small companies, resources are limited and personnel may not be available to conduct an additional check. Commenters noted that the requirement might necessitate the hiring of additional personnel. One commenter noted that if the quality control work was limited to confirming proper transcription of data, the burden would be about 30 minutes per transaction. One commenter noted that the inclusion of a quality assurance provision is no guarantee that an occasional error could not occur, and that the potential for error is reduced if the required recordkeeping and reporting are kept simple.

Response: NRC has decided not to impose additional quality assurance on the data submission. The large additional burden that would be imposed, particularly on small licensees,

is not warranted. The source tracking system will have some built-in checks; for example, an alarm will be triggered if information submitted by the transferring company and the receiving company do not match. The annual reconciliation will also serve a quality assurance function. The inspection program will also be revised to include inspections related to the National Source Tracking System. In addition, information submitted to the National Source Tracking System must be complete and accurate in all material respects as required by NRC regulations (for example, 10 CFR 30.9, 40.9, 50.9, 70.9, 76.9). If data quality becomes a problem, the NRC would consider imposing additional quality assurance requirements.

F. Data Protection

In the proposed rule, NRC specifically invited comment on whether designation of the information as Official Use only would provide sufficient protection of the information or whether to require licensees to protect the information that is reported to the National Source Tracking System and, if additional protection is necessary, at what level of protection. Six commenters addressed this topic and supported retaining the designation as Official Use Only. While commenters agreed that the data is sensitive, they did not recommend additional provisions to protect the data. Commenters were opposed to designating the data as Safeguards Information (SGI) and noted that designation of the data as SGI would be onerous to implement and could result in unintended restrictions on routine data. Commenters stated concern about protection of the aggregated information and recommended that additional protection measures be taken. One commenter stated the information should be excluded from public disclosure under 10 CFR 2.390.

Response: NRC has decided that no additional measures are necessary to protect the information possessed by individual licensees. The data does not meet the definition of SGI and will be designated as Official Use Only - Security-Related Information once it is submitted to the National Source Tracking System. The information will be treated in the same manner as other information designated as Official Use Only - Security-Related Information. A licensee will only have access to its information in the National Source Tracking System. Access for other persons, including NRC staff, will be on a need to know basis.

G. General

Comment G.1: One commenter stated that the proposed rule would make great strides towards assisting the metals industry in eliminating radioactive sources from the scrap feed stock because it provides better oversight, management, and stewardship of certain sealed sources. The commenter believes that the National Source Tracking System requirement will provide the NRC the necessary oversight to ensure that these sealed sources would be less likely to be managed in a way that could lead to their inadvertent or intentional disposal in the waste or the recycling streams.

Response: The commenter expresses general support for the rule, therefore, no response is necessary.

Comment G.2: One commenter objected to the statement that National Source Tracking "will provide greater source accountability which will foster increased control by licensees." The commenter indicated that the statement implies that the NRC believes that

licensees have not been providing adequate accountability or control for these sources in the past. The commenter disagrees with this implication and cites the excellent record of licensees.

Response: The statement was not intended to imply that licensees have not historically provided adequate accountability and control over these sources. However, in today's threat environment, NRC has determined that enhanced controls are necessary to ensure the continued protection of these materials. National Source Tracking is one aspect of the enhanced security program, and will provide NRC with information on what licensees actually possess verus what radioactive material they are authorized to possess.

Comment G.3: Two commenters stated that there is no need for a national source tracking system and another commenter stated that the rule is in excess. One commenter stated that the sources are already tracked by the respective NRC office or Agreement State via licensing and inspection, noting that licensees are required to inventory their material. The commenter stated that the source tracking system would add an additional layer of bureaucracy and would be a waste of money. The second commenter stated that the proposed rule would increase costs for licensees without improving the security of licensed material. The commenter stated that the NRC already possesses information through the existing regulatory framework on who manufactures, receives, transfers and disposes of sealed sources. One commenter suggested that if NRC wants to track sources it should be via the submission of quarterly inventories.

Response: NRC disagrees with the commenters. The Energy Policy Act of 2005 requires NRC to issue regulations for a mandatory source tracking system. Currently, sources are not tracked by either NRC or the Agreement States. Most licenses establish a maximum possession limit, but most do not list individual sources. While regulatory agencies know what material a licensee is authorized to possess, they may not know what that licensee actually possesses at its facility. While licensees are required to maintain an inventory of the radioactive materials that they possess, there is no requirement that they report their inventory to their regulatory agency, although inspectors may review the inventory listing as part of an inspection. The National Source Tracking System will provide the NRC with the up-to-date information it needs to monitor the location of higher activity material; the submission of quarterly inventories would not be a sufficient tracking mechanism for these higher-risk radioactive sources.

Comment G.4: One commenter stated that the proposed rule inappropriately references the IAEA Code of Conduct and suggests that the IAEA is asking for more than is already required in the present United States regulatory environment. The commenter expressed the belief that the United States regulatory framework for licensing already meets the IAEA requirements.

Response: NRC disagrees with the commenter. The United States Government has made a commitment to comply with the recommendations in the IAEA Code of Conduct, so it is appropriate for the proposed rule to reference the IAEA document. The IAEA Code of Conduct

specifically recommends that Member States establish a national source registry, a mechanism that is not part of the current US regulatory framework.

Comment G.5: A commenter stated that the proposed regulation violates the Agreement between the Agreement States and the Federal government.

Response: NRC disagrees with the commenter. There is no violation of the Section 274b. Agreements between certain States and the NRC. The commenter did not provide any additional information on exactly what aspect of the proposed rule was in violation. Promotion of the common defense and security was the basis for the proposed rule and on that basis NRC would not have relinquished that function to the Agreement States under Section 274b. of the Atomic Energy Act. However, upon further review the Commission has determined to promulgate the rule under its authority to protect the public health and safety.

Comment G.6: One commenter pointed out that the statement identifying Category 3 sources as those that have 1/10th of the radioactivity of Category 2 sources is misleading. The commenter noted that Category 3 sources also includes sources that have radioactive levels right up to the bottom threshold of the Category 2 sources.

Response: The commenter is correct that Category 3 sources include sources that have activities up to the lower threshold of Category 2 sources. A Category 3 source is a source containing radioactive material equal to or greater than the Category 3 threshold (1/10th of the Category 2 threshold) but less than the Category 2 threshold.

Comment G.7: One commenter noted that the majority of sources that are lost or stolen every year are portable gauges, which are well below the Category 2 threshold, and that this rule would do nothing to help safeguard those sources.

Response: The commenter is correct that this rule does not cover portable gauges. NRC issued a final rule on the security of portable gauges on January 11, 2005 (70 FR 2001). The rule became effective on July 11, 2005.

Comment G.8: One commenter expressed support for the National Source Tracking System but stated that the system should meet the need to enhance the public health and safety as well as national security. Two Agreement States stated that the rule should be promulgated under health and safety and be classified as Compatibility Category B, particularly since it will be added to 10 CFR Part 20, which delineates the general radiation safety standards. They indicated that states should be responsible for inspection and enforcement of the National Source Tracking System to ensure licensee compliance with the rule.

Response: The NRC agrees that the National Source Tracking System will benefit the public health and safety and is changing the basis for the rule, accordingly the final rule is being issued under the Commission's authority to protect the public health and safety and is classified as a Compatibility Category B. The reporting provisions are being placed in 10 CFR Part 20 because Part 20 applies to all licensees.

Comment G.9: One commenter questioned the inclusion of several radionuclides. The commenter noted that Pu is already accounted for and licensed separately as special nuclear material and a national database would be redundant. The commenter also did not understand why Th-229 and Cf-252 were included in the System since not many of these sources exist outside of DOE that exceed the threshold. The commenter asked if there were any future plans to track all sources no matter the size. One commenter also stated that the sources (Ir-192) are ill suited for use in RDDs or REDs.

Response: Transfers of Pu are tracked in a separate database. However, the database is inventory based; individual sources are not reported, therefore, the database and the National Source Tracking System are not redundant. Because the National Source Tracking System is to be a national system, it will include transactions from DOE facilities; therefore, radionuclides of concern to DOE need to be included. It is true that not many licensees actually possess these sources, so this provision does not impact many licensees. As stated in the Statements of Consideration of the proposed rule, NRC may consider expansion of the National Source Tracking System to include Category 3 sources at a later date (See Section A for further discussion of Category 3 sources). There are no plans to include other sources at this time. Ir-192 is included because it is listed in the Code of Conduct.

Comment G.10: A commenter questioned the benefit of having two categories of sources, besides adding unnecessary complexity to the regulation. The commenter noted that there are few differences between the requirements for Category 1 and Category 2 sources.

Response: The reporting requirements are identical for both Category 1 and Category 2 sources. However, the implementation date is different for the 2 categories. Future regulations codifying some of the NRC Orders may have different requirements for the two categories of sources.

Comment G.11: One State supported not only the inclusion of Category 3 sources but the inclusion of all non-exempt sources. The commenter supported the inclusion of non-exempt sources because of the view by emergency planners that any activity level of any radioactive material used in an RDD or RED would cause panic among the population.

Response: Lower activity sources are not considered likely to be used in an RDD or RED. Inclusion of all non-exempt sources would impose a huge burden on licensees and would likely overload the tracking system such that the effectiveness of the system would be reduced.

H Rule Language

Comment H.1: One commenter stated that manufacturers should only be required to report upon the transfer of sources. The commenter noted that sources are manufactured based on specific orders and that the sources are transferred quickly to the recipient (the same day or within a couple of days of each order). The commenter stated that requiring reporting of both the manufacture and the transfer of sources would impose an unnecessary burden on the manufacturer to enter the information twice. The commenter noted that entering data upon manufacture would not provide any useful information as that source would be shipped out and

that the creation date is irrelevant in the context of tracking the locations of sources once they are in use.

Response: The manufacture date is the point of origin for the source, and is needed by the system to calculate decay of the source. A manufacturer may report both the manufacture of a new source and the transfer of the source in a single report, provided that the transfer occurs within the reporting timeframe of the manufacture and the licensee submits all information for both transactions. If the transfer occurs after the close of the next business day after the date of manufacture, the licensee must make two separate reports.

Comment H.2: Two Agreement States suggested that additional information should be collected on the transactions. The commenters stated that the information should include the state in which the source is located, the state to which a source is being transferred, and the state from which a source is transferred.

Response: The NRC agrees with the commenter. The information on the states involved in a transaction is part of the system. Licensees will provide the actual address (location of a facility) when establishing an account in the system. The final rule language has also been revised to add the address of the licensee as required information.

Comment H.3: One commenter stated that the rule was missing a transaction on recycling of sources, or disposal or disassembly of sources for recycling. The commenter noted that the disposal transaction does not adequately capture this activity because it requires

a waste manifest number. The commenter noted that his company disassembled 1,809 Co-60 sources in the last year, and that these sources would have been tracked in the National Source Tracking System. The commenter noted that new sources were created out of the recovered Co-60. The commenter stated that this type of transaction should be treated similar to a disposal transaction but without a waste manifest number. The commenter provided draft rule language for consideration and also noted that NRC Form 748 would need to be revised to reflect the new transaction. Three commenters asked how remanufacturing (recycling) of sources would be handled. The commenters noted that when older sources are melted down and new sources are created, the unique serial number is lost. The commenters stated that the tracking system needs to be able to address this type of situation.

Response: The NRC agrees with the comments and has added a new transaction for disassembly of a source to the final rule. The rule requires a licensee that disassembles a source (for any reason) to report the transaction. This is an irreversible endpoint for the source within the tracking system. If the material is used to generate a new source, the licensee must report the generation as a new source manufacture. NRC Form 748 has been revised to add this new disassembly transaction.

Comment H.4: One commenter suggested that in the definition of Nationally Tracked Sealed Source, the term “permanently” should be deleted in the phrase “permanently sealed” because of recycling considerations.

Response: The NRC agrees with the commenter and the definition has been so revised.

Comment H.5: An Agreement State commented that June would be a bad month for academic licensees to conduct the required annual reconciliation of their data because school is out and some Radiation Safety Officers take summer vacation and thus would not be available to conduct the reconciliation. The commenter suggested September or October as alternatives.

Response: The month of June was selected in the proposed rule based on the proposed implementation date of the final rule. Because the implementation date of the final rule has changed, the reconciliation date has also changed. Reconciliation will be required in the month of January each year. In determining a suitable time for reconciliation, NRC took into consideration the implementation date of the new reporting requirements, the academic calendar, and peak work periods for radiographers.

Comment H.6: Two commenters requested that the reporting timeframe of the close of the next business day be extended because it would be too stringent and might be hard to meet. Commenters requested that the timeframe be extended to three to five days. One commenter noted that one individual in each office, likely the Radiation Safety Officer, would be given the responsibility to make reports and that he/she might not always be available in that timeframe, particularly when there were a lot of other activities in the office. Another commenter noted that extending the reporting requirement to 5 business days would enable

licensees involved in the transaction to verify that the transaction has been completed. One commenter stated that reporting by the close of the next business day would not be appropriate for Category 2 sources, but did not address Category 1 sources. The commenter believes the proposed reporting by the next business day requirement would be without value for enhancing the security of sources and responses to thefts and would be overly burdensome. The commenter noted that there are already requirements for immediate reporting of the loss or theft of a source and that reporting to the National Source Tracking System would not increase the physical security of the source or improve the response time of authorities in the event a source were stolen. One commenter suggested that instead of requiring reporting by the close of the next business day, that the NRC consider requiring licensees to maintain a record of the present location of the sources, make a monthly report of the movement of sources to ensure the national source registry is maintained, and to notify the planned recipient. The commenter further suggested that the NRC expand the reporting requirements in 10 CFR § 20.2201 to require reporting within 24 hours when Category 1 or Category 2 sources in transit cannot be located.

Response: Although the Energy Policy Act of 2005 requires reporting a change in possession of a source within 7 days, the final rule requires reporting by the close of the next business day. The timing of reports was discussed within the Interagency Coordinating Committee and the conclusion was that allowing up to 7 days for reporting transactions was too long for reporting transactions. The Committee indicated that reporting should be by the close of the next business day. In addition, allowing a longer timeframe could create a situation in which the source recipient might report the receipt of a source before the sender of the source

reports that the source had been transferred. NRC has determined that the close of the next business day is an appropriate timeframe for reporting.

Comment H.7: Two commenters suggested that rule language be added to specifically state that sources that decay below the Category 2 threshold values are automatically removed from the system and that no reporting would be required by licensees.

Response: Specific language is not needed in the rule text to incorporate the commenter's suggestion. A Nationally Tracked Source is defined in terms of Category 1 and Category 2 levels of any radioactive material listed in Appendix E. Once a source has decayed below the Category 2 threshold, by definition, it is no longer a nationally tracked source and is not required to be reported to the National Source Tracking System. The data on the source will, however, be retained in the system.

Comment H.8: One commenter proposed that a leak test be required (or confirmed as current) prior to shipping any Category 1 or Category 2 source to ensure that if any source is leaking that it be identified at the point of origin as opposed to the point of receipt.

Response: Leak testing is beyond the scope of this rulemaking. Licensees are required to periodically conduct leak tests on sealed sources for health and safety reasons. For the purposes of National Source Tracking, leak tests are not necessary.

Comment H.9: One commenter requested clarification on whether the activity levels in the table (Appendix E) apply to the parent radionuclides and the daughter products or just to the parent radionuclides.

Response: The activities in the table do not include daughter products.

Comment H.10: One commenter stated that for some radionuclides, such as Pu, the amount should be reported in grams instead of activity units.

Response: The official threshold unit for the National Source Tracking System is Becquerels. However, the system will allow reporting in other units, including grams. The system will automatically conduct the conversion into Becquerels.

I. Regulatory Analysis

Comment I.1: A commenter stated that Option 1 (no action) in the Regulatory Analysis is more viable and should be given consideration because the tracking system will be very costly to the stakeholders with little or nothing being gained by the stakeholders.

Response: The NRC disagrees with the comment. Although the rule does impose some additional burden on licensees, the NRC believes that the information to be gained is valuable. In addition, the Energy Policy Act of 2005, signed into law after publication of the proposed rule, requires NRC to issue regulations establishing a mandatory system for national source tracking. The no action alternative is no longer a viable option.

Comment I.2: One commenter noted that the draft Regulatory Analysis shows approximately 93 percent of the cost being borne by the NRC. The commenter stated that since the NRC acquires its revenue through fees on licensees, all of the cost of the system will be borne by the licensees and would end up costing each licensee approximately $18,000 annually. Another commenter questioned where the money to pay for the system will come from, noting if there are to be fees associated with the database, this should be spelled out now.

Response: There are no direct fees associated with the National Source Tracking System. Beginning in fiscal year 2007, the cost of the National Source Tracking System will be off of the fee base. This means that the cost will not be recovered through annual fees.

Comment I.3: One commenter questioned how the tracking system would improve public health.

Response: The Regulatory Analysis did not state that the tracking system would improve routine public health. The attribute discussed in the Regulatory Analysis is public health (accident/event) and the document stated that the tracking system would have a positive effect. The National Source Tracking System is discussed in terms of being a preventive measure and having the capability to avert potential health effects. The National Source Tracking System will provide regulators better information on where sources are located and who possesses them. Having this information should reduce the possibility that the material

could be used in an RDD or RED. As other commenters have pointed out, the tracking system should also reduce the chance of sources being introduced into the scrap metal stream.

Comment I.4: One commenter stated that the draft Regulatory Analysis grossly underestimates the cost and time it will take for industry to comply with the new requirements. The commenter stated that the NRC did not include any cost or time in order for industry to put systems in place and that licensees will need to write specific computer programs to collect the information. The commenter stated that approximately 80 man hours would be need to implement the requirements of the new rule.

Response: It should not be necessary for most licensees to put any new systems in place or write computer programs in order to implement the rule. Licensees should already have the information required to be reported to the National Source Tracking System, and will only need to log onto the system and enter their data. For those licensees that plan to use the electronic batch method, some computer programing may be necessary. The Regulatory Analysis has been revised to reflect this burden.

J. Implementation

Comment J.1: One commenter requested that industry be given adequate time to change procedures and conduct any necessary training before implementation of the rule. Another commenter requested guidance on the information technology aspects of implementing the system because it is going to take some effort to develop the process for

electronic data downloads to the system. Commenters also requested information on when the workshops would be held.

Response: The provisions for reporting transactions are not effective for over 6 months from the publication date of the final rule. Licensees should have adequate time to train staff on new or revised procedures, if necessary. The information technology guidance will be made available prior to rollout of the system. The NRC will be holding licensee workshops before the rule's effective date. The dates for the workshops have not been set. NRC will give licensees ample notice once the dates and locations for the workshops have been determined.

Comment J.2: Three commenters stated that manufacturers typically ship newly manufactured sources the same day as their manufacture or within a day or two and that it would not make sense to then require the manufacture to reenter the data for transfer of the sources. The commenters suggested allowing one entry or form to cover both transactions.

Response: NRC will allow the use of the same form for those sources that are manufactured and shipped on the same day. Licensees will need to check both transactions on the form.

Comment J.3: One commenter noted that a big education campaign needs to be conducted for both licensees and Agreement States. The commenter noted the need for NRC and Agreement State compatibility and consistency in implementation and education.

Commenters noted that implementation of the final rule will require extra effort to assure that Agreement State licensees are contacted and fully aware of the requirements of the rule.

Response: NRC agrees with the commenter on the need for training. Both NRC and Agreement State licensees will receive information on the National Source Tracking System, including information on how to establish an account, and information on training. The initial contact list will be based on licensees in the interim database. NRC will also work with the Agreement States to make sure that all impacted licensees are reached. NRC will be sponsoring workshops for both NRC and Agreement State licensees. NRC will also hold training sessions for Agreement State staff.

Comment J.4: Three commenters asked how corrections of data would be handled, both electronically and by paper. The commenters noted that without some method of noting a correction, the corrected information might be treated as a double transaction.

Response: The paper form has been revised to include a box to check for corrections. Users will also be able to correct transactions electronically. Development of the system is not complete, but in general, a licensee will be able to access its data, pick a transaction or source and click on a screen that will allow revisions.

Comment J.5: One commenter requested information on who would have access to the database and to what extent. The commenter requested information on how the database will be used and how it would improve security of nationally tracked sources. The commenter

requested an example of how the database would be used and when. One commenter stated that the low-level waste compacts should be allowed to have unqualified access to the data in the National Source Tracking System database because access would facilitate determining future regional needs for disposal of sources. The commenter further stated that access would facilitate the exportation from the compact region of devices for disposal and that records maintained by the compact would confirm occurrence of the transaction.

Response: Each licensee will have access to data on its own material and facility. 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. NRC will establish a procedure for handling requests from groups/agencies for data access. As stated in the Statement of Considerations for the proposed rule, the National Source Tracking System itself will not improve the physical security of these materials. The System may improve accountability of material and is part of the overall security program.

Comment J.6: One commenter asked whether a Radiation Safety Officer for a licensee with multiple locations in various NRC and Agreement States would have access to manage the information in the database for the various locations.

Response: Yes, a Radiation Safety Officer for multiple locations could arrange to have access to the information for all of the sites for which he/she is responsible. Access will be arranged during the setup of the account information for the licensee.

Comment J.7: Two commenters stated that there should be a provision to allow licensees to address multiple sources with a single transactional entry. The example provided is the 201 distinct sealed sources contained in a gamma knife. Each source is serialized sequentially and has nearly equal activities.

Response: Licensees will be able to report multiple sources that are serialized sequentially. The on-line and batch method will easily accommodate this action. Licensees using the paper forms will need to use the comment box to provide such data.

Comment J.8: One commenter stated that the NRC should consider the time and resources that will be needed for compliance with the rule. The commenter stated that the rule would require additional manpower and office equipment and place a significant financial burden on a healthcare delivery system already under stress. The commenter asked that NRC support efforts to lobby Congress, CMS, and private payers to increase funding for the delineated radionuclide procedures to alleviate the financial burden placed on medical institutions. The commenter also asked that source tracking be postponed until such funding is secured.

Response: NRC acknowledges that the National Source Tracking System imposes additional burden on licensees required to report transactions to the system. NRC is taking measures to reduce the reporting burden. Licensees can report using several different mechanisms, with on-line and electronic reporting being the least burdensome. Licensees will not be required to invest in any additional equipment to make their reports. Most licensees

already have computers and internet access. The request to lobby Congress and others is beyond the scope of the rulemaking.

Comment J.9: One commenter stated that the NRC should make a commitment to international harmonization on source tracking and take whatever steps are appropriate towards that goal before implementation of the tracking system. The commenter stated that harmonization is needed because tracking systems implemented by other countries need to work smoothly with NRC regulations if tracking systems are to be effective and efficient. The commenter stated that if implementation by all national authorities is based on a common set of definitions and operating principles, equitable trade opportunities will be maintained. Two commenters encouraged harmonization with other countries, specifically with Canada and the United Kingdom, to ensure a compatible web interface and data format. Another commenter stated that it is imperative that all countries implement national source tracking consistently and in the same time-frame, otherwise the rule will be only partly effective as tracking could be lost once sources are exported out of the United States. One commenter noted that if the tracking methods are identical information could be sent to both countries simultaneously.

Response: The source tracking system is a domestic system and should have no impact on trade opportunities with foreign countries. The system is not intended to track sources once they are exported out of the United States. NRC staff has met with Canadian officials to discuss source tracking. NRC staff has also attended international meetings to discuss Code of Conduct implementation, including source tracking. The import/export notifications are not part of this rulemaking.

Comment J.10: One commenter stated that the paper forms for reporting transactions are dysfunctional. The commenter stated that shipment of multiple sources would require the completion of multiple forms and would take several hours to complete. The commenter stated that the forms cannot be used in their current format and should be revised.

Response: The commenter did not provide any specifics as to the deficiencies with the form or make any suggestions for improvement. If a licensee chooses to use the paper form, it will be limited in the number of sources that can be included on the form; the size of the form is limited. Instead of filing multiple forms, the licensee could attach an addendum sheet that lists all of the sources for a transaction. The licensee would simply need to add a note to the comment section that states “see addendum for additional sources.” The NRC has revised the instructions for the form to explain this option. For reports made online, there will be no limit to the number of sources that can be included in a single transaction report.

Comment J.11: One commenter urged the NRC to combine the reporting required under the import/export final rule (70 FR 37985; July 1, 2005) with the reporting required under this rule. The commenter stated that it would be redundant for a licensee to notify the NRC twice of every international shipment and would add an undue and unnecessary paperwork burden.

Response: The initial deployment of the National Source Tracking System will not have the capability to allow licensees to report the notification information required by the import/export final rule. The System will provide this capability in a later deployment.

Comment J.12: One commenter stated that the NRC should expand its use of electronic systems for data reporting to include reporting required by the security orders to help reduce duplicative reporting. The commenter also advocated use of one central database for all notifications. Other commenters stated that NRC needs to perform a comprehensive review of all the various Orders and regulations that have been issued and proposed over the last two years to address any inconsistencies and duplication. One commenter stated that licensees are required to provide increased controls/security measures for the receipt, transfer and movement of sources and therefore the rule is repetitive.

Response: NRC disagrees that the rule is repetitive with the increased controls/security measures for the receipt transfer and movement of sources. The increased controls/security measures do not require transaction reporting to NRC and the NRC is not aware of any duplication in the measures and this rule. NRC is not aware of any inconsistencies related to this rulemaking and the various Orders, increased controls or security measures. The other comments are beyond the scope of this rulemaking.

Comment J.13: One commenter asked how the NRC is going to assure that all licensees enter data as required. The commenter asked what would be done if the recipient does not enter data and the initial shipper subsequently receives information that the source has decayed below the reporting threshold.

Response: Data entry for the National Source Tracking System is subject to inspection. If licensees are not reporting data as required, NRC can take enforcement action. The system

will have built-in features that will trigger an alarm for mis-matched transactions. The system will not catch situations in which both sides of the transaction have failed to report, however, these transaction should be captured and corrected during the annual reconciliation process. In addition, licensees reporting to the National Source Tracking System are subject to requirements in NRC regulations (for example, 10 CFR 30.9) that information provided to the NRC shall be complete and accurate in all material respects.

K. System Aspects

Comment K.1: One commenter suggested that the National Source Tracking System should be operated as a separate and independent system under the current Nuclear Materials Management and Safeguards System (NMMSS). The commenter stated that this would result in significantly lower costs for system development and operation, improved quality of the information, and less burden on licensees.

Response: This comment is beyond the scope of this rulemaking. This rulemaking establishes the reporting requirements for the National Source Tracking System. The actual database development and operation is not conducted though rulemaking; the NRC will obtain the system through a formal procurement process.

Comment K.2: A Federal agency requested that the NRC work jointly with it on a data sharing format to allow them and other agencies to use National Source Tracking System data. The commenter stated that agencies across the Federal government should have the opportunity to leverage the data collected by extracting other information useful to the American

public, thereby representing potential benefits to government agencies and the American public.

Response: An Interagency Coordinating Committee was formed to address these and other issues. Other agencies will be allowed access to the data on a need to know basis. NRC, in conjunction with the Interagency Coordinating Committee, will develop a procedure for handling requests for data access

Comment K.3: One commenter requested information on how the database information would be safeguarded from computer hackers. The commenter stated that if a terrorist gained access to the database, they would have access to a listing of all the large sources. Therefore, the commenter believes that a national database actually reduces national safety instead of improving it.

Response: NRC shares the commenter's concern about computer security. The National Source Tracking System will receive security accreditation before it can be used. The security information for the system will not be made publicly available.

Comment K.4: One commenter suggested that the source tracking notification system should include an automatic e-mail notification when a sender designates a specific licensee in a transfer entry as this would allow rapid identification of errors in the system at the time of transfer.

Response: The source tracking system will have some automatic notification features that will be designed to reduce errors.

Comment K.5: Three commenters noted that NRC should have interactions with the users of the system prior to the demonstration workshops that are planned. In addition, commenters stated that NRC should establish a users group composed of a cross-section of members of the affected community to develop the formats, input means, and reports that will be available through the system. The commenter stated that this will assure that the system is user-friendly while still meeting NRC's needs. One commenter stated that representatives of the industry must be part of the design team and that this will provide an opportunity to review the specifications for the system to understand how the web interface will operate and what kind of 'machine readable' data format will be used. Another commenter noted that NRC needs to pay attention to the human side of the database to avoid chaos with the data collection.

Response: NRC plans to have interactions with stakeholders during development of the format for the electronic batch files. The names of those licensees that have expressed interest in participating will be provided to NRC staff involved in system development. The NRC will consider the suggestion that industry representatives participate on the design team.

Comment K.6: One commenter stated that as written the rule would be extremely burdensome for both licensee and regulators. The commenter stated that NRC does not fully understand the undertaking of this rule. The commenter encouraged NRC to work with the industry in the implementation of the rule and the development of the web-based system.

Response: Although the rule does pose additional burden on licensees and NRC, the burden is not extreme. The source tracking system is an important national initiative that justifies the burden and is in fact required by statute (the Energy Policy Act of 2005). NRC has a clear understanding of the implications of this rule for both industry and NRC. (See also response to K.5.)

Comment K.7: One commenter suggested that NRC should be required to provide a unique tracking number for each source in the tracking system.

Response: The National Source Tracking System uses a combination of the manufacturer, model number, and manufacturer assigned serial number to identify the sources. The system will assign a unique number for each source entered in the system.

L. Miscellaneous

Comment L.1: One commenter requested clarification on whether the proposed rule covers transactions involving devices returned to the manufacturer for long term disposal.

Response: The rule covers all Category 1 and Category 2 sources in the possession of NRC licensees, regardless of whether they are being actively used or are in long term storage. The rule covers the source within the device and not the device itself.

Comment L.2: A commenter stated that they could not find the basis for the limits (thresholds) in the IAEA Code of Conduct. The commenter stated that the values seemed

random or arbitrary, specifically the limits for americium, Th-229, and Ir-192. The commenter further questioned the addition of several short-lived radionuclides (Ir-192, Se-75, and Yb-169) and stated that tracking these materials was neither prudent nor practical.

Response: As stated in the Statements of Consideration for the proposed rule, IAEA-TECDOC-1344 entitled "Categorization of Radioactive Sources" provides the underlying methodology for the development of the Code of Conduct thresholds. TECDOC-1344 is now RS-G-1.9. The categorization system is based on the potential for sources to cause deterministic effects and uses the 'D' values as normalizing factors. The 'D' values are radionuclide-specific activity levels for the purposes of emergency planning and response. The same methodology was used for all of the radionuclides.

Comment L.3: The commenter stated that regulations that focus on the transportation of Category 1 and Category 2 sources would be more appropriate.

Response: Transportation requirements are beyond the scope of this rulemaking.

Comment L.4: One commenter objected to the National Source Tracking System automatically delisting and no longer tracking sources at the point at which they decay below Category 2 levels. The commenter noted that many licensees may believe that their management responsibilities also cease when the source decays below the Category 2 threshold, which could result in more Category 3 sources ending up in the scrap or the recycling streams.

Response: Licensees are responsible for the safety and security of all radioactive material in their possession, regardless of activity level. Both NRC and the Agreement States have inspection programs to ensure that licensees operate within the bounds of their licenses. The National Source Tracking System only includes information on Category 1 and Category 2 sources. Once a source decays below the Category 2 threshold, the source is no longer a Category 2 source and the reporting requirements no longer apply. However, historical data on the source is not automatically deleted and will be retained by the system.

Comment L.5: Commenters noted that the Security Orders require notification of the end user of a shipment of a Category 2 source and verification of the arrival of the source, therefore, a mechanism is already in place that says the transition took place.

Response: It is correct that notification and verification requirements have been imposed on some licensees possessing Category 1 and/or Category 2 sources. However, the information is not reported to the NRC. Without the tracking system, the NRC would not have information on what sources a licensee actually possesses.

Comment L.6: One commenter noted that there are some differences between how other countries are implementing similar regulations. The commenter stated that the European Union has the High-Activity Sealed Source (HASS) directive, which has different quantities that need to be reported. The Commenter indicated that the NRC needs to look at this closely.

Response: From an international perspective, it may be desirable for all countries to implement regulations in a similar manner; however, the National Source Tracking System is a domestic tracking system. That said, the NRC does try to keep abreast of what other countries are doing. The European Union (EU) directive only applies to transfers within the bounds of the EU countries.

Comment L.7: One commenter noted that some of the countries from which they obtain material will not be providing them the specific serial numbers for the sources in advance. The commenter states that it will be difficult to track the material before it is in their possession.

Response: This final rule does not require licensees to report any information on sources that are imported until the sources are received at the licensee's facility. The import/export rule (70 FR 37985; July 1, 2005) does require importers to provide NRC notification of imports. The notification requirements do include the serial number of the source, if available.

Comment L.8: One commenter suggested that a possession threshold amount be established that, if exceeded, would trigger tracking requirements in order to avoid an undue burden on community medical facilities that only possess very small quantities of the lower activity sources.

Response: A threshold possession limit does not work for an item-level tracking system. Sources would move in and out of the system depending on how much a particular

licensee possessed at a site. A threshold that applies to all licensees is the appropriate method for tracking these sources and is how the National Source Tracking System will operate.

Comment L.9: Two commenters stated that aggregation should not be considered and thresholds for source tracking should be based solely upon the Category 1 and Category 2 limits for each source. The commenter noted that including sources because a licensee possesses a total number of sources that could exceed some arbitrary threshold would generate a great deal of confusion and not add to the security or control of materials. Total limits for sources in possession by licensees should be regulated by their individual licenses and not by the National Source Tracking System. Another commenter stated that clarification is needed to make it clear that the tracking system is for unique Category 1 or 2 sources and that a licensee's possession limit is not impacted by the rule.

Response: NRC agrees with these comments. The proposed rule and this final rule do not contain reporting requirements based on aggregation of sources and the NRC has no plans to include such requirements on aggregation for the tracking system in the future. A specific threshold has been established and all sources at or above the threshold must be reported, regardless of a licensee's total possession. The threshold currently is Category 2. The National Source Tracking System does not affect possession limits.

Comment L.10: Four commenters asked for clarification on decay and how decay of sources is handled as they go through the system and fall below the Category 2 threshold for tracking. Commenters requested information on how the tracking system will reconcile the

transition. One commenter stated that reclassification of a source from Category 1 to Category 2 due to decay should be recorded in the system. Three commenters stated that the system should automatically generate a notice when a source moves from a Category 1 to a Category 2 and when it decays below Category 2.

Response: Decay of sources will automatically be calculated by the system based on the reported manufacture date or reported activity date. Once a source has decayed below the Category 2 threshold, it is no longer considered a nationally tracked source. A licensee will no longer be required to report transactions involving what is now considered a Category 3 source. The source status will be automatically changed from an active source to a decayed source, and the information on that source will be retained by the system. The licensee will be automatically notified that transactions on the source no longer need to be reported because the source has decayed below the threshold. The system will reclassify a source from Category 1 to Category 2 when it has decayed below the Category 1 threshold. However, no notifications are necessary because the reporting requirements are the same for Category 1 and Category 2 sources.

Comment L.11: One commenter requested clarification on whether licensees will be required to reconstruct the inventory each year for the annual reconciliation and verification.

Response: No, the NRC does not expect licensees to conduct a physical inventory as part of the reconciliation process. The expectation is that the inventory listing in the database

will be compared to the inventory listing for the site and the licensee will either report that the database listing is correct or submit corrections as needed.

Comment L.12: Three commenters noted that the tracking system will need to accommodate data entries for sources that are imported into this country which were manufactured and exported before the rule went into effect.

Response: The reporting of the initial inventory for each licensee should account for all Category 1 and Category 2 sources in a licensee's possession. The origin of the source does not matter. NRC does not expect licensees to reconstruct a source's history. If a source is imported back to the United States, the source will be added to the system at that time.

Comment L.13: One commenter stated that source transfers (including permanent transfers) between the same company but under different licenses should not be reported.

Response: NRC disagrees with the commenter. Permanent transfers of sources do need to be reported. Transfers between temporary job sites do not need to be reported.

Comment L.14: One commenter supported the assignment of unique serial numbers. The commenter stated that assignment of unique serial numbers is critical to ensure that the sources are properly managed throughout their use and at the end of their useful life.

Response: No response is necessary.

Comment L.15: One commenter stated that NRC should clarify whether the unity rule applies to an individual source with multiple radionuclides.

Response: The unity rule does not apply to sources under the National Source Tracking System. Reporting is based on the activity level of the individual radionuclides in a source with multiple radionuclides. The sum of the fractions of each radionuclide does not need to be applied to the source.

Comment L.16: Three commenters asked for clarification on how NRC plans to handle changes in serial numbers that occur when a source is installed into a source holder. The commenters noted that sources used in the oil and gas industry have serial numbers that are assigned by the manufacturer. However, after the source is permanently installed into a protective pressure vessel, the source holder is given a different serial number consistent with the end-users nomenclature. The source is then tracked by the source holder serial number. The commenters recommended that the national source registry allow for these serial number changes in the life of a source. One of the commenters stated that NRC should be clear on the specific serial number that is tracked throughout the entire lifetime of a source.

Response: The National Source Tracking System tracks a source using the manufacturer's assigned serial number in combination with the manufacturer and model number. An optional reporting element is a device serial number. On the paper form, the device number can be added to the comment field. A licensee will be able to search (on-line) its own data by device number as well as the source number.

Comment L.17: One commenter stated that the rule should address any potential SGI conflicts when sources are shipped as part of a Radioactive Material Quantities of Concern (RAMQC) shipment.

Response: The NRC has reviewed the RAMQC requirements and has not identified any conflicts.

IV. Section by Section Analysis of Substantive Changes

§ 20.1003 Definitions.

A definition of nationally tracked sources is added to the regulations.

§ 20.2207 Reports of transactions involving nationally tracked sources.

A new section is added to the regulations to require licensees to report to the National Source Tracking System transactions involving nationally tracked sources. Paragraph (a) requires the reporting of the manufacture of a nationally tracked source. Paragraph (b) requires the reporting of all transfers of nationally tracked sources to another authorized facility. Paragraph (c) requires the reporting of all receipts of a nationally tracked source. The final rule includes a new transaction for reporting disassembly of a nationally tracked source, this new requirement is in paragraph (d). Paragraph (e) requires the reporting of the disposal of any nationally tracked source. Each of these paragraphs requires the licensee to report specific information for the transaction, including source information such as the manufacturer, model, serial number, radioactive material, activity and activity date. The licensee must also provide

the facility name, license number, name of the individual that prepared the report, and the transaction date. The final rule also requires reporting the address of the reporting licensee. If the transaction involves the use of the Uniform Low-Level Radioactive Waste Manifest, the licensee needs to report the waste manifest number and the container identification for the container with the source.

Paragraph (f) requires licensees to report these transactions to the National Source Tracking System by the close of the next business day. The regulations allow the licensee to report the transactions either on-line, electronically using a computer-readable format, by facsimile, by mail, or by telephone.

Paragraph (g) requires each licensee to correct any error in a previously filed report or file a new report for a missed transaction within 5 business days of the discovery of the error or missed transaction. Each licensee is also required to reconcile and verify the information in the National Source Tracking System during the month of January each year. This process involves comparing the inventory information contained in the National Source Tracking System to the actual inventory possessed by the licensee. The amendment requires any discrepancies to be resolved by filing the reports identified by paragraphs (a) through (e) described above. The final rule clarifies that once the reconciliation is complete, licensees must submit confirmation that the data in the National Source Tracking System is correct. The reconciliation month has been changed from June to January in the final rule.

Paragraph (h) requires a licensee to report its initial inventory of Category 1 nationally tracked sources by March 15, 2007, and the inventory of Category 2 nationally tracked sources by March 30, 2007. These dates have been changed from the proposed rule. Source information such as the manufacturer, model, serial number, radioactive material, activity and

activity date must be included. The licensee also needs to provide the facility name, license number, address, and name of the individual that prepared the report.

Appendix E Nationally Tracked Source Thresholds.

A new Appendix is added to Part 20 that provides the thresholds for nationally tracked sources at the Category 1 and Category 2 levels. Radium-226 has been added to the Appendix and Pu-236, Pu-239, and Pu-240 have been deleted from the Appendix. 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 practical usefulness only and are rounded after conversion. The curie values are not intended to be the regulatory standard.

§ 32.2 Definitions.

A definition of nationally tracked sources is added to the regulations.

§ 32.201 Serialization of nationally tracked sources.

A new section is added that requires manufacturers of nationally tracked sources to assign a unique serial number to each nationally tracked source that is manufactured after the effective date of the rule.

Part 150

The changes proposed for Part 150 are not included in the final rule. The proposed rule changes to Part 150 were intended for Agreement State licensees. With the change in basis

for the rule from promotion of the common defense and security to protection of the public health and safety, Agreement State licensees no longer come under Part 150 for the National Source Tracking System. Agreement States are required to issue legally binding requirements for their licensees. This could be done through promulgating a comparable rule, issuing orders, or adding or revising individual license conditions. The final rule is an immediate mandatory matter of compatibility. The Agreement States must issue the legally binding requirements such that the compliance dates for the final rule and the legally binding requirements are the same. This will ensure that both NRC and Agreement State licensees all begin reporting at the same time. The Agreement States will be responsible for implementation for their licensees, including inspection and enforcement.

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, 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 National Source Tracking System. The database would be maintained by NRC.

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 requires licensees that possess, manufacture, transfer, receive, disassemble, or dispose of nationally tracked sources to report the information relating to such transactions to the National Source Tracking System. This action does not constitute the establishment of a standard that contains generally applicable requirements.

VIII. Environmental Impact: Categorical Exclusion

The NRC has determined that this final rule is the type of action described as a categorical exclusion in 10 CFR 51.22(c)(3)(iii) for the changes to Parts 20 and 32. Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this final rule.

IX. Paperwork Reduction Act Statement

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

The burden to the public for these information collections is estimated to be 11,604 hours (NRC Form 748 - 421 hours [an average of 10 minutes per response] plus an annualized one-time burden of 5,333 hours [80 hours for 67 recordkeepers]; 10 CFR 20 - 467 hours [1 hour per response] plus an annualized one-time burden of 935 hours [8 hours each for 117 recordkeepers]; 10 CFR 32 - 450 hours [45 hours per recordkeeper]; 10 CFR 20 for Agreement State licensees - 1333 hours [1 hour per response] plus an annualized one-time burden of 2664 hours [8 hours each for 333 recordkeepers]0, 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 Internet electronic mail to INFOCOLLECTS@NRC.GOV; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0014 and 3150-0001), Office of Management and Budget, Washington, DC 20503.

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

The largest burden would likely fall on the manufacturers and distributors of nationally tracked sources because they will have the most transactions to report. The NRC believes that by allowing batch loading of information using a computer-readable format, the burden on the high transaction licensees is reduced. The present value of the costs of the National Source Tracking System to the NRC is estimated to be $29.4 million and to industry is estimated to be $3.9 million in 2006 dollars using a 3 percent discount rate. These estimated costs include the cost of development of the system and operation and maintenance through the year 2016.

The analysis is available for inspection in the NRC Public Document Room, 11555 Rockville Pike, Rockville, MD. Single copies of the regulatory analysis are available from Merri Horn, telephone (301) 415-8126, e-mail, mlh1@nrc.gov of the Office of Nuclear Material Safety and Safeguards.

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.

On the basis of information available to the Commission when the proposed rule was published, the Commission certified that the proposed rule, if adopted, would not have a significant impact on a substantial number of small entities. The Commission invited any small entity that determined that it is likely to bear a disproportionate economic impact because of its size to notify the Commission.

The Commission did not receive any comments on the impact to small entities. The final rule affects about 350 NRC licensees and an additional 1,000 Agreement State licensees. Examples of 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 is not expected to have a significant economic impact on these licensees.

The total time required by a licensee to complete each National Source Tracking Transaction report is estimated to be approximately 15 minutes, depending on the number of sources involved in the transaction and the method of reporting. This is time needed to complete the report. No research or compilation is necessary as all information is transcribed from bills of lading, in-house records kept for other purposes, sales agreements, etc. Each licensee would also spend on average 1 hour on the annual reconciliation. The total annual burden to perform the proposed reporting is approximately 11,604 hours. Based on the

regulatory analysis conducted for this action, the costs of the amendments for affected licensees are estimated to be $3.9 million total or on average about $2,889 per affected licensee. The NRC believes that the selected alternative reflected in the amendment is the least burdensome, most flexible alternative that would accomplish the NRC's regulatory objective.

XII. Backfit Analysis

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

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 Subjects

10 CFR Part 20

Byproduct material, Criminal penalties, Licensed material, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Packaging and containers,

Radiation protection, Reporting and recordkeeping requirements, Source material, Special nuclear material, Waste treatment and disposal.

10 CFR Part 32

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

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 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 is revised 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), Energy Policy Act of 2005, Pub. L. No. 109-58, 119 Stat. 594 (2005).

2. In § 20.1003, a new definition *Nationally tracked source* is added in alphabetical order to read as follows:

§ 20.1003 Definitions.

* * * * *

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

* * * * *

3. In § 20.1009 paragraph (b) is revised and paragraph (c)(6) is added to read as follows:

§20.1009 Information collection requirements: OMB approval.

* * * * *

(b) The approved information collection requirements contained in this part appear in §§ 20.1003, 20.1101, 20.1202, 20.1203, 20.1204, 20.1206, 20.1208, 20.1301, 20.1302, 20.1403, 20.1404, 20.1406, 20.1501, 20.1601, 20.1703, 20.1901, 20.1904, 20.1905, 20.1906, 20.2002, 20.2004, 20.2005, 20.2006, 20.2102, 20.2103, 20.2104, 20.2105, 20.2106, 20.2107, 20.2108,

20.2110, 20.2201, 20.2202, 20.2203, 20.2204, 20.2205, 20.2206, 20.2207, 20.2301, and appendix G to this part.

(c) * * *

(6) In § 20.2207, NRC Form 748 is approved under control number 3150-xxxx.

4. Section 20.2207 is added under Subpart M to read as follows:

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

Each licensee who manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report (NRC Form 748) as specified in paragraphs (a) through (e) of this section for each type of transaction.

(a) Each licensee who manufactures a nationally tracked source shall complete and submit a National Source Tracking Transaction Report (NRC Form 748). The report must include the following information:

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

(2) The name of the individual preparing the report;

(3) The manufacturer, model, and serial number of the source;

(4) The radioactive material in the source;

(5) The initial source strength in becquerels (curies) at the time of manufacture; and

(6) The manufacture date of the source.

(b) Each licensee that transfers a nationally tracked source to another person shall complete and submit a National Source Tracking Transaction Report (NRC Form 748). The report must include the following information:

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

(2) The name of the individual preparing the report;

(3) The name and license number of the recipient facility and the shipping address;

(4) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

(5) The radioactive material in the source;

(6) The initial or current source strength in becquerels (curies);

(7) The date for which the source strength is reported;

(8) The shipping date;

(9) The estimated arrival date; and

(10) For nationally tracked sources transferred as waste under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification of the container with the nationally tracked source.

(c) Each licensee that receives a nationally tracked source shall complete and submit a National Source Tracking Transaction Report (NRC Form 748). The report must include the following information:

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

(2) The name of the individual preparing the report;

(3) The name, address, and license number of the person that provided the source;

(4) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

(5) The radioactive material in the source;

(6) The initial or current source strength in becquerels (curies);

(7) The date for which the source strength is reported;

(8) The date of receipt; and

(9) For material received under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification with the nationally tracked source.

(d) Each licensee that disassembles a nationally tracked source shall complete and submit a National Source Tracking Transaction Report (NRC Form 748). The report must include the following information:

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

(2) The name of the individual preparing the report;

(3) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

(4) The radioactive material in the source;

(5) The initial or current source strength in becquerels (curies);

(6) The date for which the source strength is reported;

(7) The disassemble date of the source.

(e) Each licensee who disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report (NRC Form 748). The report must include the following information:

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

(2) The name of the individual preparing the report;

(3) The waste manifest number;

(4) The container identification with the nationally tracked source.

(5) The date of disposal; and

(6) The method of disposal.

(f) The reports discussed in paragraphs (a) through (e) of this section must be submitted by the close of the next business day after the transaction. A single report may be submitted for multiple sources and transactions. The reports must be submitted to the National Source Tracking System by using:

(1) The on-line National Source Tracking System;

(2) Electronically using a computer-readable format;

(3) By facsimile;

(4) By mail to the address on the National Source Tracking Transaction Report Form (NRC Form 748); or

(5) By telephone with followup by facsimile or mail.

(g) Each licensee shall correct any error in previously filed reports or file a new report for any missed transaction within 5 business days of the discovery of the error or missed transaction. Each licensee shall reconcile the inventory of nationally tracked sources possessed by the licensee against that licensee's data in the National Source Tracking System. The reconciliation must be conducted during the month of January in each year. The reconciliation process must include resolving any discrepancies between the National Source Tracking System and the actual inventory by filing the reports identified by paragraphs (a) through (e) of this section. By January 31 of each year, each licensee must submit to the National Source Tracking System confirmation that the data in the National Source Tracking System is correct.

(h) Each licensee that possesses Category 1 nationally tracked sources shall report its initial inventory of Category 1 nationally tracked sources to the National Source Tracking System by March 15, 2007. Each licensee that possesses Category 2 nationally tracked sources shall report its initial inventory of Category 2 nationally tracked sources to the National Source Tracking System by March 30, 2007. The information may be submitted by using any of the methods identified by paragraph (f)(1) through (f)(4) of this section. The initial inventory report must include the following information:

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

(2) The name of the individual preparing the report;

(3) The manufacturer, model, and serial number of each nationally tracked source or, if not available, other information to uniquely identify the source;

(4) The radioactive material in the sealed source;

(5) The initial or current source strength in becquerels (curies); and

(6) The date for which the source strength is reported.

5. In Part 20, new Appendix E is added to read as follows:

APPENDIX E TO PART 20 - NATIONALLY TRACKED SOURCE THRESHOLDS

The Terabecquerel (TBq) values are the regulatory standard. The curie (Ci) values specified are obtained by converting from the TBq value. The curie values are provided for practical usefulness only and are rounded after conversion.

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

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

6. The authority citation for Part 32 is revised 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), Energy Policy Act of 2005, Pub. L. No. 109-58, 119 Stat. 594 (2005).

7. In § 32.2, the paragraph designations are removed and a new definition *Nationally tracked source* is added in alphabetical order to read as follows:

***§* 32.2 Definitions**.

* * * * *

Nationally tracked source is a sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels 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 sealed in a capsule or closely bonded, in a solid form and which is not exempt from regulatory control. It does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet. Category 1 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 1 threshold. Category 2 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 2 threshold but less than the Category 1 threshold.

8. In § 32.8, paragraph (b) is revised to read as follows:

§ 32.8 Information collection requirements: OMB approval.

* * * * *

(b) The approved information collection requirements contained in this part appear in §§ 32.11, 32.12, 32.14, 32.15, 32.16, 32.17, 32.18, 32.19, 32.20, 32.21, 32.21a, 32.22, 32.23, 32.25, 32.26, 32.27, 32.29, 32.51, 32.51a, 32.52, 32.53, 32.54, 32.55, 32.56, 32.57, 32.58, 32.61, 32.62, 32.71, 32.72, 32.74, 32.201, and 32.210.

* * * * *

9. Section 32.201 is added under Subpart D to read as follows:

Subpart D--Specifically Licensed Items

§ 32.201 Serialization of nationally tracked sources.

Each licensee who manufactures a nationally tracked source after **[INSERT DATE 90 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]** shall assign a unique serial

number to each nationally tracked source. Serial numbers must be composed only of alpha-numeric characters.

Dated at Rockville, Maryland, this_____ day of_____, 2006.

For the Nuclear Regulatory Commission.

_____
Annette Vietti Cook
Secretary of the Commission.

Regulatory Analysis for the Final Rule on National Source Tracking of Sealed Sources - 10 CFR Parts 20 and 32

U.S. Nuclear Regulatory Commission
Office of Nuclear Material Safety and Safeguards

March 10, 2006

EXECUTIVE SUMMARY

The U.S. Nuclear Regulatory Commission (NRC) is amending its regulations to implement a new program called the National Source Tracking System. Under this program, licensees will be required to report information on the manufacture, transfer, receipt, disassembly, and disposal of nationally tracked sources. This information will be used to support the National Source Tracking System and will provide NRC with a life cycle account for nationally tracked sources and, thus, improve accountability and controls over them.

This regulatory analysis evaluates the values and impacts associated with the two regulatory alternatives considered by NRC to address the tracking of sealed sources:

- *Option 1: No Action*. The no-action alternative is the baseline for this analysis. Because the Energy Policy Act of 2005 requires NRC to issue regulations for a source tracking system, the no action alternative in not a viable option.

- *Option 2: National Source Tracking System*. Under the National Source Tracking System alternative, NRC would establish the National Source Tracking System. Under this program, each licensee who manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source would be required to: (1) report its initial inventory of Category 1 and/or 2 nationally tracked sources; (2) complete and submit a National Source Tracking Transaction Report after each transaction; (3) correct any errors in previously filed National Source Tracking Transaction Reports within five business days of the discovery; and (4) reconcile and verify its inventory of nationally tracked sources on an annual basis. In addition, licensees who manufacture nationally tracked sources after the effective date of the rule would be required to assign a unique serial number to each nationally tracked source.

The primary function of Option 1 is to establish the baseline condition from which the incremental values and impacts associated with the National Source Tracking System are calculated.

NRC estimated the incremental costs to industry and NRC under Option 2. These costs were estimated for the years 2006 through 2016. All costs incurred in the future were calculated in 2006 dollars using discount rates of 7 and 3 percent. The results are presented in Table ES-1.

Table ES-1
Present Value of the Total Costs Under Option 2,
the National Source Tracking System Alternative: 2006 - 2016 [a]
(2006 dollars)

Discount Rate	Costs to Industry	Cost to Agreement States	Costs to NRC	Total Costs
7%	$3,600,000	$700,000	$25,100,000	$29,300,000
3%	$3,900,000	$800,000	$29,300,000	$34,000,000

[a] Table includes rounding error.

As shown in Table ES-1, the net present value under Option 2, using a 7 percent discount rate, is estimated to be a total cost of $29,300,000. Using a 3 percent discount rate, the net present value is estimated to be a total cost of $34,000,000.

NRC staff believes that the expected qualitative values contribute substantially to the benefits of the National Source Tracking System. These qualitative values include:

- *Improved Accountability and Control for Nationally Tracked Sources.* The National Source Tracking System is expected to result in improved accountability and control over nationally tracked sources. This is expected to improve public health (accident/event) and avert potential offsite property damage and costs by decreasing the risk of a security-related event involving nationally tracked sources.

- *Improved Understanding of the Location of Nationally Tracked Sources.* Information contained in the National Source Tracking System would improve the information available to NRC, as well as other government entities (e.g., Department of Homeland Security, Agreement States), concerning the locations of nationally tracked sources.

- *Improved Regulatory Efficiency.* The establishment of a national program to monitor the location of nationally tracked sources would improve regulatory efficiency by: (1) increasing accountability among all parties associated with a nationally tracked source transaction and (2) responding to a recommendation in the IAEA's Code of Conduct.

- *Enhanced Ability to Promote and Maintain the Common Defense and Security*. Information contained in the National Source Tracking System would allow NRC to better monitor the location of nationally tracked sources and, thus, improve accountability and controls over them. Consequently, the National Source Tracking System would enhance NRC's ability to maintain and promote the common defense and security.

- *Increased Public Confidence.* Information contained in the National Source Tracking System would allow NRC to better monitor the location of nationally tracked sources. This is expected to result in increased public confidence in NRC's regulation of inventories of radioactive materials that could be used in the production of radiological dispersal devices (RDDs) and radiological exposure devices (REDs).

The Energy Policy Act of 2005 requires NRC to promulgate regulations establishing a national source tracking system by August 8, 2006. In addition, NRC believes that the incremental costs to licensees and NRC under Option 2 are justified because the requested actions and information are necessary to monitor the location of nationally tracked sources.

TABLE OF CONTENTS

1. Introduction

The U.S. Nuclear Regulatory Commission (NRC) is amending its regulations to implement a new program called the National Source Tracking System. Under this program, licensees will be required to report information on the manufacture, transfer, receipt, disassembly, and disposal of nationally tracked sources. This information will be used to support the National Source Tracking System and will provide NRC with a life cycle account for nationally tracked sources and, thus, improve accountability and controls over them.

The purpose of this regulatory analysis is to evaluate the values and impacts associated with the National Source Tracking system. NRC considers the regulatory analysis process an integral part of its statutory mission to promote the common defense and security, to ensure adequate protection of public health and safety, and to protect the environment from civilian uses of byproduct, source, and special nuclear materials. This document presents background material, describes the objectives of the regulatory action, and evaluates the values and impacts of the regulatory alternatives.

1.1 Background

As a result of the terrorist attacks in the U.S. on September 11, 2001, NRC has undertaken a comprehensive review of nuclear material security requirements, with particular focus on radioactive material of concern. This radioactive material, including Cobalt-60, Cesium-137, Iridium-192, and Americium-24, has the potential to be used in a radiological dispersal device (RDD) or a radiological exposure device (RED) in the absence of proper security measures. NRC's review takes into consideration the changing domestic and international threat environments and related U.S. Government supported international initiatives in the nuclear security area, particularly activities conducted by the International Atomic Energy Agency (IAEA).

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

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

The U.S. Government has formally notified the Director General of the IAEA of its political commitment for the current Code of Conduct. Although the Code of Conduct does not have the stature of an international treaty, and its provisions are non-binding on IAEA member States, the U.S. Government has endorsed the Code of Conduct and is working toward implementation of its various provisions. The Commission is conducting this rulemaking to reflect those Code of Conduct recommendations that are consistent with NRC's responsibilities under the Atomic Energy Act.

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

Efforts to improve controls over sealed sources face significant challenges, especially with regard to the need to secure the materials without discouraging their beneficial use in academic, medical, and industrial applications. Radioactive materials provide critical capabilities in the oil and gas, electrical power, construction, and food industries; are used to treat millions of patients each year in diagnostic and therapeutic procedures; are used in a variety of military applications; and are used in technology research and development involving academic, government, and private institutions. These materials are as diverse in geographical location as they are in functional use.

National source tracking is part of a comprehensive radioactive source control program for radioactive materials of greatest concern. Although neither a national source tracking system nor a source registry can ensure the physical protection of sources, they will provide greater source accountability. Thus, NRC believes that a national source tracking system, in conjunction with other activities, should result in improved security for radioactive sources. It is also required by the Energy Policy Act of 2005.

1.2 Objectives of the Regulatory Action

There is broad U.S. Government and international interest in tracking radioactive sources to improve accountability and control. Currently, there is no single U.S. source of information to verify the licensed users, locations, and quantities of these materials. Separate NRC and Agreement State systems contain information on licensees and the maximum amounts of materials they are authorized to possess but do not record actual sources.

To address this lack of information on actual material possessed, NRC, with the cooperation of the Agreement States, began working on an interim database of risk-significant sources (Category 1 and Category 2). In November 2003, both NRC and Agreement State licensees were contacted and requested to provide some basic information on the sealed sources located at their facilities. Of the approximately 2,600 licensees contacted, over half of the licensees reported possessing Category 1 or Category 2 sealed sources. The interim database was updated in 2005 and is being updated for 2006. NRC plans to replace the interim database with the National Source Tracking System. While the interim database provides a snapshot in time, the National Source Tracking System is expected to provide information on an ongoing basis.

Development of the National Source Tracking System includes information technology (IT) development and maintenance activities. When completely operational, the National Source Tracking System will be a web-based system that will allow licensees to meet the reporting requirements on-line with ease. This rulemaking establishes the regulatory foundation for the National Source Tracking System.

To inform the development of the National Source Tracking System, NRC established an Interagency Coordinating Committee to provide guidance regarding interagency issues associated with the development, coordination, and implementation of the system. The Committee membership consists of representatives from various Federal agencies with an interest in source security and a representative from the Agreement States. The views of the Committee were included in the development of the requirements for the National Source Tracking System and this rulemaking.

2. Identification and Preliminary Analysis of Alternative Approaches

This regulatory analysis evaluates the values and impacts of complying with the Energy Policy Act of 2005 with regard to the establishment of a source tracking system.

2.1 Option 1: No Action

Option 1 is the baseline for this analysis. Because the Energy Policy Act of 2005 requires NRC to issue regulations for a source tracking system, the no action alternative in not a viable option.

2.2 Option 2: National Source Tracking System

Under Option 2, NRC would establish the National Source Tracking System. The final rule implements current United States policy for a National Source Tracking System for Category 1 and Category 2 sources. Under this program, each licensee who manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source would be required to:

- Report its initial inventory of Category 1 nationally tracked sources to the National Source Tracking System by March 15, 2007.

- Report its initial inventory of Category 2 nationally tracked sources to the National Source Tracking System by March 30, 2007

- Complete and submit a National Source Tracking Transaction Report (i.e., NRC Form 748) after each transaction

- Correct any errors in previously filed National Source Tracking Transaction Reports within five business days of the discovery

- Reconcile and verify the inventory of nationally tracked sources it possesses against the data in the National Source Tracking System on an annual basis

In addition, each licensee who manufactures a nationally tracked source after the effective date of the rule would be required to assign a unique serial number to each nationally tracked source.

NRC considered the inclusion of Category 3 sources in the National Source Tracking System. However, at the time of the proposed rule neither the Interagency Coordinating Committee, Steering Committee or Working Group recommended their inclusion. The proposed rule invited specific comment on the inclusion of Category 3 sources and sought information on the burden to licensees. The information was sought so an informed decision on the inclusion of Category 3 sources could be made at a later date. NRC does not have adequate information on the number of sources and the number of impacted licensees. If Category 3 sources were included in the National Source Tracking System, for consistency of treatment would they also need to be included in the import/export provisions and other security related requirements that rely on the Category 1 and Category 2 thresholds? Many Category 3 sources are possessed under general license; questions related to this also need to be addressed before a final decision is made. Additionally, the Category 3 sources do not pose the same risk as Category 1 and Category 2 sources. The Energy Policy Act of 2005 requires the formation of the interagency Radiation Source Protection and Security Task Force. This Task Force will be evaluating, among other things, whether modifications to the source tracking system should be made. The Interagency Coordinating Committee will also continue to look at the National Source Tracking System.

3. Analysis of Values and Impacts

The three subsections below describe the analysis conducted to identify and evaluate the values and impacts expected to result from the implementation of the National Source Tracking System. Subsection 3.1 identifies the attributes that the National Source Tracking System is expected to affect. Subsection 3.2 describes the methodology used to analyze the values and impacts associated with the National Source Tracking System. Subsection 3.3 discusses the results of the analysis.

3.1 Identification of Affected Attributes

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

Source Tracking System is presented below.

The National Source Tracking System is expected to affect the following attributes:

- *Public Health (Accident/Event)*. The National Source Tracking System will require licensees to report information on the manufacture, transfer, receipt, and disposal of nationally tracked sources. This information provides a life cycle account for these sources. As a result, the regulatory action is expected to improve accountability and controls over them. This reduces the risk that terrorists may obtain and use radioactive materials in the production of RDDs and REDs and, therefore, has a positive effect on public health.

- *Offsite Property*. As stated above, licensees will be required to provide a life cycle account for nationally tracked sources. Improvement in the accountability and controls over these sources is expected to avert potential offsite property damage and costs (e.g., long-term relocation, emergency response) that may follow from a terrorist attack in which RDDs and/or REDs are used.

- *Industry Implementation*. The regulatory action will require licensees to report their initial inventory of Category 1 and 2 nationally tracked sources to the National Source Tracking System. Licensees who reported nationally tracked source information to the interim database will only need to verify or update their reported inventory information. Licensees who did not provide nationally tracked source information to the interim database will need to report their inventory information by the specified dates. As a result, licensees (i.e., industry) will incur one-time implementation costs under the regulatory action.

- *Industry Operation*. The regulatory action will require licensees to: (1) complete and submit a National Source Tracking Transaction Report after each transaction; (2) correct any errors in previously filed National Source Tracking Transaction Reports within five business days of the discovery; (3) reconcile and verify the inventories of nationally tracked sources they possess against the data in the National Source Tracking System on an annual basis; and (4) assign a unique serial number to each nationally tracked source they manufacture (if applicable). As a result, licensees (i.e., industry) will incur annual operating costs under the regulatory action.

- *NRC Implementation*. To implement the regulatory action, NRC will conduct IT development activities. Specifically, NRC will arrange to develop a web-based National Source Tracking System, as well as guidance on how to report information on nationally tracked source transactions to the National Source Tracking System.[1] NRC will also conduct training workshops. As a result, NRC will incur one-time implementation costs under the regulatory action.

- *NRC Operation*. Under the regulatory action, NRC staff will review nationally tracked source information submitted to the National Source Tracking System and arrange for

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

- operation and maintenance activities on the web-based National Source Tracking System. NRC will also conduct inspections related to the system. As a result, NRC will incur annual operating costs under the regulatory action.

- *Other Government*. Under the regulatory action, other Federal agencies and State and local governments (e.g., Department of Homeland Security, Agreement States) will have access to and benefit from the information contained in the National Source Tracking System. This information may allow them to better monitor the location of nationally tracked sources and focus resources on higher risk licensees (e.g., based on the number of nationally tracked sources they possess). In addition, the information contained in the National Source Tracking System should improve coordination among the various agencies.

- *Improvements in Knowledge*. The regulatory action will require licensees to report information on the manufacture, transfer, receipt, disassembly, and disposal of nationally tracked sources. This information will allow NRC to better know the location of nationally tracked sources.

- *Regulatory Efficiency*. The regulatory action will improve regulatory efficiency by establishing a national source tracking program to monitor the location of nationally tracked sources. Consequently, there should be increased accountability among all parties associated with a nationally tracked source transaction. In addition, the regulatory action would improve regulatory efficiency by implementing applicable features of the IAEA's Code of Conduct.

- *Safeguards and Security Considerations*. The regulatory action will require licensees to provide a life cycle account for nationally tracked sources. This information will allow NRC to better monitor the location of nationally tracked sources and thus, improve accountability and controls over them. Consequently, the regulatory action will enhance NRC's ability to maintain and promote the common defense and security.

- *Other Considerations*. The regulatory action will require licensees to provide a life cycle account for nationally tracked sources. This information will allow NRC to better monitor the location of nationally tracked sources. As a result, the regulatory action may increase public confidence in NRC's regulation of inventories of radioactive materials that could be used in the production of RDDs and REDs.

The National Source Tracking System is *not* expected to affect the following attributes:

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

3.2 Methodology

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

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

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

3.2.1 Baseline for Analysis

The analysis measures the incremental values and impacts of the implementation and operation of the National Source Tracking System relative to a baseline (Option 1, the no-action alternative), which is how the world would be in the absence of the National Source Tracking System.

3.2.2 Assumptions

The following subsections discuss the assumptions used in the analysis.

3.2.2.1 Number of Licensees that Possess Nationally Tracked Sources

Based on data from NRC's interim database of nationally tracked sources and NRC staff's best judgment, NRC estimates that there will be 1,350 licensees that may possess Category 1 and/or 2 nationally tracked sources. Of the 1,350 licensees, 350 are assumed to be NRC licensees and 1,000 are assumed to be Agreement State licensees. These values provide an upper bound for cost estimates, the actual numbers are expected to be lower. .

3.2.2.2 Number of Nationally Tracked Sources

Based on data in NRC's interim database of nationally tracked sources and NRC staff's best judgment, NRC estimates that, collectively, licensees possess approximately 75,000 Category 1 and/or 2 nationally tracked sources. The interim database contains information on about 3,600 of these sources[2].

3.2.2.3 Method of Submitting National Source Tracking Transaction Reports

[2] In providing nationally tracked source information for the interim database, licensees were allowed to treat irradiators and gamma knives as a single source to encourage reporting of some data. Each gamma knife actually has 201 individual sources and each irradiator has from a few sources to over 1,500 individual sources.

Based on best judgment, NRC anticipates that, of the 1,350 licenses with nationally tracked sources, about 75 percent (1,015 licensees) would report nationally tracked source transaction information using on-line forms, about 15 percent (200 licensees) using computer-readable format files, about 4.75 percent (64 licensees) by fax, about 4.75 percent (64 licensees) by mail, and about 0.5 percent (7 licensees) by telephone with followup by fax or mail. These assumptions are reflected in Table 1.

Table 1
Estimated Number of Licensees that Possess Nationally Tracked Sources, by Report Submission Method

Submission Method	Total Number of Licensees
On-line forms	1,015
Computer-readable format file	200
Fax	64
Mail	64
Telephone with followup by fax or mail	7
Total	1,350

3.2.2.4 Number of National Source Tracking Transaction Reports

Based on data in NRC's interim database of nationally tracked sources and NRC staff's best judgment, NRC estimates that, each year, licensees perform up to 73,050 nationally tracked source "transactions." NRC estimates that, of these 73,050 transactions, 15,000 are associated with the manufacture of new nationally tracked sources, 24,000 with the transfer of nationally tracked sources, 24,000 with the receipt of nationally tracked sources, 10,000 with the disassembly of nationally tracked sources, and 50 with the disposal of nationally tracked sources. These numbers are based on the assumption that gamma knife sources are replaced every five years, radiography sources are replaced every four months, and one tenth of the irradiator sources are exchanged every year. These assumptions are reflected in Table 2.

Table 2
Estimated Annual Number of Nationally Tracked Source Transactions

Type of Transaction	Number of Transactions
Manufacture	15,000
Transfer	24,000
Receipt	24,000
Disassemble	10,000
Disposal	50
Total	73,050

For each of the 73,050 transactions identified in Table 2, licensees would be required to complete and submit a National Source Tracking Transaction Report using on-line forms, computer-readable format files, fax, mail, or telephone with followup by fax or mail. NRC is uncertain about the number of National Source Tracking Transaction Reports that will be submitted each year for each type of transaction and submission method (e.g., manufacture/on-line forms, manufacture/fax). However, NRC anticipates that the majority of the reports will be submitted by manufacturers and distributors. These entities are expected to report their transaction information electronically using computer-readable format files, given the large volume of transactions they perform. For purposes of this analysis, NRC made the following simplifying assumptions:

- Manufacture:
  - -- Each year, licensees perform 15,000 transactions associated with the manufacture of new nationally tracked sources
  - -- All reports associated with the manufacture of new nationally tracked sources will be submitted using computer-readable format files
  - -- Each report will contain information on 100 transactions

- Transfer and receipt:
  - -- Each year, licensees perform 48,000 transactions associated with the transfer and receipt of nationally tracked sources
  - -- Reports associated with the transfer and receipt of nationally tracked sources will be submitted as follows:
    - 5,288 using on-line forms
    - 42,000 using computer-readable format files
    - 338 by fax
    - 338 by mail
    - 36 by telephone with followup by fax or mail
  - -- Each report submitted using computer-readable format files will contain information on 100 transactions; reports submitted using any other method will contain information on three transactions
  - -- The number of transfer reports equals the number of receipt reports

- Disassemble:
  - -- Each year, licensees perform 10,000 transactions associated with the disassembly of nationally tracked sources
  - -- All reports associated with the disassembly of nationally tracked sources will be submitted using computer-readable format files
  - -- Each report will contain information on 100 transactions

- Disposal:
  - -- Each year, licensees perform 50 transactions associated with the disposal of nationally tracked sources
  - -- All reports associated with the disposal of nationally tracked sources will be submitted using on-line forms
  - -- Each report will contain information on three transactions

These assumptions are reflected in Table 3.

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

Type of Transaction	Submission Method					Total
	On-Line Forms	Computer-Readable Format File	Fax	Mail	Telephone with Followup by Fax or Mail	
Manufacture	0	150	0	0	0	150
Transfer	882	210	56	56	6	1,210
Receipt	882	210	56	56	6	1,210
Disassemble	0	100	0	0	0	100
Disposal	17	0	0	0	0	17
Total	1,781	670	112	112	12	2,687

3.2.3 Analysis

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

- IT development/maintenance activities
- National Source Tracking System account set-up
- Initial inventory of nationally tracked sources
- National Source Tracking Transaction Reports
- Correction of previously filed National Source Tracking Transaction Reports
- Annual inventory reconciliation of nationally tracked sources
- Nationally tracked source unique serial numbers

The cost assumptions for each of the above impact categories are discussed in the following subsections. Note that all costs presented in this subsection are in 2006 dollars.

3.2.3.1 IT Development/Maintenance Activities

In implementing the regulatory action, NRC expects to perform IT development/maintenance activities. Among other things, these activities include development of the final rule, guidance documents, and licensee training; development, enhancement, and maintenance and operation of the web-based National Source Tracking System.

NRC estimates that, between 2006 and 2008, NRC will incur $11,700,000 to develop the National Source Tracking System. This value represents both NRC staff and contractor time and effort. NRC anticipates that, of this $11,700,000, $3,300,000 will be incurred in Fiscal Year (FY) 2006, and $4,300,000 in FY 2007 and $4,100,000 in FY 2008.[3] Once the system is developed, NRC estimates that approximately $2,700,000 a year will be expended for the maintenance and operation of the system, beginning in FY 2009.[4] This includes NRC and contractor effort.

3.2.3.2 National Source Tracking System Account Set-Up

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

NRC estimates that, on average, 0.5 hour (30 minutes) of licensee staff time will be required to establish an account with the National Source Tracking System. Using an estimated average labor rate of $87 per hour for licensee staff[5], the cost for establishing an account is estimated to be $43.50 per licensee (i.e., 0.5 hour x $87/hour). As shown in Table 1, NRC anticipates that, of the 1,350 licensees with nationally tracked sources, 1,215 (i.e., 1,015 + 200) would report transaction information electronically using on-line forms or computer-readable format files. Thus, industry's total cost for establishing accounts with the National Source Tracking System is estimated to be $52,853 (i.e., 1,215 licensees x $43.50/licensee).

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

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[3] FY 2006 covers the period between October 1, 2005 and September 30, 2006. FY 2007 covers the period between October 1, 2006 and September 30, 2007. FY 2008 covers the period between October 1, 2007 and September 30, 2008.

[4] FY 2009 covers the period between October 1, 2008 and September 30, 2009.

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

with the National Source Tracking System in 2007.

In addition, to account set-up, licensees planning to use the computer-readable format files will also expend some programing effort to establish the ability to report using this method. Some programing will be necessary to collect the information from current computer files. NRC estimates that, on average, 80 hours of licensee staff time will be required to conduct the necessary programming. Using an estimated average labor rate of $87 per hour for licensee staff, the cost of programing is estimated to be $6960 per licensee (i.e., 80 hours x $87/hour). As shown in Table 1, NRC estimates that 200 licensees will report transaction information electronically using computer-readable format files. Thus, industry's total programming cost is estimated to be $1,392,000 (i.e., 200 licensees x $6960/licensee). It is assumed that this effort would occur in 2007.

Licensees may also expend some effort on training. NRC will be sponsoring workshops for licensees and will also offer training via an on-line demonstration of the system. Each licensee is assumed to expend 4 hours per person to conduct the training and to train 2 individuals in use of the system. Using an average labor rate of $87 per hour for licensee staff, the cost of training is estimated to be $696 per licensee (i.e., 8 hours x $87/hour). Thus, industry's total training cost is estimated to be $939,600 (i.e., 1350 licensees x $696 per licensee). It is assumed that this effort would occur in 2007.

3.2.3.3 Initial Inventory of Nationally Tracked Sources

Under existing regulations, licensees are required to conduct an inventory of their sealed sources. The regulatory action will require licensees to report their initial inventory of Category 1 and 2 nationally tracked sources to the National Source Tracking System. Licensees that reported nationally tracked source information to the interim database will only need to verify or update their inventory information. Licensees that did not provide nationally tracked source information to the interim database will need to report their initial inventory of Category 1 nationally tracked sources to the National Source Tracking System by March 15, 2007, and their initial inventory of Category 2 nationally tracked sources by March 30, 2007.

NRC estimates that licensees will require, on average, 0.50 hour (30 minutes) to verify/update or report initial inventory information on their nationally tracked sources.[6] Using an estimated average labor rate of $87 per hour for licensee staff, the labor cost for verifying/updating or initially reporting this information is estimated to be $43.50 per licensee (i.e., 0.50 hour x $87/hour). As shown in Table 1, NRC estimates that 1,350 licensees will verify/update or initially report inventory information for nationally tracked sources. Thus, the labor cost to licensees is estimated to be $58,725 (i.e., 1,350 licensees x $43.50/licensee).

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

- *On-Line Forms and Computer-Readable Format Files.* NRC considers Internet access

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

to be a standard business practice. Therefore, for purposes of this analysis, the cost associated with the purchase of Internet access services is not considered an incremental cost to licensees.

- *Fax.* NRC estimates that each of the 64 licensees submitting information by fax (see Table 1) will incur a materials cost of $0.15 for faxing the information to the National Source Tracking System.[7] Thus, the materials cost to licensees submitting information by fax is estimated to be $9.60 (i.e., 64 licensees x $0.15/licensee).

- *Mail.* NRC estimates that each of the 64 licensees submitting information by mail (see Table 1) will incur a materials cost of $3.64 for mailing the information to the National Source Tracking System.[8] Thus, the materials cost to licensees submitting information by mail is estimated to be $232.96 (i.e., 64 licensees x $3.64/licensee).

- *Telephone with Followup by Fax or Mail.* NRC estimates that each of the seven licensees submitting information by telephone with followup by fax or mail will incur a materials cost of $4.16 for making a telephone call and mailing the information to the National Source Tracking System.[9] Thus, the materials cost to licensees submitting information by telephone with followup by fax or mail is estimated to be $29.12 (i.e., 7 licensees x $4.16/licensee).

Based on the above, the materials cost to licensees is estimated to be $271.68 (i.e., $0 + $9.60 + $232.96 + $29.12).

In summary, NRC estimates that industry's total one-time cost for verifying/updating or initially reporting nationally tracked source inventory information would be $58,997 (i.e., $58,725 + $271.68). For purposes of this analysis, NRC assumes that all of this *one-time* industry implementation cost will be incurred in 2007.

3.2.3.4 National Source Tracking Transaction Reports

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

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

- *Reports Submitted Using On-Line Forms*. NRC estimates that, on average, 10 minutes of licensee staff time will be required to complete and submit a National Source

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[7] Based on the cost of a two-minute State-to-State telephone call.

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

[9] Includes a cost of $0.52 for making a seven-minute State-to-State telephone call and a cost of $3.64 for mailing the inventory information to the National Source Tracking System.

Tracking Transaction Report on-line. Using an estimated average labor rate of $87 per hour for licensee staff, the cost for conducting these activities is estimated to be $14.50 per report (i.e., [10 minutes/60 minutes] x $87/hour).[10]

As shown in Table 3, NRC estimates that licensees will complete and submit 1,781 reports on-line each year. Thus, the industry's total annual cost for completing and submitting National Source Tracking Transaction Reports on-line is estimated to be $25,825 (i.e., 1,781 reports x $14.50/report).

- *Reports Submitted Using a Computer-Readable Format File*. NRC estimates that, on average, five minutes of licensee staff time will be required to complete and submit a National Source Tracking Transaction Report electronically using a computer-readable format file. Using an estimated average labor rate of $87 per hour for licensee staff, the cost for conducting these activities is estimated to be $7.25 per report (i.e., [5 minutes/60 minutes] x $87/hour).[11]

  As shown in Table 3, NRC estimates that, each year, licensees would complete and submit 670 reports using computer-readable format files. Thus, the industry's total annual cost for completing and submitting National Source Tracking Transaction Reports electronically using computer-readable format files is estimated to be $4,858 (i.e., 670 reports x $7.25/report).

- *Reports Submitted by Fax*. NRC estimates that, on average, 0.25 hour (15 minutes) of licensee staff time will be required to complete and submit a National Source Tracking Transaction Report by fax. Using an estimated average labor rate of $87 per hour for licensee staff, the labor cost for conducting these activities is estimated to be $21.75 (i.e., 0.25 hours x $87/hour). In addition, NRC estimates that, on average, licensees would incur a materials cost of $0.15 for each report they fax to the National Source Tracking System.[12] Thus, the total cost for completing and submitting a report is estimated to be $21.90 (i.e., $21.75 + $0.15).

  NRC further estimates that, each year, licensees will complete and submit 112 reports by fax. Thus, the industry's total annual cost for completing and submitting National Source Tracking Transaction Reports by fax is estimated to be $2,453 (i.e., 112 reports x $21.90/report).

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[10] NRC considers Internet access to be a standard business practice. Therefore, for purposes of this analysis, the cost associated with the purchase of Internet access services is not considered an incremental cost to licensees.

[11] NRC considers Internet access to be a standard business practice. Therefore, for purposes of this analysis, the cost associated with the purchase of Internet access services is not considered an incremental cost to licensees.

[12] Based on the cost of a two-minute State-to-State telephone call.

- *Reports Submitted by Mail*. NRC estimates that, on average, 0.25 hour (15 minutes) of licensee staff time will be required to complete and submit a National Source Tracking Transaction Report by mail. Using an estimated average labor rate of $87 per hour for licensee staff, the labor cost for conducting these activities is estimated to be $21.75 (i.e., 0.25 hours x $87/hour). In addition, NRC estimates that, on average, licensees will incur a materials cost of $3.64 for each report they mail to the National Source Tracking System.[13] Thus, the total cost for completing and submitting a report is estimated to be $25.39 (i.e., $21.75 + $3.64).

  NRC further estimates that, each year, licensees will complete and submit 112 reports by mail. Thus, the industry's total annual cost for completing and submitting National Source Tracking Transaction Reports by mail is estimated to be $2,844 (i.e., 112 reports x $25.39/report).

- *Reports Submitted by Telephone with Followup by Fax or Mail*. NRC estimates that, on average, 0.30 hours (18 minutes) of licensee staff time will be required to complete and submit a National Source Tracking Transaction Report by telephone with followup by fax or mail.[14] Using an estimated average labor rate of $87 per hour for licensee staff, the labor cost for conducting these activities is estimated to be $26.10 (i.e., 0.30 hours x $87/hour). In addition, NRC estimates that, on average, licensees will incur a cost of $3.86 for each report they submit by telephone to the National Source Tracking System.[15] Thus, the total cost for completing and submitting a report is estimated to be $29.96 (i.e., $26.10 + $3.86).

  NRC further estimates that, each year, licensees will complete and submit 12 reports by telephone. Thus, the industry's total annual cost for completing and submitting National Source Tracking Transaction Reports by telephone with followup by fax or mail is estimated to be $360 (i.e., 12 reports x $29.96/report).

Based on the above, NRC estimates that industry's total annual cost for completing and submitting National Source Tracking Transaction Reports will be $36,338 (i.e., $25,825 + $4,858 + $2,453 + $2,844 + $360). For purposes of this analysis, NRC assumes that this *annual* industry operating cost will be incurred for the first time in 2007.

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[13] Includes costs associated with mailing a five-ounce package by certified mail in a manila envelope ($1.29 for postage, $2.30 for the certified-mail fee, and $0.05 for a manila envelope).

[14] For purposes of this analysis, NRC assumes that licensees submitting information by telephone with followup by fax or mail would spend three minutes more than licensees submitting information by mail or fax. This estimate takes into account the additional time they will need to report the information by telephone.

[15] Includes a cost of $0.22 for making a three-minute State-to-State telephone call and a cost of $3.64 for mailing the National Source Tracking Transaction Report.

3.2.3.5 Correction of Previously Filed National Source Tracking Transaction Reports

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

NRC estimates that, on average, 0.05 hour (3 minutes) of licensee staff time will be required to correct and re-submit a previously filed National Source Tracking Transaction Report on-line. Using an estimated average labor rate of $87 per hour for licensee staff, the cost for conducting these activities is estimated to be $4.35 per report (i.e., 0.05 hour x $87/hour).[16] As shown in Table 3, NRC estimates that, each year, licensees will submit 2,687 National Source Tracking Transaction Reports. Based on best judgment, NRC estimates that licensees will correct and re-submit one percent of these reports (i.e., 2,687 x 0.01 = 27 reports). Thus, the industry's total annual cost for correcting and re-submitting previously filed National Source Tracking Transaction Reports is estimated to be $117 (i.e., 26 reports x $4.35/report).

Note that, for purposes of this analysis, NRC assumes that this *annual* industry operating cost would be incurred for the first time in 2007.

3.2.3.6 Annual Inventory Reconciliation of Nationally Tracked Sources

Under existing regulations, licensees are required to conduct inventories of their sealed sources. The regulatory action will require each licensee to reconcile and verify its inventory of nationally tracked sources against the data in the National Source Tracking System. This verification would be conducted during the month of January each year. As part of the verification process, licensees will be required to resolve any discrepancies between the National Source Tracking System and their actual inventory by filing the necessary National Source Tracking Transaction Report(s).

NRC estimates that licensees will require, on average, one hour to reconcile inventory information on their nationally tracked sources.[17] Using an estimated average labor rate of $87 per hour for licensee staff, the labor cost for reconciling and documenting this information is estimated to be $87 per licensee (i.e., 1 hour x $87/hour). As shown in Table 1, NRC estimates that 1,350 licensees will reconcile and verify inventory information for nationally tracked sources. Thus, the labor cost to licensees is estimated to be $117,450 (i.e., 1,350 licensees x $87/licensee).

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

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

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

- *On-Line Forms and Computer-Readable Format Files.* NRC considers Internet access to be a standard business practice. Therefore, for purposes of this analysis, the cost associated with the purchase of Internet access services is not considered an incremental cost to licensees.

- *Fax.* NRC estimates that each of the 64 licensees submitting information by fax (see Table 1) will incur a materials cost of $0.15 for faxing the information to the National Source Tracking System.[18] Thus, the materials cost to licensees submitting information by fax is estimated to be $9.60 (i.e., 64 licensees x $0.15/licensee).

- *Mail.* NRC estimates that each of the 64 licensees submitting information by mail (see Table 1) will incur a materials cost of $3.64 for mailing the information to the National Source Tracking System.[19] Thus, the materials cost to licensees submitting information by mail is estimated to be $232.96 (i.e., 64 licensees x $3.64/licensee).

- *Telephone with Followup by Fax or Mail.* NRC estimates that each of the seven licensees submitting information by telephone with followup by fax or mail will incur a materials cost of $4.16 for making a telephone call and mailing the information to the National Source Tracking System.[20] Thus, the materials cost to licensees submitting information by telephone with followup by fax or mail is estimated to be $29.12 (i.e., 7 licensees x $4.16/licensee).

Based on the above, the materials cost to licensees is estimated to be $271.68 (i.e., $0 + $9.60 + $232.96 + $29.12).

In summary, NRC estimates that industry's total annual cost for reconciling and verifying its inventory of nationally tracked sources will be $117,722 (i.e., $117,450 + $271.68). For purposes of this analysis, NRC assumes that this *annual* industry operating cost will be incurred for the first time in 2008.

3.2.3.7 Nationally Tracked Source Unique Serial Numbers

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

NRC estimates that, on average, two minutes of licensee staff time will be required to assign a unique serial number to a nationally tracked source. Using an estimated average labor rate of $87 per hour for licensee staff, the cost for assigning a serial number is estimated to be $2.90 per source (i.e., [2 minutes/60 minutes] x $87/hour). NRC estimates that 15,000 nationally

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[18] Based on the cost of a two-minute State-to-State telephone call.

[19] Includes costs associated with mailing a five-ounce package by certified mail in a manila envelope ($1.29 for postage, $2.30 for the certified-mail fee, and $0.05 for a manila envelope).

[20] Includes a cost of $0.52 for making a seven-minute State-to-State telephone call and a cost of $3.64 for mailing the inventory information to the National Source Tracking System.

tracked sources are manufactured each year. Thus, the industry's total *annual* cost for assigning unique serial numbers to nationally tracked sources is estimated to be $43,500 (i.e., 15,000 sources x $2.90/source), beginning in 2007.

3.2.3.8 Inspection Costs

NRC and Agreement States will conduct inspections of the National Source Tracking System reporting requirements. These inspections would be included as part of routine inspections. NRC estimates between one half to one hour would be needed to conduct the inspection for National Source Tracking. Thus, the total effort would be $30,450 (i.e., $87 per hour x 1 hour per licensee x 350 licensees) for NRC and $87,000 (i.e., $87 per hour x 1 hour per licensee x 1000 licensees) for the Agreement States for 2008. In later years, the inspection effort would be based on reporting discrepancies, therefore, beginning in 2009, the cost would be $10,500 for NRC and $29,000 for Agreement States.

3.2.3.8 Agreement State Costs

Agreement States will need to issue legally binding requirements to their licensees to require the licensees to report to the National Source Tracking System. This could be done through promulgating a comparable rule, issuing orders, or adding or revising individual license conditions. It may involve more than one activity. The final rule is Compatibility Category "B"; therefore, an Agreement State should adopt program elements essentially identical to those of NRC. The NRC program elements in this category are those that apply to activities that have direct and significant transboundary implications. National Source Tracking System is a national system and every one must begin reporting at the same time and using the same requirements for the system to be useful. Since each of the 34 Agreement States may choose different implementation mechanisms and have different numbers of licensees, it is difficult to estimate the costs for each Agreement State. The legally binding requirements need to be essentially word-for-word compatible, the process should be relatively simple. NRC estimates that on average, each Agreement State would expend 0.2 FTE at $76,000/FTE for each state. By the time the rule is published, there will be 34 Agreement States, therefore, the total cost for all Agreement States would be approximately $516,800.

3.3 Results

Under the National Source Tracking System alternative (Option 2), NRC will require licensees to report information on the manufacture, transfer, receipt, disassembly, and disposal of nationally tracked sources.

Using the cost assumptions discussed in Section 3.2 of this document, NRC staff estimated the incremental costs to industry and NRC under Option 2. These costs were estimated for the years 2006 through 2016. All costs incurred in the future were calculated in 2006 dollars using discount rates of 7 and 3 percent. Discounting all costs to year 2006 adjusts for the fact that costs incurred at different points in time are not equivalent. The results are presented in Table 4.

As shown in Table 4, the net present value under Option 2, using a 7 percent discount rate, is estimated to be a total cost of about $29,300,000. Using a 3 percent discount rate, the net present value is estimated to be a total cost of about $34,000,000.

NRC staff believes that the expected qualitative values contribute substantially to the benefits of the National Source Tracking System. These qualitative values include:

- *Improved Security for Nationally Tracked Sources.* The National Source Tracking System is expected to result in improved accountability and controls over nationally tracked sources. This is expected to improve public health (accident/event) and avert potential offsite property damage and costs by decreasing the risk of a security-related event involving nationally tracked sources.

- *Improved Understanding of the Location of Nationally Tracked Sources.* Information contained in the National Source Tracking System will improve the information available to NRC, as well as other government entities (e.g., Department of Homeland Security, Agreement States), concerning the locations of nationally tracked sources.

- *Improved Regulatory Efficiency.* The establishment of a national program to monitor the location of nationally tracked sources would improve regulatory efficiency by: (1) increasing accountability among all parties associated with a nationally tracked source transaction, (2) responding to a recommendation in the IAEA's Code of Conduct, and (3) responding to the statutory mandate of the Energy Policy Act of 2005.

- *Enhanced Ability to Promote and Maintain the Common Defense and Security.* Information contained in the National Source Tracking System will allow NRC to better monitor the location of nationally tracked sources and, thus, improve accountability and controls over them. Consequently, the National Source Tracking System should enhance NRC's ability to maintain and promote the common defense and security.

- *Increased Public Confidence.* Information contained in the National Source Tracking System will allow NRC to better monitor the location of nationally tracked sources. This is expected to result in increased public confidence in NRC’s regulation of inventories of radioactive materials that could be used in the production of RDDs and REDs.

Table 4
Present Value of the Costs Under the National Source Tracking System Alternative (Option 2): 2005 - 2016 [a]
(2005 dollars)

Category	7% Discount Rate				3%	
	Costs to Industry	Costs to Agreement States	Costs to NRC	Total Costs	Costs to Industry	Cost Agree Stat
IT Development/Maintenance Activities	$0	$0	$24,981,811	$24,981,811	$0	$0
National Source Tracking System Account Set-Up	$49,395	$0	$0	$49,395	$51,314	$0
Licensee Programming	$1,300,935	$0	$0	$1,300,935	$1,351,456	$0
Licensee Training	$878,131	$0	$0	$878,131	$912,233	$0
Initial Inventory of Nationally Tracked Sources	$55,137	$0	$0	$55,137	$57,279	$0
National Source Tracking Transaction Reports	$255,223	$0	$0	$255,223	$309,971	$0
Correction of Previously Filed National Source Tracking Transaction Reports	$822	$0	$0	$822	$998	$0
Annual Inventory Reconciliation of Nationally Tracked Sources	$716,810	$0	$0	$716,810	$889,899	$0
Nationally Tracked Source Unique Serial Numbers	$305,526	$0	$0	$305,526	$371,064	$0
Inspection Cost	$0	$227,241	$79,534	$79,534	$0	$273
Agreement State Regulation Development	$0	$459,809	$0	$459.809	$0	$490
Total	$3,561,978	$687,050	$25,061,346	$29,310,374	$3,944,213	$764

[a] Table includes rounding error.

4. Backfit Analysis

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

5. Decision Rationale

For the two regulatory alternatives identified, the values and impacts have been considered. Option 2, the National Source Tracking System alternative, was determined to be the preferred option because it is expected to: (1) enhance NRC's ability to promote and maintain the common defense and security, (2) improve understanding of the location of nationally tracked sources, (3) improve regulatory efficiency (by increasing accountability among all parties associated with a nationally tracked source transaction), (4) improve public health and safety, and (5) increase public confidence. NRC believes that the incremental costs to licensees and NRC under Option 2 are justified because the Energy Policy Act of 2005 requires NRC to issue regulations for a source tracking system. Option 1 or no action is not a viable action and merely provides the baseline.

6. Implementation

The regulatory action will be enacted through a Final Rule. No impediments to implementation of the recommended alternative have been identified. The Final Rule implements United States policy to have a National Source Tracking System for Category 1 and Category 2 sources.

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

NRC is currently in the process of developing the National Source Tracking System and expects to finalize its development by spring 2007. When completely operational, the National Source Tracking System will be a web-based system that will allow licensees to easily meet the reporting requirements.

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 20 and 32

RIN: 3150-AH48

National Source Tracking of Sealed Sources

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations to establish a National Source Tracking System for certain sealed sources. The NRC is proposing to change the basis for the rule from the NRC's authority to promote the common defense and security to protection of the public health and safety and is seeking public comment on this issue.

DATES: Submit comments on the basis change by **(INSERT DATE 20 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER)**. Comments received after the above date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after these dates.

ADDRESSES: You may submit comments by any one of the following methods. Please include the following number (RIN 3150-AH48) in the subject line of your comments.

Comments on rulemakings submitted in writing or in electronic form will be made available to the public in their entirety on the NRC rulemaking web site. Personal information will not be removed from your comments.

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

E-mail comments to: SECY@nrc.gov. If you do not receive a reply e-mail confirming that we have received your comments, contact us directly at (301) 415-1966. You may also submit comments via the NRC's rulemaking web site at http://ruleforum.llnl.gov. Address questions about our rulemaking website to Carol Gallagher (301) 415-5905; email cag@nrc.gov. Comments can also be submitted via the Federal Rulemaking Portal http://www.regulations.gov.

Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 am and 4:15 pm Federal workdays. (Telephone (301) 415-1966).

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

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

Publicly available documents related to this rulemaking may be examined and copied for a fee at the NRC's Public Document Room (PDR), Public File Area O1 F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland. Selected documents, including comments, can be viewed and downloaded electronically via the NRC rulemaking web site at http://ruleforum.llnl.gov.

Publicly available documents created or received at the NRC after November 1, 1999, are available electronically at the NRC's Electronic Reading Room at

http://www.nrc.gov/NRC/ADAMS/index.html. From this site, the public can gain entry into the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC Public Document Room (PDR) Reference staff at 1-800-397-4209, 301-415-4737 or by email to pdr@nrc.gov.

FOR FURTHER INFORMATION CONTACT: Merri Horn, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-8126, e-mail, mlh1@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The proposed rule on national source tracking was published in the Federal Register on July 28, 2005 (70 FR 43646) for public comment. The comment period closed October 11, 2005. The proposed rule was issued under the NRC's statutory authority to promote common defense and security. After publication of the proposed rule, the NRC issued Orders requiring increased controls for the remainder of the licensees possessing risk-significant quantities of radioactive material under the NRC's statutory authority to protect the public health and safety. Agreement States issued legally binding requirements for the increased controls for their licensees. The NRC has reevaluated the underlying basis for the National Source Tracking rule

and is now proposing that the rule be issued under its statutory authority to protect the public health and safety. The change in basis is consistent with the framework established for the increased controls that were issued by December 2005. The basis change will allow the Agreement States to issue legally binding requirements for their licensees and to conduct the national source tracking inspections of their licensees. The proposed changes to 10 CFR Part 150 would not be included in the final rule as these were to cover the Agreement State licensees.

The database for the National Source Tracking System would still be maintained by the NRC. Both NRC and Agreement State licensees would report their transactions to the National Source Tracking System.

The NRC is specifically inviting comment on the issue of the change in the basis for issuing the rule to protection of the public health and safety. Because the issue on which comment is sought is limited to a change in the basis under which the rule is to be issued, NRC is providing a limited comment period. With the change in basis, the final rule would be an immediate mandatory matter of compatibility and be classified as Compatibility Category “B.” The Agreement State Compatibility section of the Statement of Considerations would be revised and is provided below.

II. 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, the final rule would be classified as Compatibility Category "B." The NRC program elements in this category are those that apply to activities that have direct and significant transboundary implications. An Agreement State should adopt program elements essentially identical to those of NRC. Agreement State and NRC licensees would report their transactions to the National Source Tracking System. The database would be maintained by NRC.

Dated at Rockville, Maryland, this_____ day of_____, 2006.

For the Nuclear Regulatory Commission.

_____
Annette Vietti Cook
Secretary of the Commission.

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 20, 32, and 150

RIN: 3150-AH48

National Source Tracking of Sealed Sources

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations to implement a National Source Tracking System for certain sealed sources. The amendments require licensees to report certain transactions involving these sealed sources to the National Source Tracking System. These transactions include manufacture, transfer, receipt, disassembly, or disposal of nationally tracked sources. The amendments also require each licensee to provide its initial inventory of nationally tracked sources to the National Source Tracking System and annually reconcile the information in the system with the licensee's actual inventory. In addition, the amendments require manufacturers to assign a unique serial number to each nationally tracked source.

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

Compliance Dates: Compliance with the reporting provisions in 10 CFR 20.2207 and 150.18 is required by March 15, 2007, for Category 1 sources and March 30, 2007, for Category 2 sources.

FOR FURTHER INFORMATION CONTACT: Merri Horn, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-8126, e-mail, mlh1@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

After the terrorist attacks in the United States on September 11, 2001, the NRC conducted a comprehensive review of nuclear material security requirements, with particular focus on radioactive material of concern. This radioactive material (which includes Cobalt-60, Cesium-137, Iridium-192 (Ir-192), and Americium-241, as well as other radionuclides) has the potential to be used in a radiological dispersal device (RDD) or a radiological exposure device

(RED) in the absence of proper security and control measures. The NRC's review took into consideration the changing domestic and international threat environments and related U.S. Government-supported international initiatives in the nuclear security area, particularly activities conducted by the International Atomic Energy Agency (IAEA).

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

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

Category 2 radioactive sources as described in Annex 1 of the Code of Conduct. The source registry recommendation addressed 16 radionuclides.

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

The U.S. Government has formally notified the Director General of the IAEA of its strong support for the current Code of Conduct. Although the Code of Conduct does not have the stature of an international treaty and its provisions are non-binding on IAEA Member States, the U.S. Government has endorsed the Code of Conduct and is working toward implementation of its various provisions. This rulemaking reflects those Code of Conduct recommendations related to a source registry which are consistent with NRC responsibilities under the Atomic Energy Act, including promotion of the common defense and security.

Efforts to improve controls over sealed sources face significant challenges, especially balancing the need to secure the materials without discouraging their beneficial use in

academic, medical, and industrial applications. Radioactive materials provide critical capabilities in the oil and gas, electrical power, construction, and food industries; are used to treat millions of patients each year in diagnostic and therapeutic procedures; are used in a variety of military applications; and are used in technology research and development by academic, government, and private institutions. These materials are as diverse in geographical location as they are in functional use.

NRC considers national source tracking to be part of a comprehensive radioactive source control program for radioactive materials of greatest concern. Although a national source tracking system can not ensure the physical protection of sources, it can provide greater source accountability, which should foster increased control by licensees. A national source tracking system in conjunction with controls such as those imposed by Orders on irradiator licensees, manufacturer and distributor licensees, and other material licensees will result in improved security and control for radioactive sources.

The NRC is developing and will implement national source tracking under its statutory authority to promote the common defense and security. To inform the development of the National Source Tracking System, the NRC established an Interagency Coordinating Committee to provide guidance regarding interagency issues associated with the development, coordination, and implementation of the system and to prevent licensees from receiving similar requests from more than one agency. The Committee consists of representatives from various Federal Agencies with an interest in source security and a representative from the Agreement States. The views of the Committee were included in the development of the requirements for the National Source Tracking System and this rulemaking. NRC will be the database manager of the National Source Tracking System, however, the other agencies may become users of the

system and have limited access. DOE will have greater access as they will be responsible for entering data on sources for DOE facilities.

Development of the National Source Tracking System is a two-part activity that includes both a rulemaking and an information technology development component. When completely operational, the National Source Tracking System will be a web-based system that will allow licensees to meet the proposed reporting requirements on-line. The system will contain information on NRC licensees, Agreement State licensees, and DOE facilities.

This final rulemaking establishes the regulatory foundation for the National Source Tracking System recommended in the DOE/NRC report and expands on implementation of the Code of Conduct recommendation to develop a national source registry. This rule imposes requirements on both NRC and Agreement State licensees.

There is clearly broad U.S. Government and international interest in tracking radioactive sources to improve accountability and control. There is no single U.S. source of information to verify the licensed users, locations, quantities and movement of these materials. Separate NRC and Agreement State systems contain information on licensees and the maximum amounts of materials they are authorized to possess, but these systems do not record actual sources or their movements.

To address this lack of information on such issues as actual material possessed, the NRC, in cooperation with the Agreement States, began working on an interim database of sources of concern. In November 2003, both NRC and Agreement State licensees were contacted and requested to voluntarily provide some basic information on the sealed sources located at their facilities. Of the approximately 2600 licensees contacted, over half of the licensees reported possessing Category 1 or Category 2 sealed sources. The interim database

was updated in 2005 and will continue to be updated until the National Source Tracking System is operational. The interim database will ultimately be replaced by the National Source Tracking System. While the interim database provides a snapshot in time, the National Source Tracking System will provide information on an ongoing basis.

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

This final rule on National Source Tracking meets the requirements enumerated above imposed by the Energy Policy Act of 2005 applicable to source tracking. The rule requires the reporting of transfers and receipts of sources by the close of the next business day which meets the requirement for reporting within 7 days of any change of possession. The

information to be reported includes the serial number of the source which addresses identification of each source by serial number. On-line reporting is one of the methods by which licensees may report; this meets the requirement to allow reporting through a secure internet connection. Current NRC and Agreement State regulations require licensees to immediately report, after its occurrence becomes known to the licensee, any lost, stolen, or missing licensed material at the Category 1 or 2 level. Therefore, this final rule does not include provisions for reporting loss of control of, or accountability for, a radiation source.

II. Discussion

A. *What Action is the NRC Taking?*

The NRC is issuing a rule that implements a new program called the National Source Tracking System. The final rule requires licensees to report information on the manufacture, transfer, receipt, disassembly, and disposal of nationally tracked sources. This information captures the origin of each nationally tracked source (manufacture or import), all transfers to other licensees, all receipts of nationally tracked sources, and endpoints of each nationally tracked source (disassembly, disposal, decay, or export). Ultimately, the National Source Tracking System will be able to provide a domestic life history account of all nationally tracked sources.

A system of this type needs prompt updating to be useful and accurate. In order to capture information as soon as possible, this rule requires licensees to report information on nationally tracked source transactions by the close of the next business day. Although the Energy Policy Act of 2005 provides for reporting within 7 days, the rule requires reporting by the

close of the next business day. After discussions within the Interagency Coordinating Committee, NRC determined that 7 days was too long a time period. NRC has determined that the close of the next business day is the appropriate timeframe for reporting.

To ease the burden on licensees, the NRC is establishing a secure Internet-based interface to the National Source Tracking System. While on-line access should be fast, accurate, and convenient for licensees, the NRC will also allow licensees the option of completing and mailing or faxing paper forms. In addition, licensees will also be able to provide batch information using a computer-readable format file. The format will be specified in a guidance document on implementation of the National Source Tracking System.

B. What is a Nationally Tracked Source?

A sealed source consists of radioactive material that is sealed in a capsule or is 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. A nationally tracked source is a sealed source containing a quantity of radioactive material equal to or greater than the Category 2 levels listed in the new Appendix E to 10 CFR Part 20. A nationally tracked source may be either a Category 1 source or a Category 2 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 were to be placed in a matrix material, the sealed source would still be covered by the rule.

Category 1 nationally tracked sources are those containing a quantity equal to or greater than the Category 1 threshold. Category 2 nationally tracked sources are those containing a quantity equal to or greater than the Category 2 threshold but less than the Category 1 threshold. The definition of nationally tracked source is based on the IAEA Code of Conduct and is consistent with the definition of sealed sources in other parts of the NRC regulations and with definitions contained in Agreement State regulations.

The specific radioactive material and amounts covered by this rule are listed in Appendix E to Part 20. The radionuclides and thresholds of 16 of the radionuclides are identical to the Table I values from the Code of Conduct. The IAEA Code of Conduct includes a recommendation that these radionuclides and thresholds be included in a national source registry. The U.S. Government has formally endorsed these values. The NRC has adopted the Category 2 values to allow alignment between domestic and international efforts to increase the safety and security of radioactive sources. The Energy Policy Act of 2005 states that Category 1 and Category 2 sources are to be included in the National Source Tracking System.

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 practical usefulness only and are rounded after conversion. The curie values are not intended to be the regulatory standard.

Table I of the IAEA Code of Conduct lists 16 radionuclides that should be included in a national source registry. Included in this listing is radium (Ra)-226. Before the Energy Policy

Act of 2005 was signed into law, the NRC did not have the authority to regulate Ra-226; therefore it was not included in the proposed rule for national source tracking. Section 651(e) of the Energy Policy Act of 2005 amends section 11e. of the Atomic Energy Act to give NRC authority over discrete sources of Ra-226 and other radioactive materials if they are produced, extracted, or converted after extraction for use in commercial, medical, or research activities. Therefore, NRC is adding Ra-226 to Appendix E in this final rule. Ra-226 sealed sources will now be included in the National Source Tracking System. The term 'discrete source' will be defined in a separate rulemaking to implement section 651(e) of the Energy Policy Act of 2005. That final rule is to be issued by February 7, 2007.

In the proposed rule, the Commission expanded the National Source Tracking System list of radionuclides to include 6 radionuclides that are not on the Code of Conduct list and one radionuclide that is listed in the Code of Conduct but is not included in the source registry recommendation. The 7 additional radionuclides included in the proposed rule were actinium (Ac)-227, plutonium (Pu)-236, Pu-239, Pu-240, polonium-210, thorium (Th)-228, and Th-229. The DOE/NRC RDD report recommendation for a National Source Tracking System included these 7 radionuclides. The thresholds for these radionuclides were developed using the same methodology as those listed in the Code of Conduct. These radionuclides are also included in the interim database. Based on information from the interim database, NRC and Agreement State licensees do not possess large numbers of nationally tracked sources containing these radionuclides. Because this is a national system, it needs to include information from DOE facilities. DOE facilities are more likely to possess these radionuclides and DOE agreed that these radionuclides should be included in the National Source Tracking System. Therefore, the Commission included them in the proposed rule. The source tracking system NRC is required

to establish under the Energy Policy Act of 2005 covers “radiation sources” as defined in the Act (Category 1 and Category 2 sources and any other material as determined by the Commission other than spent nuclear fuel and special nuclear materials). Three plutonium (Pu) isotopes (Pu-236, Pu-239, Pu-240) are being removed from Appendix E because these isotopes are not “radiation sources” within the meaning of the Act. Two other Pu isotopes (Pu-238 and Pu-239/Be) are being retained in Appendix E because they are listed in the Code of Conduct.

C. *Who Does This Action Affect?*

The final rule applies to any person (entity or individual) in possession of a Category 1 or Category 2 source. It applies to all licensees, both those with NRC licenses and those with Agreement State licenses; including, for example:

Manufacturers and distributors of Category 1 and Category 2 sources;

Medical facilities, radiographers, irradiators, reactors, and any other licensees that are the end users of nationally tracked sources; and

Disposal facilities and waste brokers.

The final rule applies whether the source is actively used or in long-term storage.

Nationally tracked sources are possessed by all types of licensees, but primarily by byproduct material licensees. Nationally tracked sources are used in the oil and gas, electrical power, construction, medical, and food industries. They are used in a variety of military applications and in technology research and development. Nationally tracked sources are classified either Category 1 or 2 based on the activity level of the radioactive material of concern. Category 1 sources are typically used in devices such as radiothermal generators and

irradiators, and in practices such as radiation teletherapy. Category 2 sources are typically used in industrial gamma radiography, blood irradiators, and some well logging.

D. *How Will Information Be Reported to the National Source Tracking System?*

Licensees have several options for reporting transaction information to the National Source Tracking System. These reporting methods include on-line, computer-readable format files, paper, fax, and telephone. For most licensees, the most convenient, least burdensome method will be to report the information on-line (e.g. through the internet). To report information on-line, a licensee will need to establish an account with the National Source Tracking System. Once an account is established, the licensee will be provided with password information that will allow access to the on-line system. A licensee will have access only to information regarding its own material or facility; a licensee will not have access to information concerning other licensees or facilities. When logged on, the licensee will be able to type the necessary information onto the on-line forms. Once a source is in the system, the licensee will be able to click on the source and report a transfer or other transaction. Identifying information such as license number, facility name, address, manufacturer, model number, serial number, etc. will not need to be typed in a second time.

Many licensees conduct a large number of transactions, especially manufacturing and distribution licensees. We recognize that most licensees have a system for maintaining their information on sources. The National Source Tracking System will be able to accept batch load information from licensees systems using a computer-readable format. This will ease the reporting burden for a licensee with a large number of transactions. The licensee will be able to electronically send a batch load using a computer-readable format file that contains all of the

transactions that occurred that day. Licensees can also use this format to report their initial inventory.

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

Additional guidance on submitting information will be provided before the effective date of the reporting requirements. The guidance will contain mailing addresses and telephone and fax numbers for providing information to the National Source Tracking System, as well as information on the computer-readable format to be used. The NRC plans to hold several workshops on reporting information to the National Source Tracking System which will include hands-on training. The workshops will be held before the effective date of the reporting requirements. Licensees (both NRC and Agreement State) will receive information on when and where the workshops will be held.

E. *Will a Licensee Need to Report Its Current Inventory to The System?*

Yes, licensees are required to report their current inventory of nationally tracked sources by a specified date. There are separate reporting dates for Category 1 and Category 2 nationally tracked sources. Licensees are required to report all Category 1 sources to the National Source Tracking System by March 15, 2007, and all Category 2 sources by March 30, 2007.

To ease the reporting process, information already in the interim database will be downloaded to the National Source Tracking System. Each licensee that reported information to the interim database will be provided a copy of its information and asked to either verify the information or provide updated information. NRC staff and the company that will operate the

National Source Tracking System will work with licensees to make sure the initial inventory information is correct. Licensees that did not provide information to the interim database must provide the information on their nationally tracked source inventory by the specified dates. Disposal facilities do not need to report sources that have already been buried or otherwise disposed.

For sources that are stored in a device, the licensee must report the serial number of the source within the device. Licensees are not required to report the device number. Sources are usually not placed permanently in the device, but are removed from the device at the end of the source's useful life. Because some licensees track their sources by device number, the National Source Tracking System contains an optional reporting field for reporting the device serial number. Licensees will be able to search their data by device number. For licensees reporting by the paper form, the device number can be added to the comment field.

F. *What Information Will Be Collected on Source Origin?*

Each time a nationally tracked source is manufactured in the United States, the licensee must report the source information to the National Source Tracking System. The information must be reported by the close of the next business day. The licensee must report the manufacturer (make), model number, serial number, radioactive material, activity at manufacture, and manufacture date for each source. The licensee must also provide its license number, facility name, address, and the name of the individual that prepared the report. Manufacturers may make one report that includes both the manufacture and transfer of sources, as long as the transfer occurs within the reporting timeframe of the manufacture. The information required for both transactions will need to be included in the report.

Some sources are recycled or reconfigured. For example, a source that has decayed below its usefulness is sometimes 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 date must be reported to the National Source Tracking System.

For every nationally tracked source that is imported, the facility obtaining the source must report the source information to the National Source Tracking System by the close of the next business day after receipt of the imported source at the site. For the purposes of the National Source Tracking System, this is 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 must also provide its license number, facility name, address, and the name of the individual that prepared the report and the date of receipt. The licensee must also provide information on the facility (name and address) that sent the source and the import license number.

Under separate regulations on import/export of radioactive material, licensees are required to notify the NRC of imports of radioactive material at Category 2 levels or above (70 FR 37985; July 1, 2005). This notification includes source identification information, if available. Initially, NRC staff will enter the notification information into the National Source Tracking System, but eventually, import/export licensees will be able to make the notifications to the NRC using the on-line reporting mechanism of the National Source Tracking System. For example, if the notification includes the detailed source information, a licensee that is receiving an imported nationally tracked source will be able to report the transaction as a simple receipt using the on-

line method. Much of the source information will already be in the National Source Tracking System; the licensee will be able to click on the pending import and then click on the source to indicate that the source had been received at the site.

G. *What Information Will Be Collected on Source Transfer?*

Each time a nationally tracked source is transferred to another authorized facility, the licensee must report the transfer to the National Source Tracking System by the close of the next business day. The licensee must report the recipient name (facility the source is being transferred to), address, and license number, the shipping date, the estimated arrival date, and the identifying source information (manufacturer, model number, serial number, and radioactive material). If the source is being exported, the export license number is reported for the recipient's license number. The licensee also must 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 must also report the waste manifest number and the container identification number for the container with the nationally tracked source.

Source transfer transactions are transfers between different licensees and transfers from a licensee to another authorized facility, such as a DOE site or a foreign entity. A source transfer transaction does not include transfers to a temporary domestic job site. Domestic transactions in which the nationally tracked source remains in the possession of the licensee do not require a report to the National Source Tracking System. For example, a radiographer conducting business does not need to report transfers between temporary job sites, even if the temporary job site is located in another state or if the work is conducted under a reciprocity agreement.

H. *What Information Will Be Reported for Receipt of Sources?*

A licensee must 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 must include its facility name, address, and license number and the name of the individual that prepared the report. The licensee must also provide the name, address, and license number of the facility that sent the source because this information is necessary to match the transactions. If the source is an import, the licensee must report the source activity and associated activity date. The import license number is reported as the license number of the sending facility. 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. To avoid unnecessary exposure, these licensees are not expected to open the waste container to verify the presence of the nationally tracked source; they may rely on the information from the licensee who shipped the source.

I. *What Information Will Be Reported on Source Endpoints?*

Endpoints for a source include export, disassembly, disposal, decay, loss or theft, and destruction of the source. Some of the endpoints are reversible (export, loss, theft) and some are permanent (disassembly, disposal, destruction). Exports are treated as a transfer. (See Section G for more information on source transfer.) An export is considered a reversible endpoint because the source can be imported back into the country. The export license number is reported as the license number of the receiving facility.

Some licensees disassemble sources for possible recycle. The source is taken apart, the radioactive material is removed, and the material may be used for manufacture of new sources or sent for disposal. This is not the same as reconfiguration where the source is not destroyed. The licensee must report the disassembly of any nationally tracked source to the National Source Tracking System by the close of the next business day. Once a source has been disassembled, it is no longer tracked. This is a permanent endpoint. Licensees that report a disassembly transaction must include the source information (manufacturer, model number, serial number, and radioactive material), license information (name, address, license number, name of person making the report), and the date of the disassembly.

Disposal of a source is reported by the licensee conducting the actual burial in a low-level disposal facility or other authorized disposal mechanism. Licensees sending a source to a low-level burial ground for disposal treat the transaction as a transfer. The licensee must include the waste manifest number and the container identification number. The disposal facility is not expected to open the waste container to verify the contents, and may report the information from the licensee who sent the waste for disposal. The disposal facility must report to the National Source Tracking System 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 who prepared the report. The report must be made by the close of the next business day.

The National Source Tracking System automatically calculates the decay of a source so licensees do not need to report an endpoint of decay. Once a source has decayed below Category 2 levels, it is no longer considered to be a nationally tracked source. The source will

be automatically removed from a licensee's active inventory in the National Source Tracking System. The licensee will receive a notification that the source has decayed below the tracking level and that transactions for this source no longer need to be reported. The data on the source will, however, be retained in the system.

Licensees must continue to report accidental destruction of sources to the NRC Operations Center or to their Agreement State. The Agreement States provide the information to the NRC Operations Center. NRC staff will enter the information from the event report into the National Source Tracking System. Because sealed sources are designed to be robust, accidental destruction is rare. Examples of accidental destruction include sources destroyed during attempts to remove them from devices, and well logging sources that become disconnected downhole and destroyed during retrieval attempts.

Other endpoints that will be captured by the National Source Tracking System include the loss or theft of a source or the abandonment of a source in a well. 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 National Source Tracking System. Agreement State licensees must continue to report to their 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 National Source Tracking System. Agreement State staff may also enter this information into the system. Loss and theft of a source are considered to be reversible endpoints and source abandonment in a well is considered a permanent endpoint.

J. *How Will the National Source Tracking System Information Be Kept Current?*

Data integrity for the National Source Tracking System is extremely important. Licensees are expected to provide correct information to the National Source Tracking System

and to double-check the accuracy of their information before submission. However, 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 National Source Tracking System will contain correct, up-to-date information. However, we recognize that some transactions may be missed and that errors may be introduced into the system over time. Discrepancies might result from the failure to report the receipt of a source or failure to report the transfer of a source to another licensee. Inaccuracies can result from errors in the initial inventory report, selection of the wrong model number, or incorrectly typing the serial number. Each licensee is required to correct any errors or missed transactions that it becomes aware of within 5 business days of the discovery.

In addition, each licensee is required to reconcile its on-site inventory of nationally tracked sources with the information previously reported to the National Source Tracking System. This reconciliation occurs during the month of January each year. Each licensee will be able to print a copy of its inventory information from the National Source Tracking System. Licensees without on-line access will receive a paper copy from the NRC of their information in the National Source Tracking System. Each licensee must compare the information contained in the system to the its own inventory, 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. The NRC's regulations already require licensees to conduct physical inventories either annually, semi-annually, or quarterly, depending on the type of license. Each licensee must reconcile any differences by reporting the appropriate transaction(s) or

corrections to the National Source Tracking System. The reconciliation must be completed by January 31 of each year.

In addition, each licensee must report to the National Source Tracking System that their data in the National Source Tracking System is correct. Licensees reporting their reconciliation using non-electronic methods will have to use a hard copy form, which will be provided with the paper copy of the information contained in the National Source Tracking System. The first reconciliation will occur in January 2008.

K. How Will Incorrect Information Be Changed in the National Source Tracking System?

Licensees will be able to correct errors in the National Source Tracking System at any time, either online or through any other permitted reporting mechanism. Each licensee is responsible for correcting any errors in its inventory information in the National Source Tracking System, regardless of the source of the error, within 5 business days of the discovery.

L. *Some Licensees Now Must Report Similar Information to the Nuclear Materials Management Safeguards System. Will This Rule Result in a Duplication in Reporting?*

Yes, some information on plutonium (Pu) and thorium (Th) is collected by both the Nuclear Materials Management Safeguards System (NMMSS) and the National Source Tracking System. The current regulations require reporting transfers, receipts, and inventories to NMMSS of one gram or more of Pu and any Th that has foreign obligations. However, NMMSS does not collect information at the source level; therefore, the detailed information (make, model, serial number) on sealed sources cannot be extracted from NMMSS to provide input into the National Source Tracking System. The National Source Tracking System will only have information on sealed sources and will not contain information on sources that are not considered sealed or on any bulk material that a licensee may possess. The thresholds are

also different for the two systems. Therefore, NRC will not be able to extract information from the National Source Tracking System to support NMMSS. Neither system is able to collect the needed information for the other system without modifications to the databases and additional changes to the regulations. The two systems also have different purposes.

In practice, NRC finds that these Pu and Th sources are typically held by licensees for long time periods and are not routinely transferred to other licensees, so incidences of double-reporting are expected to be rare. Only 10 licensees reported possessing Pu Category 1 or Category 2 sources and no licensee reported Th sources to the interim database. The NRC does not believe that the limited number of licensees and transactions likely to be affected by this dual reporting requirement imposes an unnecessary burden. The NMMSS and the National Source Tracking System collect information on these radionuclides for different purposes and in different formats and with different levels of detail and thresholds as needed by each system. Therefore, the Commission believes that NMMSS and the National Source Tracking System should remain separate.

M. *Are the Actions Consistent with International Obligations*?

Yes, the National Source Tracking System is consistent with international obligations. The system is intended to respond to the recommendation in the IAEA Code of Conduct for development of a national source registry. In addition, attendance at international meetings provides the NRC staff with information on the actions of other countries to implement Code of Conduct recommendations. To the extent feasible, NRC will utilize data formats compatible with those of other countries.

N. *When Do These Actions Become Effective?*

The requirements for Category 1 nationally tracked sources will be implemented by March 15, 2007. This means that by this date any licensee that possesses a Category 1 level source must have reported its initial inventory and must begin reporting all transactions involving Category 1 sources to the National Source Tracking System. The requirements for Category 2 nationally tracked sources will be implemented by March 30, 2007. By this date, all licensees must have reported their initial inventory of nationally tracked sources and begin reporting all transactions to the National Source Tracking System. For all other provisions, the final rule is effective 90 days after publication in the *Federal Register*.

O. Who Will Have Access to the Information and What Will It be Used For?

Information in the National Source Tracking System is considered Official Use Only - Security-Related Information; the information is not considered to be Safeguards Information or Safeguards Information - Modified Handling. A licensee will be able to view its own data, but not data for other licensees. NRC, as the database manager, will have access to all of the information. Agreement State staff will be able to view information on the licensees in their state, but will not be able to view information on licensees in other states. The one exception is information related to lost or stolen sources. Agreement State staff will be able to view the information on lost or stolen sources for all licensees. This will enable better coordination of recovery efforts. Other Federal and State agencies will also be able to view the information on lost or stolen sources and other information on a need-to-know basis.

The National Source Tracking System will be used for a variety of purposes. This standardized, centralized information will help NRC and Agreement States to monitor the location and use of nationally tracked sources; conduct inspections and investigations; communicate nationally tracked source information to other government agencies; verify

legitimate ownership and use of nationally tracked sources; and further analyze hazards attributable to the possession and use of these sources.

P. What Other Things Are Required by This Action?

The final rule also requires manufacturers of nationally tracked sources to use a unique serial number for each source. The combination of manufacturer, model, and serial number will be used in the National Source Tracking System to track the history of each source.

III. Analysis of Public Comments on the Proposed Rule

The proposed rule on National Source Tracking was published on July 28, 2005 (70 FR 43646). The comment period ended on October 11, 2005. The NRC received 33 comment letters on the proposed rule. The NRC also held two public meetings on the proposed rule during the comment period. The first meeting was held in Rockville, Maryland on August 29, 2005, and the second meeting was held in Houston, Texas on September 20, 2005. Approximately 90 people attended the two meetings, with 17 individuals providing comments. The overall commenter mix on the proposed included federal agencies, states, licensees, industry organizations, and individuals. Copies of the public comments and the public meeting transcripts are available for review in the NRC Public Document Room, 11555 Rockville Pike, Rockville, MD or on the NRC's rulemaking web site located at http://ruleforum.llnl.gov.

The comments and responses have been grouped into 12 areas. NRC specifically sought comments on the first six areas: (1) inclusion of Category 3 Sources; (2) inclusion of Ra-226; (3) inclusion of transfers between temporary job sites; (4) inspection of waste shipments; (5) data quality assurance; and (6) data protection. The other six comment areas

are: (1) general; (2) rule language; (3) regulatory analysis; (4) implementation; (5) system aspects; and (6) miscellaneous. To the extent possible, all of the comments on a particular subject are grouped together. A discussion of the comments and the NRC staff's responses follow.

A. Category 3 Sources

In the proposed rule, NRC specifically invited comment on whether Category 3 sources should be included in the National Source Tracking System. Category 3 sources are those containing a quantity equal to or greater than the Category 3 threshold (1/10th of the Category 2 threshold) but less than the Category 2 threshold. Although the NRC did not plan to include Category 3 sources in this rulemaking, Category 3 sources could be included in the National Source Tracking System in the future. The potential issue was that a licensee possessing a large number of Category 3 sources could present a security concern. Therefore, NRC sought information on the number of additional licensees that would be impacted, the number of Category 3 sources possessed by licensees, and how often those sources changed hands.

Twenty-four commenters addressed the issue of Category 3 sources, including three Agreement States. The majority of commenters on this issue were opposed to including Category 3 sources in the National Source Tracking System; only six commenters supported the inclusion, including two Agreement States and one non-Agreement State. Reasons for inclusion varied. According to one commenter, the higher activity Category 3 sources may pose a threat nearly comparable to the threat posed by Category 2 sources and should be tracked aggressively. Some commenters thought that Category 3 sources should be included

because an accumulation of sources could possibly threaten national security. Others stated that any level of any radioactive material used in an RDD or RED would cause panic among the population. One commenter noted that the IAEA has indicated that Category 3 sources carry a potential risk of harm that warrants inclusion in a tracking system, but Member States did not want to include the Category 3 sources in the national registry recommendation because the large number of such sources and the economic cost for tracking them could be overly burdensome. The commenter stated that Category 3 sources should be included unless it can be shown that to do so is unreasonably burdensome (due to the large number of sources and the economic cost of tracking them). The commenter noted that, by IAEA definition, Category 3 sources are dangerous and could result in permanent injury, as well as cause serious social and economic impact, if not managed or securely protected.

Commenters argued that the Category 3 sources should be tracked to help prevent their possible entry into the scrap metal industry, pointing out that the Category 3 sources were more likely to be introduced into the recycle stream. Commenters stated that the Category 3 sources present a danger to the metals-recycling industry, its employees, and their communities. Two commenters provided data on clean-up costs for contaminated steel mills. Commenters stated that public health and safety concerns, as well as security concerns, support the inclusion of Category 3 sources at this time. One commenter stated that with modest additional investment, NRC has the ability to track Category 3 sources and that the failure to do so will foreclose an opportunity to advance a rule which would be truly protective of public safety and the environment. Another commenter stated that additional data needs to be collected on the inclusion of Category 3 sources, but noted that any study should not be done in such a way that would disrupt the current implementation schedule for Category 1 and Category 2 source

tracking. One commenter argued that the data from the inclusion of Category 3 sources would enable the government to more effectively manage the protection of the public health and safety and the economic vitality of the United States scrap metal industry and that the data could be used to monitor market trends, establish projections for low-level waste disposal, and allocate resources for programs to identify and develop alternate technologies.

Most of the commenters opposed to the inclusion of Category 3 sources cited the increased burden that would be imposed on licensees and the NRC. One commenter noted that the inclusion of Category 3 sources would require over 7,000 additional transaction reports every year for his company; most commenters did not provide specific numbers, but indicated that there would be a significant increase in the transaction reports from thousands to tens of thousands.

According to one commenter, inclusion of Category 3 sources would significantly increase the number of impacted licensees and all medical facilities that perform radiation therapy procedures would be impacted. One commenter noted that most of the sources are used in teletherapy or gamma sterotactic radiosurgery units and that once the sources are placed in the machines, tampering or stealing the sources becomes very difficult. A couple of commenters pointed out that many of these sources are used extensively in generally licensed gauges at fixed facilities and that most of the individuals possessing these materials do not even realize that they have an NRC or Agreement State license. The commenters felt that these individuals would be unlikely to understand the tracking system and would need additional education to understand their responsibilities under the tracking system. Commenters stated that including Category 3 sources in the tracking system would unduly burden manufacturers and licensees due to the large number of Category 3 sources that are in

common use throughout the United States. Other commenters pointed out that licensees are required to maintain inventory records and that this should be sufficient. Some of the commenters suggested inventory reporting instead of source transactions.

Commenters pointed out that many of the Category 3 sources are lower risk and do not pose a significant terrorist threat in comparison to Category 1 and 2 sources. One commenter stated that including Category 3 sources would go beyond the IAEA Code of Conduct recommendation and that to maintain consistency with the Code of Conduct, NRC should not include Category 3 sources. One commenter opposed the inclusion of Category 3 sources now and in the future because implementing standards more stringent than the IAEA code of conduct will generate confusion and not integrate the United States plan with international efforts in this regard. One Agreement State stated that inclusion of Category 3 sources does not fall within the security requirements and should not be included. The State noted that if a licensee possessed enough sources in the aggregate it would be under increased security control requirements.

Several commenters expressed concern that inclusion of Category 3 sources would bog down the system development process, hinder the timely implementation of the system, and potentially degrade the quality of the information in the database. Commenters noted that there will be a breaking-in period while both the regulated and regulators learn to complete, report, and maintain the necessary reports. Commenters noted that inclusion of Category 3 sources would dramatically increase the number of records and would diminish the effectiveness of the rule (by increasing the likelihood of data entry error, impacting timeliness, and through sheer volume). Several commenters noted that the issue could be revisited after the National Source Tracking System has been implemented and is running smoothly. Two commenters suggested

that before including Category 3 sources, the NRC should conduct a roundtable discussion with stakeholders to fully understand the impact of the rulemaking on the medical community and to ensure that final regulations do not impose unintended problems in the practice of medicine.

Response: As part of the proposed rulemaking on the National Source Tracking System, NRC requested the views of potentially impacted stakeholders on the inclusion of Category 3 sources in the National Source Tracking System. The comments received expressed strong views on this topic. It was not NRC's intent to include Category 3 sources in the tracking system at this time. Rather, NRC intended to gather information for future consideration. At this point NRC staff does not have adequate information to support inclusion of Category 3 sources. There are also issues related to possession of Category 3 sources under a general license that need to be addressed before a final decision can be made. In addition, the Radiation Source Protection and Security Task Force, established by the Energy Policy Act of 2005, will be reviewing whether changes to the National Source Tracking System are necessary, including whether Category 3 sources should be included.

At this time, NRC is not including Category 3 sources in the National Source Tracking System. The development and implementation of the National Source Tracking System should be completed before adding another tier of sources and licensees. The NRC staff will continue to evaluate adding Category 3 sources to the tracking system. If a decision is made to include Category 3 sources, a separate rulemaking would be conducted with an opportunity for public comment.

B. Ra-226

At the time the proposed rule was published, NRC did not have authority over Ra-226. Because the IAEA Code of Conduct included Ra-226 in its recommendation for a source registry, NRC specifically invited comment on whether States would be willing to develop regulations that would require their licensees to report Ra-226 to either the State or to the National Source Tracking System. NRC received input from six commenters, including four States. The commenters all supported the inclusion of Ra-226 in the tracking system.

The Energy Policy Act of 2005 brought discrete sources of Ra-226 that are produced, extracted, or converted after extraction, for use in a medical, research, or commercial activity, under the regulatory authority of the NRC. Because the NRC now has authority over Ra-226 sealed sources, Ra-226 has been added to Appendix E in this final rule. The NRC is currently developing a rulemaking that will, among other things, define discrete sources of Ra-226. NRC intends to issue final regulations by February 7, 2007, which will provide licensees adequate time to become familiar with new Ra-226 requirements before the implementation of the National Source Tracking System.

C. Temporary Job Sites

As drafted, the proposed rule only covered source transfers between different licensees and/or authorized facilities such as a DOE site or an export. It did not include transfer to a temporary job site. Therefore, transactions in which the nationally tracked source remained in the possession of the licensee would not have required a report to the National Source Tracking System. NRC specifically invited comment on whether licensees should be required to report as a transaction the use of a nationally tracked source at temporary job sites, whether in the same state or a different state, and if temporary job site transactions were included in the

System, how much additional burden would be involved and what the reporting timeframe should be. Twenty-four commenters addressed this issue, including two Agreement States. The overwhelming majority of commenters were opposed to reporting transactions for source use at temporary job sites. One state supported the inclusion of transfers to temporary job sites arguing that security at temporary job sites could easily be compromised and reporting would provide information on what sources are on the state highways. Two Agreement States stated that while reporting use at temporary job sites would be useful, it should only be required when licensees perform temporary jobs across state lines. The information could then be compared to existing reciprocity reports if the host state was allowed access to the necessary information. The commenters stated that host states should be allowed access to the data to confirm what sources are within their borders.

Commenters opposed to the inclusion of reporting transactions at temporary job sites indicated that this would impose a large burden, the information reported would not add any value, and in fact would be out of date by the time it was reported. Commenters stated that many licensees can work at several job sites per day, noting that crews could conceivably go to eight different jobs each day. The commenters stated that reporting these movements would not add anything to the physical security of the sources, a point the NRC acknowledged in the Statement of Considerations for the proposed rule. Commenters also pointed out that these sources are used at tens of thousands of temporary job-sites annually and that their inclusion in the System would increase the already burdensome proposal by factors of hundreds or thousands. One commenter estimated that his company would amass an additional 41,250 reports annually if temporary job site transfers were included. Other commenters noted that it would require additional staff to make the reports; the estimates provided ranged from a quarter

person-year to an additional full-time person. One commenter estimated that it would cost $41,600 annually to report source use at temporary job sites. Commenters also noted that due to the transitory nature of the temporary job sites, there may be no easy means of providing the information (i.e., no computer, no internet, fax, etc. at the remote locations). Commenters indicated that by the time the information was reported, it would no longer be valid as the source would already be at a new location. Commenters also pointed out that radiographers are required to maintain a utilization log for each source and that the logs are available for review by NRC or Agreement State inspectors.

Commenters stated that as long as the source remains in the possession of the licensee, there would be an appropriate level of security. Several commenters noted that they are under an immediate detection assessment and response order; therefore, they already need to know where their sources are, and are required to respond to and report any problem to the NRC. They indicated that reporting temporary job site transfers would not improve incident response time. Several commenters stated that the volume of reports generated on temporary job sites would inundate the system and would likely require more manpower at the NRC. Another commenter noted that the risk of error would be increased due to the amount of movement of the sources on a daily basis. One commenter stated that the meaningless information would compromise the integrity of the entire database. Lastly, several commenters suggested that instead of reporting transactions involving temporary job sites, a shorter (monthly or quarterly) source inventory verification period should be imposed.

Response: NRC has carefully considered the information provided by the commenters and has determined that temporary job site transactions should not be reported to the National Source Tracking System. Requiring reporting of temporary job site transfers would impose a

large additional burden on licensees without a corresponding benefit. The information would not be beneficial as it would likely be out of date by the time it was reported to the tracking system. Thus, States would not be able to use the information for checking what sources are within their borders because the sources would likely have been relocated before the data could be entered. As for requiring a more frequent reconciliation period instead of temporary job site reporting, the purpose of temporary job site reporting, if required, was not to provide verification that a licensee is still in possession of a source. A more frequent inventory reconciliation would impose a large burden without a corresponding benefit. NRC is not requiring the reporting of sources being transferred to temporary job sites to the National Source Tracking System.

D. Inspection of Waste Shipments

Waste brokers and disposal facilities are examples of licensees that might receive a nationally tracked source as part of a waste shipment. Because opening waste containers can result in unnecessary exposure for workers, these licensees typically do not open the containers to check contents, although a waste broker may open containers in order to consolidate shipments. After acceptance of a waste shipment, disposal facilities routinely move the container to the disposal area. The proposed rule did not require disposal facilities and waste brokers to verify the presence of the nationally tracked source in a waste container; they may rely on the verification of the licensee who shipped the source. Because there was to be no verification by the recipient that the source was in the waste container, NRC specifically invited comment on whether the waste broker or disposal facility should be required, at a minimum, to investigate the container for any indication of tampering. The inspection for tampering would provide additional assurance that the source was still in the container.

Six commenters provided input on this question, including two Agreement States. The comments on this issue were mixed. One commenter stated that one cannot assume the material is present and that verification of the presence of the source in the disposal container is necessary for an efficient tracking system. The commenter noted problems at several sites with trying to go back and determine exactly what happened to the material to be disposed. Two commenters supported some sort of verification but suggested the use of a tamper-proof seal for a visual indication of possible tampering with a container. Two commenters stated that the current system is adequate and that waste broker and disposal facilities should not be required to open the containers because it would subject workers to additional radiation exposure. The commenters also noted that the tamper proof seals currently required on transport containers provide sufficient indication that the source is still in the container. One commenter stated that due to ALARA considerations, content verification should be performed only once, with subsequent reliance on container tamper seals. The commenter suggested that two signatures be obtained to verify contents of the package before the seal is applied and that this would be the responsibility of the original licensee packaging the source.

Response: NRC has determined that no additional requirements are necessary for verifying waste shipments. NRC agrees that due to ALARA considerations waste brokers and disposal facilities should not open a container to verify the presence of a source. Licensees must incorporate a feature, such as a seal, that is not readily breakable and that, while intact, would be evidence that the package has not been opened by unauthorized persons. Licensees generally verify that the seal is intact before handling the container, and NRC does not believe that it is necessary to require such a practice. If this becomes a problem, NRC would consider imposing additional requirements.

E. Quality Assurance

The quality of the information reported to the National Source Tracking System is extremely important. While the proposed rule did contain a provision to correct errors within five days of discovery, there were no required pre-submission data quality checks. To address data quality assurance concerns, NRC specifically invited comment on a proposal to require licensees to double-check the accuracy of the data by using two independent checkers before submission of the transaction report. NRC sought information concerning whether the proposed quality assurance requirement was the appropriate requirement for quality assurance and if not, suggestions for appropriate requirements, and what additional burden a quality assurance requirement would impose on licensees.

Twelve commenters, including three Agreement States, addressed quality assurance in their comments. Two of the commenters were in favor of quality assurance requirements. One commenter stated that inclusion of a quality assurance provision on data submission would be a good idea if it could be managed electronically, but was opposed to a counter signature approach. The other commenter supported a quality assurance provision if the verification was limited to comparison with manufacturer-supplied data or manifests and confirmation of tamper seal integrity.

Ten commenters opposed adding additional quality assurance requirements. Several of the commenters stated that annual reconciliation should be adequate to ensure quality assurance. Several commenters stated that there is no reason to believe that the information provided by the shipper would not be accurate and that the validity of the information could be checked during inspection. Commenters also noted that some data quality assurance would occur when two parties are involved in a transaction; the recipient of a source verifies the data

when acknowledging receipt of a source. One commenter stated that mandating a second review is too prescriptive. The commenter noted that most companies have a quality assurance program and should be able to make the decision internally whether a second review is required. The commenter was not aware of any other regulation that specifically requires a quality assurance check prior to submission of data to the NRC.

Most of the commenters stated that requiring an independent check before data submission or any other requirement would impose a large financial burden on licensees, particularly smaller licensees. Commenters stated that for many small companies, resources are limited and personnel may not be available to conduct an additional check. Commenters noted that the requirement might necessitate the hiring of additional personnel. One commenter noted that if the quality control work was limited to confirming proper transcription of data, the burden would be about 30 minutes per transaction. One commenter noted that the inclusion of a quality assurance provision is no guarantee that an occasional error could not occur, and that the potential for error is reduced if the required recordkeeping and reporting are kept simple.

Response: NRC has decided not to impose additional quality assurance on the data submission. The large additional burden that would be imposed, particularly on small licensees, is not warranted. The source tracking system will have some built-in checks; for example, an alarm will be triggered if information submitted by the transferring company and the receiving company do not match. The annual reconciliation will also serve a quality assurance function. The inspection program will also be revised to include inspections related to the National Source Tracking System. In addition, information submitted to the National Source Tracking System must be complete and accurate in all material respects as required by NRC regulations

(for example, 10 CFR 30.9, 40.9, 50.9, 70.9, 76.9). If data quality becomes a problem, the NRC would consider imposing additional quality assurance requirements.

F. Data Protection

In the proposed rule, NRC specifically invited comment on whether designation of the information as Official Use only would provide sufficient protection of the information or whether to require licensees to protect the information that is reported to the National Source Tracking System and, if additional protection is necessary, at what level of protection. Six commenters addressed this topic and supported retaining the designation as Official Use Only. While commenters agreed that the data is sensitive, they did not recommend additional provisions to protect the data. Commenters were opposed to designating the data as Safeguards Information (SGI) and noted that designation of the data as SGI would be onerous to implement and could result in unintended restrictions on routine data. Commenters stated concern about protection of the aggregated information and recommended that additional protection measures be taken. One commenter stated the information should be excluded from public disclosure under 10 CFR 2.390.

Response: NRC has decided that no additional measures are necessary to protect the information possessed by individual licensees. The data does not meet the definition of SGI and will be designated as Official Use Only - Security-Related Information once it is submitted to the National Source Tracking System. The information will be treated in the same manner as other information designated as Official Use Only - Security-Related Information. A licensee will only have access to its information in the National Source Tracking System. Access for other persons, including NRC staff, will be on a need to know basis.

G. General

Comment G.1: One commenter stated that the proposed rule would make great strides towards assisting the metals industry in eliminating radioactive sources from the scrap feed stock because it provides better oversight, management, and stewardship of certain sealed sources. The commenter believes that the National Source Tracking System requirement will provide the NRC the necessary oversight to ensure that these sealed sources would be less likely to be managed in a way that could lead to their inadvertent or intentional disposal in the waste or the recycling streams.

Response: The commenter expresses general support for the rule, therefore, no response is necessary.

Comment G.2: One commenter objected to the statement that National Source Tracking "will provide greater source accountability which will foster increased control by licensees." The commenter indicated that the statement implies that the NRC believes that licensees have not been providing adequate accountability or control for these sources in the past. The commenter disagrees with this implication and cites the excellent record of licensees.

Response: The statement was not intended to imply that licensees have not historically provided adequate accountability and control over these sources. However, in today's threat environment, NRC has determined that enhanced controls are necessary to ensure the continued protection of these materials. National Source Tracking is one aspect of the

enhanced security program, and will provide NRC with information on what licensees actually possess verus what radioactive material they are authorized to possess.

Comment G.3: Two commenters stated that there is no need for a national source tracking system and another commenter stated that the rule is in excess. One commenter stated that the sources are already tracked by the respective NRC office or Agreement State via licensing and inspection, noting that licensees are required to inventory their material. The commenter stated that the source tracking system would add an additional layer of bureaucracy and would be a waste of money. The second commenter stated that the proposed rule would increase costs for licensees without improving the security of licensed material. The commenter stated that the NRC already possesses information through the existing regulatory framework on who manufactures, receives, transfers and disposes of sealed sources. One commenter suggested that if NRC wants to track sources it should be via the submission of quarterly inventories.

Response: NRC disagrees with the commenters. The Energy Policy Act of 2005 requires NRC to issue regulations for a mandatory source tracking system. Currently, sources are not tracked by either NRC or the Agreement States. Most licenses establish a maximum possession limit, but most do not list individual sources. While regulatory agencies know what material a licensee is authorized to possess, they may not know what that licensee actually possesses at its facility. While licensees are required to maintain an inventory of the radioactive materials that they possess, there is no requirement that they report their inventory to their regulatory agency, although inspectors may review the inventory listing as part of an

inspection. The National Source Tracking System will provide the NRC with the up-to-date information it needs to monitor the location of higher activity material; the submission of quarterly inventories would not be a sufficient tracking mechanism for these high-risk radioactive sources.

Comment G.4: One commenter stated that the proposed rule inappropriately references the IAEA Code of Conduct and suggests that the IAEA is asking for more than is already required in the present United States regulatory environment. The commenter expressed the belief that the United States regulatory framework for licensing already meets the IAEA requirements.

Response: NRC disagrees with the commenter. The United States Government has made a commitment to comply with the recommendations in the IAEA Code of Conduct, so it is appropriate for the proposed rule to reference the IAEA document. The IAEA Code of Conduct specifically recommends that Member States establish a national source registry, a mechanism that is not part of the current US regulatory framework.

Comment G.5: A commenter stated that the proposed regulation violates the Agreement between the Agreement States and the Federal government.

Response: NRC disagrees with the commenter. There is no violation of the Section 274b. Agreements between certain States and the NRC. The commenter did not provide any additional information on exactly what aspect of the proposed rule was in violation.

Promotion of the common defense and security is the basis for this rule and NRC has not relinquished that function to the Agreement States under Section 274b. of the Atomic Energy Act. Moreover, Section 274m. provides that no agreement made under Section 274b. shall affect the Authority of the Commission to issue rules, regulations, and orders to protect the common defense and security.

Comment G.6: One commenter pointed out that the statement identifying Category 3 sources as those that have 1/10th of the radioactivity of Category 2 sources is misleading. The commenter noted that Category 3 sources also includes sources that have radioactive levels right up to the bottom threshold of the Category 2 sources.

Response: The commenter is correct that Category 3 sources include sources that have activities up to the lower threshold of Category 2 sources. A Category 3 source is a source containing radioactive material equal to or greater than the Category 3 threshold (1/10th of the Category 2 threshold) but less than the Category 2 threshold.

Comment G.7: One commenter noted that the majority of sources that are lost or stolen every year are portable gauges, which are well below the Category 2 threshold, and that this rule would do nothing to help safeguard those sources.

Response: The commenter is correct that this rule does not cover portable gauges. NRC issued a final rule on the security of portable gauges on January 11, 2005 (70 FR 2001). The rule became effective on July 11, 2005.

Comment G.8: One commenter expressed support for the National Source Tracking System but stated that the system should meet the need to enhance the public health and safety as well as national security. Two Agreement States stated that the rule should be promulgated under health and safety and be classified as Compatibility Category B, particularly since it will be added to 10 CFR Part 20, which delineates the general radiation safety standards. They indicated that states should be responsible for inspection and enforcement of the National Source Tracking System to ensure licensee compliance with the rule.

Response: While NRC agrees that the National Source Tracking System will benefit the public health and safety, the rule is being issued under the Commission's authority to promote the common defense and security. The reporting provisions are being placed in 10 CFR Part 20 because Part 20 applies to all licensees.

Comment G.9: One commenter questioned the inclusion of several radionuclides. The commenter noted that Pu is already accounted for and licensed separately as special nuclear material and a national database would be redundant. The commenter also did not understand why Th-229 and Cf-252 were included in the System since not many of these sources exist outside of DOE that exceed the threshold. The commenter asked if there were any future plans to track all sources no matter the size. One commenter also stated that the sources (Ir-192) are ill suited for use in RDDs or REDs.

Response: Transfers of Pu are tracked in a separate database. However, the database is inventory based; individual sources are not reported, therefore, the database and the

National Source Tracking System are not redundant. Because the National Source Tracking System is to be a national system, it will include transactions from DOE facilities; therefore, radionuclides of concern to DOE need to be included. It is true that not many licensees actually possess these sources, so this provision does not impact many licensees. As stated in the Statements of Consideration of the proposed rule, NRC may consider expansion of the National Source Tracking System to include Category 3 sources at a later date (See Section A for further discussion of Category 3 sources). There are no plans to include other sources at this time. Ir-192 is included because it is listed in the Code of Conduct.

Comment G.10: A commenter questioned the benefit of having two categories of sources, besides adding unnecessary complexity to the regulation. The commenter noted that there are few differences between the requirements for Category 1 and Category 2 sources.

Response: The reporting requirements are identical for both Category 1 and Category 2 sources. However, the implementation date is different for the 2 categories. Future regulations codifying some of the NRC Orders may have different requirements for the two categories of sources.

Comment G.11: One State supported not only the inclusion of Category 3 sources but the inclusion of all non-exempt sources. The commenter supported the inclusion of non-exempt sources because of the view by emergency planners that any activity level of any radioactive material used in an RDD or RED would cause panic among the population.

Response: Lower activity sources are not considered likely to be used in an RDD or RED. Inclusion of all non-exempt sources would impose a huge burden on licensees and would likely overload the tracking system such that the effectiveness of the system would be reduced.

H Rule Language

Comment H.1: One commenter stated that manufacturers should only be required to report upon the transfer of sources. The commenter noted that sources are manufactured based on specific orders and that the sources are transferred quickly to the recipient (the same day or within a couple of days of each order). The commenter stated that requiring reporting of both the manufacture and the transfer of sources would impose an unnecessary burden on the manufacturer to enter the information twice. The commenter noted that entering data upon manufacture would not provide any useful information as that source would be shipped out and that the creation date is irrelevant in the context of tracking the locations of sources once they are in use.

Response: The manufacture date is the point of origin for the source, and is needed by the system to calculate decay of the source. A manufacturer may report both the manufacture of a new source and the transfer of the source in a single report, provided that the transfer occurs within the reporting timeframe of the manufacture and the licensee submits all information for both transactions. If the transfer occurs after the close of the next business day after the date of manufacture, the licensee must make two separate reports.

Comment H.2: Two Agreement States suggested that additional information should be collected on the transactions. The commenters stated that the information should include the state in which the source is located, the state to which a source is being transferred, and the state from which a source is transferred.

Response: The NRC agrees with the commenter. The information on the states involved in a transaction is part of the system. Licensees will provide the actual address (location of a facility) when establishing an account in the system. The final rule language has also been revised to add the address of the licensee as required information.

Comment H.3: One commenter stated that the rule was missing a transaction on recycling of sources, or disposal or disassembly of sources for recycling. The commenter noted that the disposal transaction does not adequately capture this activity because it requires a waste manifest number. The commenter noted that his company disassembled 1,809 Co-60 sources in the last year, and that these sources would have been tracked in the National Source Tracking System. The commenter noted that new sources were created out of the recovered Co-60. The commenter stated that this type of transaction should be treated similar to a disposal transaction but without a waste manifest number. The commenter provided draft rule language for consideration and also noted that NRC Form 748 would need to be revised to reflect the new transaction. Three commenters asked how remanufacturing (recycling) of sources would be handled. The commenters noted that when older sources are melted down and new sources are created, the unique serial number is lost. The commenters stated that the tracking system needs to be able to address this type of situation.

Response: The NRC agrees with the comments and has added a new transaction for disassembly of a source to the final rule. The rule requires a licensee that disassembles a source (for any reason) to report the transaction. This is an irreversible endpoint for the source within the tracking system. If the material is used to generate a new source, the licensee must report the generation as a new source manufacture. NRC Form 748 has been revised to add this new disassembly transaction.

Comment H.4: One commenter suggested that in the definition of Nationally Tracked Sealed Source, the term “permanently” should be deleted in the phrase “permanently sealed” because of recycling considerations.

Response: The NRC agrees with the commenter and the definition has been so revised.

Comment H.5: An Agreement State commented that June would be a bad month for academic licensees to conduct the required annual reconciliation of their data because school is out and some Radiation Safety Officers take summer vacation and thus would not be available to conduct the reconciliation. The commenter suggested September or October as alternatives.

Response: The month of June was selected in the proposed rule based on the proposed implementation date of the final rule. Because the implementation date of the final rule has changed, the reconciliation date has also changed. Reconciliation will be required in

the month of January each year. In determining a suitable time for reconciliation, NRC took into consideration the implementation date of the new reporting requirements, the academic calendar, and peak work periods for radiographers.

Comment H.6: Two commenters requested that the reporting timeframe of the close of the next business day be extended because it would be too stringent and might be hard to meet. Commenters requested that the timeframe be extended to three to five days. One commenter noted that one individual in each office, likely the Radiation Safety Officer, would be given the responsibility to make reports and that he/she might not always be available in that timeframe, particularly when there were a lot of other activities in the office. Another commenter noted that extending the reporting requirement to 5 business days would enable licensees involved in the transaction to verify that the transaction has been completed. One commenter stated that reporting by the close of the next business day would not be appropriate for Category 2 sources, but did not address Category 1 sources. The commenter believes the proposed reporting by the next business day requirement would be without value for enhancing the security of sources and responses to thefts and would be overly burdensome. The commenter noted that there are already requirements for immediate reporting of the loss or theft of a source and that reporting to the National Source Tracking System would not increase the physical security of the source or improve the response time of authorities in the event a source were stolen. One commenter suggested that instead of requiring reporting by the close of the next business day, that the NRC consider requiring licensees to maintain a record of the present location of the sources, make a monthly report of the movement of sources to ensure the national source registry is maintained, and to notify the planned recipient. The commenter

further suggested that the NRC expand the reporting requirements in 10 CFR § 20.2201 to require reporting within 24 hours when Category 1 or Category 2 sources in transit cannot be located.

Response: Although the Energy Policy Act of 2005 requires reporting a change in possession of a source within 7 days, the final rule requires reporting by the close of the next business day. The timing of reports was discussed within the Interagency Coordinating Committee and the conclusion was that allowing up to 7 days for reporting transactions was too long for reporting transactions. The Committee indicated that reporting should be by the close of the next business day. In addition, allowing a longer timeframe could create a situation in which the source recipient might report the receipt of a source before the sender of the source reports that the source had been transferred. NRC has determined that the close of the next business day is an appropriate timeframe for reporting.

Comment H.7: Two commenters suggested that rule language be added to specifically state that sources that decay below the Category 2 threshold values are automatically removed from the system and that no reporting would be required by licensees.

Response: Specific language is not needed in the rule text to incorporate the commenter's suggestion. A Nationally Tracked Source is defined in terms of Category 1 and Category 2 levels of any radioactive material listed in Appendix E. Once a source has decayed below the Category 2 threshold, by definition, it is no longer a nationally tracked source and is

not required to be reported to the National Source Tracking System. The data on the source will, however, be retained in the system.

Comment H.8: One commenter proposed that a leak test be required (or confirmed as current) prior to shipping any Category 1 or Category 2 source to ensure that if any source is leaking that it be identified at the point of origin as opposed to the point of receipt.

Response: Leak testing is beyond the scope of this rulemaking. Licensees are required to periodically conduct leak tests on sealed sources for health and safety reasons. For the purposes of National Source Tracking, leak tests are not necessary.

Comment H.9: One commenter requested clarification on whether the activity levels in the table (Appendix E) apply to the parent radionuclides and the daughter products or just to the parent radionuclides.

Response: The activities in the table do not include daughter products.

Comment H.10: One commenter stated that for some radionuclides, such as Pu, the amount should be reported in grams instead of activity units.

Response: The official threshold unit for the National Source Tracking System is Becquerels. However, the system will allow reporting in other units, including grams. The system will automatically conduct the conversion into Becquerels.

I. Regulatory Analysis

Comment I.1: A commenter stated that Option 1 (no action) in the Regulatory Analysis is more viable and should be given consideration because the tracking system will be very costly to the stakeholders with little or nothing being gained by the stakeholders.

Response: The NRC disagrees with the comment. Although the rule does impose some additional burden on licensees, the NRC believes that the information to be gained is valuable. In addition, the Energy Policy Act of 2005, signed into law after publication of the proposed rule, requires NRC to issue regulations establishing a mandatory system for national source tracking. The no action alternative is no longer a viable option.

Comment I.2: One commenter noted that the draft Regulatory Analysis shows approximately 93 percent of the cost being borne by the NRC. The commenter stated that since the NRC acquires its revenue through fees on licensees, all of the cost of the system will be borne by the licensees and would end up costing each licensee approximately $18,000 annually. Another commenter questioned where the money to pay for the system will come from, noting if there are to be fees associated with the database, this should be spelled out now.

Response: There are no direct fees associated with the National Source Tracking System. The cost of the system will be recovered through agency overhead. Beginning in fiscal year 2007, the cost of the National Source Tracking System will be off of the fee base. This means that the cost will not recovered through annual fees.

Comment I.3: One commenter questioned how the tracking system would improve public health.

Response: The Regulatory Analysis did not state that the tracking system would improve routine public health. The attribute discussed in the Regulatory Analysis is public health (accident/event) and the document stated that the tracking system would have a positive effect. The National Source Tracking System is discussed in terms of being a preventive measure and having the capability to avert potential health effects. The National Source Tracking System will provide regulators better information on where sources are located and who possesses them. Having this information should reduce the possibility that the material could be used in an RDD or RED. As other commenters have pointed out, the tracking system should also reduce the chance of sources being introduced into the scrap metal stream.

Comment I.4: One commenter stated that the draft Regulatory Analysis grossly underestimates the cost and time it will take for industry to comply with the new requirements. The commenter stated that the NRC did not include any cost or time in order for industry to put systems in place and that licensees will need to write specific computer programs to collect the information. The commenter stated that approximately 80 man hours would be need to implement the requirements of the new rule.

Response: It should not be necessary for most licensees to put any new systems in place or write computer programs in order to implement the rule. Licensees should already have the information required to be reported to the National Source Tracking System, and will

only need to log onto the system and enter their data. For those licensees that plan to use the electronic batch method, some computer programing may be necessary. The Regulatory Analysis has been revised to reflect this burden.

J. Implementation

Comment J.1: One commenter requested that industry be given adequate time to change procedures and conduct any necessary training before implementation of the rule. Another commenter requested guidance on the information technology aspects of implementing the system because it is going to take some effort to develop the process for electronic data downloads to the system. Commenters also requested information on when the workshops would be held.

Response: The provisions for reporting transactions are not effective for over 6 months from the publication date of the final rule. Licensees should have adequate time to train staff on new or revised procedures, if necessary. The information technology guidance will be made available prior to rollout of the system. The NRC will be holding licensee workshops before the rule's effective date. The dates for the workshops have not been set. NRC will give licensees ample notice once the dates and locations for the workshops have been determined.

Comment J.2: Three commenters stated that manufacturers typically ship newly manufactured sources the same day as their manufacture or within a day or two and that it would not make sense to then require the manufacture to reenter the data for transfer of the sources. The commenters suggested allowing one entry or form to cover both transactions.

Response: NRC will allow the use of the same form for those sources that are manufactured and shipped on the same day. Licensees will need to check both transactions on the form.

Comment J.3: One commenter noted that a big education campaign needs to be conducted for both licensees and Agreement States. The commenter noted the need for NRC and Agreement State compatibility and consistency in implementation and education. Commenters noted that implementation of the final rule will require extra effort to assure that Agreement State licensees are contacted and fully aware of the requirements of the rule.

Response: NRC agrees with the commenter on the need for training. Because this rule applies to both NRC and Agreement State licensees, there is no compatibility issue. Both NRC and Agreement State licensees will receive information on the final rule, including information on how to establish an account, and information on training. The initial contact list will be based on licensees in the interim database. NRC will also work with the Agreement States to make sure that all impacted licensees are reached. NRC will be sponsoring workshops for both NRC and Agreement State licensees. NRC will also hold training sessions for Agreement State staff.

Comment J.4: Three commenters asked how corrections of data would be handled, both electronically and by paper. The commenters noted that without some method of noting a correction, the corrected information might be treated as a double transaction.

Response: The paper form has been revised to include a box to check for corrections. Users will also be able to correct transactions electronically. Development of the system is not complete, but in general, a licensee will be able to access its data, pick a transaction or source and click on a screen that will allow revisions.

Comment J.5: One commenter requested information on who would have access to the database and to what extent. The commenter requested information on how the database will be used and how it would improve security of nationally tracked sources. The commenter requested an example of how the database would be used and when. One commenter stated that the low-level waste compacts should be allowed to have unqualified access to the data in the National Source Tracking System database because access would facilitate determining future regional needs for disposal of sources. The commenter further stated that access would facilitate the exportation from the compact region of devices for disposal and that records maintained by the compact would confirm occurrence of the transaction.

Response: Each licensee will have access to data on its own material and facility. 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. NRC will establish a procedure for handling requests from groups/agencies for data access. As stated in the Statement of Considerations for the proposed rule, the National Source Tracking System itself will not improve the physical security of these materials. The System may improve accountability of material and is part of the overall security program.

Comment J.6: One commenter asked whether a Radiation Safety Officer for a licensee with multiple locations in various NRC and Agreement States would have access to manage the information in the database for the various locations.

Response: Yes, a Radiation Safety Officer for multiple locations could arrange to have access to the information for all of the sites for which he/she is responsible. Access will be arranged during the setup of the account information for the licensee.

Comment J.7: Two commenters stated that there should be a provision to allow licensees to address multiple sources with a single transactional entry. The example provided is the 201 distinct sealed sources contained in a gamma knife. Each source is serialized sequentially and has nearly equal activities.

Response: Licensees will be able to report multiple sources that are serialized sequentially. The on-line and batch method will easily accommodate this action. Licensees using the paper forms will need to use the comment box to provide such data.

Comment J.8: One commenter stated that the NRC should consider the time and resources that will be needed for compliance with the rule. The commenter stated that the rule would require additional manpower and office equipment and place a significant financial burden on a healthcare delivery system already under stress. The commenter asked that NRC support efforts to lobby Congress, CMS, and private payers to increase funding for the delineated radionuclide procedures to alleviate the financial burden placed on medical

institutions. The commenter also asked that source tracking be postponed until such funding is secured.

Response: NRC acknowledges that the National Source Tracking System imposes additional burden on licensees required to report transactions to the system. NRC is taking measures to reduce the reporting burden. Licensees can report using several different mechanisms, with on-line and electronic reporting being the least burdensome. Licensees will not be required to invest in any additional equipment to make their reports. Most licensees already have computers and internet access. The request to lobby Congress and others is beyond the scope of the rulemaking.

Comment J.9: One commenter stated that the NRC should make a commitment to international harmonization on source tracking and take whatever steps are appropriate towards that goal before implementation of the tracking system. The commenter stated that harmonization is needed because tracking systems implemented by other countries need to work smoothly with NRC regulations if tracking systems are to be effective and efficient. The commenter stated that if implementation by all national authorities is based on a common set of definitions and operating principles, equitable trade opportunities will be maintained. Two commenters encouraged harmonization with other countries, specifically with Canada and the United Kingdom, to ensure a compatible web interface and data format. Another commenter stated that it is imperative that all countries implement national source tracking consistently and in the same time-frame, otherwise the rule will be only partly effective as tracking could be lost

once sources are exported out of the United States. One commenter noted that if the tracking methods are identical information could be sent to both countries simultaneously.

Response: The source tracking system is a domestic system and should have no impact on trade opportunities with foreign countries. The system is not intended to track sources once they are exported out of the United States. NRC staff has met with Canadian officials to discuss source tracking. NRC staff has also attended international meetings to discuss Code of Conduct implementation, including source tracking. The import/export notifications are not part of this rulemaking.

Comment J.10: One commenter stated that the paper forms for reporting transactions are dysfunctional. The commenter stated that shipment of multiple sources would require the completion of multiple forms and would take several hours to complete. The commenter stated that the forms cannot be used in their current format and should be revised.

Response: The commenter did not provide any specifics as to the deficiencies with the form or make any suggestions for improvement. If a licensee chooses to use the paper form, it will be limited in the number of sources that can be included on the form; the size of the form is limited. Instead of filing multiple forms, the licensee could attach an addendum sheet that lists all of the sources for a transaction. The licensee would simply need to add a note to the comment section that states “see addendum for additional sources.” The NRC has revised the instructions for the form to explain this option. For reports made online, there will be no limit to the number of sources that can be included in a single transaction report.

Comment J.11: One commenter urged the NRC to combine the reporting required under the import/export final rule (70 FR 37985; July 1, 2005) with the reporting required under this rule. The commenter stated that it would be redundant for a licensee to notify the NRC twice of every international shipment and would add an undue and unnecessary paperwork burden.

Response: The initial deployment of the National Source Tracking System will not have the capability to allow licensees to report the notification information required by the import/export final rule. The System will provide this capability in a later deployment.

Comment J.12: One commenter stated that the NRC should expand its use of electronic systems for data reporting to include reporting required by the security orders to help reduce duplicative reporting. The commenter also advocated use of one central database for all notifications. Other commenters stated that NRC needs to perform a comprehensive review of all the various Orders and regulations that have been issued and proposed over the last two years to address any inconsistencies and duplication. One commenter stated that licensees are required to provide increased controls/security measures for the receipt, transfer and movement of sources and therefore the rule is repetitive.

Response: NRC disagrees that the rule is repetitive with the increased controls/security measures for the receipt transfer and movement of sources. The increased controls/security measures do not require transaction reporting to NRC and the NRC is not aware of any duplication in the measures and this rule. NRC is not aware of any inconsistencies related to

this rulemaking and the various Orders, increased controls or security measures. The other comments are beyond the scope of this rulemaking.

Comment J.13: One commenter asked how the NRC is going to assure that all licensees enter data as required. The commenter asked what would be done if the recipient does not enter data and the initial shipper subsequently receives information that the source has decayed below the reporting threshold.

Response: Data entry for the National Source Tracking System is subject to inspection. If licensees are not reporting data as required, NRC can take enforcement action. The system will have built-in features that will trigger an alarm for mis-matched transactions. The system will not catch situations in which both sides of the transaction have failed to report, however, these transaction should be captured and corrected during the annual reconciliation process. In addition, licensees reporting to the National Source Tracking System are subject to requirements in NRC regulations (for example, 10 CFR 30.9) that information provided to the NRC shall be complete and accurate in all material respects.

K. System Aspects

Comment K.1: One commenter suggested that the National Source Tracking System should be operated as a separate and independent system under the current Nuclear Materials Management and Safeguards System (NMMSS). The commenter stated that this would result in significantly lower costs for system development and operation, improved quality of the information, and less burden on licensees.

Response: This comment is beyond the scope of this rulemaking. This rulemaking establishes the reporting requirements for the National Source Tracking System. The actual database development and operation is not conducted though rulemaking; the NRC will obtain the system through a formal procurement process.

Comment K.2: A Federal agency requested that the NRC work jointly with it on a data sharing format to allow them and other agencies to use National Source Tracking System data. The commenter stated that agencies across the Federal government should have the opportunity to leverage the data collected by extracting other information useful to the American public, thereby representing potential benefits to government agencies and the American public.

Response: An Interagency Coordinating Committee was formed to address these and other issues. Other agencies will be allowed access to the data on a need to know basis. NRC, in conjunction with the Interagency Coordinating Committee, will develop a procedure for handling requests for data access

Comment K.3: One commenter requested information on how the database information would be safeguarded from computer hackers. The commenter stated that if a terrorist gained access to the database, they would have access to a listing of all the large sources. Therefore, the commenter believes that a national database actually reduces national safety instead of improving it.

Response: NRC shares the commenter's concern about computer security. The National Source Tracking System will receive security accreditation before it can be used. The security information for the system will not be made publicly available.

Comment K.4: One commenter suggested that the source tracking notification system should include an automatic e-mail notification when a sender designates a specific licensee in a transfer entry as this would allow rapid identification of errors in the system at the time of transfer.

Response: The source tracking system will have some automatic notification features that will be designed to reduce errors.

Comment K.5: Three commenters noted that NRC should have interactions with the users of the system prior to the demonstration workshops that are planned. In addition, commenters stated that NRC should establish a users group composed of a cross-section of members of the affected community to develop the formats, input means, and reports that will be available through the system. The commenter stated that this will assure that the system is user-friendly while still meeting NRC's needs. One commenter stated that representatives of the industry must be part of the design team and that this will provide an opportunity to review the specifications for the system to understand how the web interface will operate and what kind of 'machine readable' data format will be used. Another commenter noted that NRC needs to pay attention to the human side of the database to avoid chaos with the data collection.

Response: NRC plans to have interactions with stakeholders during development of the format for the electronic batch files. The names of those licensees that have expressed interest in participating will be provided to NRC staff involved in system development. The NRC will consider the suggestion that industry representatives participate on the design team.

Comment K.6: One commenter stated that as written the rule would be extremely burdensome for both licensee and regulators. The commenter stated that NRC does not fully understand the undertaking of this rule. The commenter encouraged NRC to work with the industry in the implementation of the rule and the development of the web-based system.

Response: Although the rule does pose additional burden on licensees and NRC, the burden is not extreme. The source tracking system is an important national initiative that justifies the burden and is in fact required by statute (the Energy Policy Act of 2005). NRC has a clear understanding of the implications of this rule for both industry and NRC. (See also response to K.5.)

Comment K.7: One commenter suggested that NRC should be required to provide a unique tracking number for each source in the tracking system.

Response: The National Source Tracking System uses a combination of the manufacturer, model number, and manufacturer assigned serial number to identify the sources. The system will assign a unique number for each source entered in the system.

L. Miscellaneous

Comment L.1: One commenter requested clarification on whether the proposed rule covers transactions involving devices returned to the manufacturer for long term disposal.

Response: The rule covers all Category 1 and Category 2 sources in the possession of either NRC or Agreement State licensees, regardless of whether they are being actively used or are in long term storage. The rule covers the source within the device and not the device itself.

Comment L.2: A commenter stated that they could not find the basis for the limits (thresholds) in the IAEA Code of Conduct. The commenter stated that the values seemed random or arbitrary, specifically the limits for americium, Th-229, and Ir-192. The commenter further questioned the addition of several short-lived radionuclides (Ir-192, Se-75, and Yb-169) and stated that tracking these materials was neither prudent nor practical.

Response: As stated in the Statements of Consideration for the proposed rule, IAEA-TECDOC-1344 entitled “Categorization of Radioactive Sources” provides the underlying methodology for the development of the Code of Conduct thresholds. TECDOC-1344 is now RS-G-1.9. The categorization system is based on the potential for sources to cause deterministic effects and uses the ‘D’ values as normalizing factors. The ‘D’ values are radionuclide-specific activity levels for the purposes of emergency planning and response. The same methodology was used for all of the radionuclides.

Comment L.3: The commenter stated that regulations that focus on the transportation of Category 1 and Category 2 sources would be more appropriate.

Response: Transportation requirements are beyond the scope of this rulemaking.

Comment L.4: One commenter objected to the National Source Tracking System automatically delisting and no longer tracking sources at the point at which they decay below Category 2 levels. The commenter noted that many licensees may believe that their management responsibilities also cease when the source decays below the Category 2 threshold, which could result in more Category 3 sources ending up in the scrap or the recycling streams.

Response: Licensees are responsible for the safety and security of all radioactive material in their possession, regardless of activity level. Both NRC and the Agreement States have inspection programs to ensure that licensees operate within the bounds of their licenses. The National Source Tracking System only includes information on Category 1 and Category 2 sources. Once a source decays below the Category 2 threshold, the source is no longer a Category 2 source and the reporting requirements no longer apply. However, historical data on the source is not automatically deleted and will be retained by the system.

Comment L.5: Commenters noted that the Security Orders require notification of the end user of a shipment of a Category 2 source and verification of the arrival of the source, therefore, a mechanism is already in place that says the transition took place.

Response: It is correct that notification and verification requirements have been imposed on some licensees possessing Category 1 and/or Category 2 sources. However, the information is not reported to the NRC. Without the tracking system, the NRC would not have information on what sources a licensee actually possesses.

Comment L.6: One commenter noted that there are some differences between how other countries are implementing similar regulations. The commenter stated that the European Union has the High-Activity Sealed Source (HASS) directive, which has different quantities that need to be reported. The Commenter indicated that the NRC needs to look at this closely.

Response: From an international perspective, it may be desirable for all countries to implement regulations in a similar manner; however, the National Source Tracking System is a domestic tracking system. That said, the NRC does try to keep abreast of what other countries are doing. The European Union (EU) directive only applies to transfers within the bounds of the EU countries.

Comment L.7: One commenter noted that some of the countries from which they obtain material will not be providing them the specific serial numbers for the sources in advance. The commenter states that it will be difficult to track the material before it is in their possession.

Response: This final rule does not require licensees to report any information on sources that are imported until the sources are received at the licensee's facility. The import/export rule (70 FR 37985; July 1, 2005) does require importers to provide NRC

notification of imports. The notification requirements do include the serial number of the source, if available.

Comment L.8: One commenter suggested that a possession threshold amount be established that, if exceeded, would trigger tracking requirements in order to avoid an undue burden on community medical facilities that only possess very small quantities of the lower activity sources.

Response: A threshold possession limit does not work for an item-level tracking system. Sources would move in and out of the system depending on how much a particular licensee possessed at a site. A threshold that applies to all licensees is the appropriate method for tracking these sources and is how the National Source Tracking System will operate.

Comment L.9: Two commenters stated that aggregation should not be considered and thresholds for source tracking should be based solely upon the Category 1 and Category 2 limits for each source. The commenter noted that including sources because a licensee possesses a total number of sources that could exceed some arbitrary threshold would generate a great deal of confusion and not add to the security or control of materials. Total limits for sources in possession by licensees should be regulated by their individual licenses and not by the National Source Tracking System. Another commenter stated that clarification is needed to make it clear that the tracking system is for unique Category 1 or 2 sources and that a licensee's possession limit is not impacted by the rule.

Response: NRC agrees with these comments. The proposed rule and this final rule do not contain reporting requirements based on aggregation of sources and the NRC has no plans to include such requirements on aggregation for the tracking system in the future. A specific threshold has been established and all sources at or above the threshold must be reported, regardless of a licensee's total possession. The threshold currently is Category 2. The National Source Tracking System does not affect possession limits.

Comment L.10: Four commenters asked for clarification on decay and how decay of sources is handled as they go through the system and fall below the Category 2 threshold for tracking. Commenters requested information on how the tracking system will reconcile the transition. One commenter stated that reclassification of a source from Category 1 to Category 2 due to decay should be recorded in the system. Three commenters stated that the system should automatically generate a notice when a source moves from a Category 1 to a Category 2 and when it decays below Category 2.

Response: Decay of sources will automatically be calculated by the system based on the reported manufacture date or reported activity date. Once a source has decayed below the Category 2 threshold, it is no longer considered a nationally tracked source. A licensee will no longer be required to report transactions involving what is now considered a Category 3 source. The source status will be automatically changed from an active source to a decayed source, and the information on that source will be retained by the system. The licensee will be automatically notified that transactions on the source no longer need to be reported because the source has decayed below the threshold. The system will reclassify a source from

Category 1 to Category 2 when it has decayed below the Category 1 threshold. However, no notifications are necessary because the reporting requirements are the same for Category 1 and Category 2 sources.

Comment L.11: One commenter requested clarification on whether licensees will be required to reconstruct the inventory each year for the annual reconciliation and verification.

Response: No, the NRC does not expect licensees to conduct a physical inventory as part of the reconciliation process. The expectation is that the inventory listing in the database will be compared to the inventory listing for the site and the licensee will either report that the database listing is correct or submit corrections as needed.

Comment L.12: Three commenters noted that the tracking system will need to accommodate data entries for sources that are imported into this country which were manufactured and exported before the rule went into effect.

Response: The reporting of the initial inventory for each licensee should account for all Category 1 and Category 2 sources in a licensee's possession. The origin of the source does not matter. NRC does not expect licensees to reconstruct a source's history. If a source is imported back to the United States, the source will be added to the system at that time.

Comment L.13: One commenter stated that source transfers (including permanent transfers) between the same company but under different licenses should not be reported.

Response: NRC disagrees with the commenter. Permanent transfers of sources do need to be reported. Transfers between temporary job sites do not need to be reported.

Comment L.14: One commenter supported the assignment of unique serial numbers. The commenter stated that assignment of unique serial numbers is critical to ensure that the sources are properly managed throughout their use and at the end of their useful life.

Response: No response is necessary.

Comment L.15: One commenter stated that NRC should clarify whether the unity rule applies to an individual source with multiple radionuclides.

Response: The unity rule does not apply to sources under the National Source Tracking System. Reporting is based on the activity level of the individual radionuclides in a source with multiple radionuclides. The sum of the fractions of each radionuclide does not need to be applied to the source.

Comment L.16: Three commenters asked for clarification on how NRC plans to handle changes in serial numbers that occur when a source is installed into a source holder. The commenters noted that sources used in the oil and gas industry have serial numbers that are assigned by the manufacturer. However, after the source is permanently installed into a protective pressure vessel, the source holder is given a different serial number consistent with the end-users nomenclature. The source is then tracked by the source holder serial number.

The commenters recommended that the national source registry allow for these serial number changes in the life of a source. One of the commenters stated that NRC should be clear on the specific serial number that is tracked throughout the entire lifetime of a source.

Response: The National Source Tracking System tracks a source using the manufacturer's assigned serial number in combination with the manufacturer and model number. An optional reporting element is a device serial number. On the paper form, the device number can be added to the comment field. A licensee will be able to search (on-line) its own data by device number as well as the source number.

Comment L.17: One commenter stated that the rule should address any potential SGI conflicts when sources are shipped as part of a Radioactive Material Quantities of Concern (RAMQC) shipment.

Response: The NRC has reviewed the RAMQC requirements and has not identified any conflicts.

IV. Section by Section Analysis of Substantive Changes

§ 20.1003 Definitions.

A definition of nationally tracked sources is added to the regulations.

§ 20.2207 Reports of transactions involving nationally tracked sources.

A new section is added to the regulations to require licensees to report to the National Source Tracking System transactions involving nationally tracked sources. Paragraph (a) requires the reporting of the manufacture of a nationally tracked source. Paragraph (b) requires the reporting of all transfers of nationally tracked sources to another authorized facility. Paragraph (c) requires the reporting of all receipts of a nationally tracked source. The final rule includes a new transaction for reporting disassembly of a nationally tracked source, this new requirement is in paragraph (d). Paragraph (e) requires the reporting of the disposal of any nationally tracked source. Each of these paragraphs requires the licensee to report specific information for the transaction, including source information such as the manufacturer, model, serial number, radioactive material, activity and activity date. The licensee must also provide the facility name, license number, name of the individual that prepared the report, and the transaction date. The final rule also requires reporting the address of the reporting licensee. If the transaction involves the use of the Uniform Low-Level Radioactive Waste Manifest, the licensee needs to report the waste manifest number and the container identification for the container with the source.

Paragraph (f) requires licensees to report these transactions to the National Source Tracking System by the close of the next business day. The regulations allow the licensee to report the transactions either on-line, electronically using a computer-readable format, by facsimile, by mail, or by telephone.

Paragraph (g) requires each licensee to correct any error in a previously filed report or file a new report for a missed transaction within 5 business days of the discovery of the error or missed transaction. Each licensee is also required to reconcile and verify the information in the National Source Tracking System during the month of January each year. This process

involves comparing the inventory information contained in the National Source Tracking System to the actual inventory possessed by the licensee. The amendment requires any discrepancies to be resolved by filing the reports identified by paragraphs (a) through (e) described above. The final rule clarifies that once the reconciliation is complete, licensees must submit confirmation that the data in the National Source Tracking System is correct. The reconciliation month has been changed from June to January in the final rule.

Paragraph (h) requires a licensee to report its initial inventory of Category 1 nationally tracked sources by March 15, 2007, and the inventory of Category 2 nationally tracked sources by March 30, 2007. These dates have been changed from the proposed rule. Source information such as the manufacturer, model, serial number, radioactive material, activity and activity date must be included. The licensee also needs to provide the facility name, license number, address, and name of the individual that prepared the report.

Appendix E Nationally Tracked Source Thresholds.

A new Appendix is added to Part 20 that provides the thresholds for nationally tracked sources at the Category 1 and Category 2 levels. Radium-226 has been added to the Appendix and Pu-236, Pu-239, and Pu-240 have been deleted from the Appendix. 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 practical usefulness only and are rounded after conversion. The curie values are not intended to be the regulatory standard.

§ 32.2 Definitions.

A definition of nationally tracked sources is added to the regulations.

§ 32.201 Serialization of nationally tracked sources.

A new section is added that requires manufacturers of nationally tracked sources to assign a unique serial number to each nationally tracked source that is manufactured after the effective date of the rule.

§ 150.3 Definitions

A definition of nationally tracked sources is added to the regulations.

§150.15 Persons not exempt

A new section is added that requires source manufacturers licensed by Agreement States to assign a unique serial number for each nationally tracked source that is manufactured after the effective date of the rule.

§ 150.18 Submission to Commission of nationally tracked source transaction reports.

A new section is added to the regulations to require Agreement State licensees to report to the National Source Tracking System all transactions involving nationally tracked sources. Paragraph (a) requires the reporting of the manufacture of a nationally tracked source. Paragraph (b) requires the reporting of all transfers of nationally tracked sources to another authorized facility. Paragraph (c) requires the reporting of all receipts of a nationally tracked source. The final rule includes a new transaction for reporting disassembly of a nationally

tracked source, this new requirement is in paragraph (d). Paragraph (e) requires the reporting of the disposal of any nationally tracked source. Each of these paragraphs requires the licensee to report specific information for the transaction, including source information such as the manufacturer, model, serial number, radioactive material, activity and activity date. The licensee must also provide the facility name, license number, name of the individual that prepared the report, and the transaction date. The final rule also requires reporting the address of the reporting licensee. If the transaction involves the use of the Uniform Low-Level Radioactive Waste Manifest, the licensee needs to report the waste manifest number and the container identification for the container with the source.

Paragraph (f) requires licensees to report these transactions to the National Source Tracking System by the close of the next business day. The regulations allows the licensee to report the transactions either on-line, electronically using a computer-readable format, by facsimile, by mail, or by telephone.

Paragraph (g) requires each licensee to correct any error in a previously filed report or file a new report for a missed transaction within 5 business days of the discovery of the error or missed transaction. Each licensee is also required to reconcile and verify the information in the National Source Tracking System during the month of January each year. This process involves comparing the inventory information contained in the National Source Tracking System to the actual inventory possessed by the licensee. The amendment requires any discrepancies to be resolved by filing the reports identified by paragraphs (a) through (e) described above. The final rule clarifies that once the reconciliation is complete, licensees must submit confirmation that the data in the National Source Tracking System is correct. The reconciliation month has been changed from June to January in the final rule.

Paragraph (h) requires a licensee to report its initial inventory of Category 1 nationally tracked sources by March 15, 2007, and the inventory of Category 2 nationally tracked sources by March 30, 2007. These dates have been changed from the proposed rule. Source information such as the manufacturer, model, serial number, radioactive material, activity and activity date must be included. The licensee also needs to provide the facility name, license number, address, and name of the individual that prepared the report.

V. Criminal Penalties

For the purpose of Section 223 of the Atomic Energy Act (AEA), the Commission is amending 10 CFR Parts 20, 32, and 150 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, the final rule is classified as Compatibility Category "NRC." The NRC program elements in this category are those that relate directly to areas of regulation reserved to the NRC by the Atomic Energy Act of 1954, as amended (AEA), or the provisions of Title 10 of the Code of Federal Regulations. Although an Agreement State may not adopt program elements reserved to NRC, it may wish to inform its

licensees of certain requirements via a mechanism that is consistent with the particular State's administrative procedure laws but does not confer regulatory authority on the State.

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 requires licensees that possess, manufacture, transfer, receive, disassemble, or dispose of nationally tracked sources to report the information relating to such transactions to the National Source Tracking System. This action does not constitute the establishment of a standard that contains generally applicable requirements.

VIII. Environmental Impact: Categorical Exclusion

The NRC has determined that this final rule is the type of action described as a categorical exclusion in 10 CFR 51.22(c)(1) for the changes to Part 150 and as described in 10 CFR 51.22(c)(3)(iii) for the changes to Parts 20 and 32. Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this final rule.

IX. Paperwork Reduction Act Statement

This final rule contains new or amended information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These requirements were approved by the Office of Management and Budget, approval numbers 3150-0014, 3150-0001, and 3150-0032 and 3150-xxxx.

The burden to the public for these information collections is estimated to be 11,604 hours (NRC Form 748 - 421 hours [an average of 10 minutes per response] plus an annualized one time burden of 5,333 hours [80 hours for 67 recordkeepers]; 10 CFR 20 - 467 hours [1 hour per response]; 10 CFR 32 - 450 hours [45 hours per recordkeeper]; 10 CFR 150 - 1333 hours [1 hour per response] plus an annualized one-time burden of 2,664 hours [8 hours for 333 recordkeepers]), 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 Internet electronic mail to INFOCOLLECTS@NRC.GOV; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0014, 3150-0001, and 3150-0032), Office of Management and Budget, Washington, DC 20503.

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

The largest burden would likely fall on the manufacturers and distributors of nationally tracked sources because they will have the most transactions to report. The NRC believes that by allowing batch loading of information using a computer-readable format, the burden on the high transaction licensees is reduced. The present value of the costs of the National Source Tracking System to the NRC is estimated to be $29.4 million and to industry is estimated to be $3.9 million in 2006 dollars using a 3 percent discount rate. These estimated costs include the cost of development of the system and operation and maintenance through the year 2016.

The analysis is available for inspection in the NRC Public Document Room, 11555 Rockville Pike, Rockville, MD. Single copies of the regulatory analysis are available from Merri Horn, telephone (301) 415-8126, e-mail, mlh1@nrc.gov of the Office of Nuclear Material Safety and Safeguards.

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.

On the basis of information available to the Commission when the proposed rule was published, the Commission certified that the proposed rule, if adopted, would not have a significant impact on a substantial number of small entities. The Commission invited any small entity that determined that it is likely to bear a disproportionate economic impact because of its size to notify the Commission.

The Commission did not receive any comments on the impact to small entities. The final rule affects about 350 NRC licensees and an additional 1,000 Agreement State licensees. Examples of 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 is not expected to have a significant economic impact on these licensees.

The total time required by a licensee to complete each National Source Tracking Transaction report is estimated to be approximately 15 minutes, depending on the number of sources involved in the transaction and the method of reporting. This is time needed to complete the report. No research or compilation is necessary as all information is transcribed from bills of lading, in-house records kept for other purposes, sales agreements, etc. Each licensee would also spend on average 1 hour on the annual reconciliation. The total annual burden to perform the proposed reporting is approximately 11,604 hours. Based on the

regulatory analysis conducted for this action, the costs of the amendments for affected licensees are estimated to be $3.9 million total or on average about $2,889 per affected licensee. The NRC believes that the selected alternative reflected in the amendment is the least burdensome, most flexible alternative that would accomplish the NRC's regulatory objective.

XII. Backfit Analysis

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

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 Subjects

10 CFR Part 20

Byproduct material, Criminal penalties, Licensed material, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Packaging and containers,

Radiation protection, Reporting and recordkeeping requirements, Source material, Special nuclear material, Waste treatment and disposal.

10 CFR Part 32

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

10 CFR Part 150

Criminal penalties, Hazardous materials transportation, Intergovernmental relations, Nuclear materials, Reporting and recordkeeping requirements, Security measures, Source material, Special nuclear material.

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, 32, and 150.

PART 20 --STANDARDS FOR PROTECTION AGAINST RADIATION

1. The authority citation for Part 20 is revised 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), Energy Policy Act of 2005, Pub. L. No. 109-58, 119 Stat. 594 (2005).

2. In § 20.1003, a new definition *Nationally tracked source* is added in alphabetical order to read as follows:

§ 20.1003 Definitions.

* * * * *

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

* * * * *

3. In § 20.1009 paragraph (b) is revised and paragraph (c)(6) is added to read as follows:

§20.1009 Information collection requirements: OMB approval.

* * * * *

(b) The approved information collection requirements contained in this part appear in §§ 20.1003, 20.1101, 20.1202, 20.1203, 20.1204, 20.1206, 20.1208, 20.1301, 20.1302, 20.1403, 20.1404, 20.1406, 20.1501, 20.1601, 20.1703, 20.1901, 20.1904, 20.1905, 20.1906, 20.2002, 20.2004, 20.2005, 20.2006, 20.2102, 20.2103, 20.2104, 20.2105, 20.2106, 20.2107, 20.2108, 20.2110, 20.2201, 20.2202, 20.2203, 20.2204, 20.2205, 20.2206, 20.2207, 20.2301, and appendix G to this part.

(c) * * *

(6) In § 20.2207, NRC Form 748 is approved under control number 3150-xxxx.

4. Section 20.2207 is added under Subpart M to read as follows:

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

Each licensee who manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report (NRC Form 748) as specified in paragraphs (a) through (e) of this section for each type of transaction.

(a) Each licensee who manufactures a nationally tracked source shall complete and submit a National Source Tracking Transaction Report (NRC Form 748). The report must include the following information:

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

(2) The name of the individual preparing the report;

(3) The manufacturer, model, and serial number of the source;

(4) The radioactive material in the source;

(5) The initial source strength in becquerels (curies) at the time of manufacture; and

(6) The manufacture date of the source.

(b) Each licensee that transfers a nationally tracked source to another person shall complete and submit a National Source Tracking Transaction Report (NRC Form 748). The report must include the following information:

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

(2) The name of the individual preparing the report;

(3) The name and license number of the recipient facility and the shipping address;

(4) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

(5) The radioactive material in the source;

(6) The initial or current source strength in becquerels (curies);

(7) The date for which the source strength is reported;

(8) The shipping date;

(9) The estimated arrival date; and

(10) For nationally tracked sources transferred as waste under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification of the container with the nationally tracked source.

(c) Each licensee that receives a nationally tracked source shall complete and submit a National Source Tracking Transaction Report (NRC Form 748). The report must include the following information:

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

(2) The name of the individual preparing the report;

(3) The name, address, and license number of the person that provided the source;

(4) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

(5) The radioactive material in the source;

(6) The initial or current source strength in becquerels (curies);

(7) The date for which the source strength is reported;

(8) The date of receipt; and

(9) For material received under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification with the nationally tracked source.

(d) Each licensee that disassembles a nationally tracked source shall complete and submit a National Source Tracking Transaction Report (NRC Form 748). The report must include the following information:

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

(2) The name of the individual preparing the report;

(3) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

(4) The radioactive material in the source;

(5) The initial or current source strength in becquerels (curies);

(6) The date for which the source strength is reported;

(7) The disassemble date of the source.

(e) Each licensee who disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report (NRC Form 748). The report must include the following information:

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

(2) The name of the individual preparing the report;

(3) The waste manifest number;

(4) The container identification with the nationally tracked source.

(5) The date of disposal; and

(6) The method of disposal.

(f) The reports discussed in paragraphs (a) through (e) of this section must be submitted by the close of the next business day after the transaction. A single report may be submitted for multiple sources and transactions. The reports must be submitted to the National Source Tracking System by using:

(1) The on-line National Source Tracking System;

(2) Electronically using a computer-readable format;

(3) By facsimile;

(4) By mail to the address on the National Source Tracking Transaction Report Form (NRC Form 748); or

(5) By telephone with followup by facsimile or mail.

(g) Each licensee shall correct any error in previously filed reports or file a new report for any missed transaction within 5 business days of the discovery of the error or missed transaction. Each licensee shall reconcile the inventory of nationally tracked sources possessed by the licensee against that licensee's data in the National Source Tracking System. The reconciliation must be conducted during the month of January in each year. The reconciliation process must include resolving any discrepancies between the National Source Tracking System and the actual inventory by filing the reports identified by paragraphs (a) through (e) of this section. By January 31 of each year, each licensee must submit to the National Source Tracking System confirmation that the data in the National Source Tracking System is correct.

(h) Each licensee that possesses Category 1 nationally tracked sources shall report its initial inventory of Category 1 nationally tracked sources to the National Source Tracking System by March 15, 2007. Each licensee that possesses Category 2 nationally tracked sources shall report its initial inventory of Category 2 nationally tracked sources to the National Source Tracking System by March 30, 2007. The information may be submitted by using any

of the methods identified by paragraph (f)(1) through (f)(4) of this section. The initial inventory report must include the following information:

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

(2) The name of the individual preparing the report;

(3) The manufacturer, model, and serial number of each nationally tracked source or, if not available, other information to uniquely identify the source;

(4) The radioactive material in the sealed source;

(5) The initial or current source strength in becquerels (curies); and

(6) The date for which the source strength is reported.

5. In Part 20, new Appendix E is added to read as follows:

APPENDIX E TO PART 20 - NATIONALLY TRACKED SOURCE THRESHOLDS

The Terabecquerel (TBq) values are the regulatory standard. The curie (Ci) values specified are obtained by converting from the TBq value. The curie values are provided for practical usefulness only and are rounded after conversion.

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

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

6. The authority citation for Part 32 is revised 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), Energy Policy Act of 2005, Pub. L. No. 109-58, 119 Stat. 594 (2005).

7. In § 32.2, the paragraph designations are removed and a new definition *Nationally tracked source* is added in alphabetical order to read as follows:

***§* 32.2 Definitions**.

* * * * *

Nationally tracked source is a sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels 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 sealed in a capsule or closely bonded, in a solid form and which is not exempt from regulatory control. It does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet. Category 1 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 1 threshold. Category 2 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 2 threshold but less than the Category 1 threshold.

8. In § 32.8, paragraph (b) is revised to read as follows:

§ 32.8 Information collection requirements: OMB approval.

* * * * *

(b) The approved information collection requirements contained in this part appear in §§ 32.11, 32.12, 32.14, 32.15, 32.16, 32.17, 32.18, 32.19, 32.20, 32.21, 32.21a, 32.22, 32.23, 32.25, 32.26, 32.27, 32.29, 32.51, 32.51a, 32.52, 32.53, 32.54, 32.55, 32.56, 32.57, 32.58, 32.61, 32.62, 32.71, 32.72, 32.74, 32.201, and 32.210.

* * * * *

9. Section 32.201 is added under Subpart D to read as follows:

Subpart D--Specifically Licensed Items

§ 32.201 Serialization of nationally tracked sources.

Each licensee who manufactures a nationally tracked source after **[INSERT DATE 90 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]** shall assign a unique serial number to each nationally tracked source. Serial numbers must be composed only of alpha-numeric characters.

PART 150--EXEMPTIONS AND CONTINUED REGULATORY AUTHORITY IN AGREEMENT STATES AND IN OFFSHORE WATERS UNDER SECTION 274

10. The authority citation for Part 150 is revised to read as follows:

AUTHORITY: Sec. 161, 68 Stat. 948, as amended, sec. 274, 73 Stat. 688 (42 U.S.C. 2201, 2021); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note). Sections 150.3, 150.15, 150.15a, 150.31, 150.32 also issued under secs. 11e(2), 81, 68 Stat. 923, 935, as amended, secs. 83, 84, 92 Stat. 3033, 3039 (42 U.S.C. 2014e(2), 2111, 2113, 2114). Section 150.14 also issued under sec. 53, 68 Stat. 930, as amended (42 U.S.C. 2073). Section 150.15 also issued under secs. 135, 141, Pub. L. 97-425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161). Section 150.17a also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Section 150.30 also issued under sec. 234, 83 Stat. 444 (42 U.S.C. 2282), Energy Policy Act of 2005, Pub. L. No. 109-58, 119 Stat. 594 (2005).

11. In § 150.3, a new definition *Nationally tracked source* is added in alphabetical order to read as follows:

§ 150.3 Definitions.

* * * * *

Nationally tracked source is a sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels 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 sealed in a capsule or closely bonded, in a solid form and which is not exempt from regulatory control. It does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet. Category 1 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 1 threshold. Category 2 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 2 threshold but less than the Category 1 threshold.

* * * * *

12. In §150.8, paragraph (b) is revised and paragraph (c)(3) is added to read as follows:

§ 150.8 Information collection requirements: OMB approval.

* * * * *

(b) The approved information collection requirements contained in this part appear in §§ 150.16, 150.17, 150.17a, 150.18, 150.19, 150.20, and 150.31.

(c) * * *

(3) In § 150.18, NRC Form 748 is approved under control number 3150-xxxx.

13. In §150.15, paragraph (a)(10) is added to read as follows:

§ 150.15 Persons not exempt.

(a) * * *

(10) The assignment of unique serial numbers to each newly manufactured nationally tracked source as required by § 32.201 of this chapter.

* * * * *

14. Section 150.18 is added to read as follows:

***§* 150.18 Submission to Commission of National Source Tracking Transaction Reports.**

Each person who, under an Agreement State specific license, manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report (NRC Form 748) as specified in paragraphs (a) through (e) of this section for each type of transaction.

(a) Each licensee who manufactures a nationally tracked source shall complete and submit a National Source Tracking Transaction Report (NRC Form 748). The report must include the following information:

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

(2) The name of the individual preparing the report;

(3) The manufacturer, model, and serial number of the source;

(4) The radioactive material in the source;

(5) The initial source strength in becquerels (curies) at the time of manufacture; and

(6) The manufacture date of the source.

(b) Each licensee that transfers a nationally tracked source to another person shall complete and submit a National Source Tracking Transaction Report (NRC Form 748). The report must include the following information:

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

(2) The name of the individual preparing the report;

(3) The name and license number of the recipient facility and the shipping address;

(4) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

(5) The radioactive material in the source;

(6) The initial or current source strength in becquerels (curies);

(7) The date for which the source strength is reported;

(8) The shipping date;

(9) The estimated arrival date; and

(10) For nationally tracked sources transferred as waste under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification of the container with the nationally tracked source.

(c) Each licensee that receives a nationally tracked source shall complete and submit a National Source Tracking Transaction Report (NRC Form 748). The report must include the following information:

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

(2) The name of the individual preparing the report;

(3) The name, address, and license number of the person that provided the source;

(4) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

(5) The radioactive material in the source;

(6) The initial or current source strength in becquerels (curies);

(7) The date for which the source strength is reported;

(8) The date of receipt; and

(9) For material received under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification with the nationally tracked source.

(d) Each licensee that disassembles a nationally tracked source shall complete and submit a National Source Tracking Transaction Report (NRC Form 748). The report must include the following information:

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

(2) The name of the individual preparing the report;

(3) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

(4) The radioactive material in the source;

(5) The initial or current source strength in becquerels (curies);

(6) The date for which the source strength is reported;

(7) The disassemble date of the source.

(e) Each licensee who disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report (NRC Form 748). The report must include the following information:

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

(2) The name of the individual preparing the report;

(3) The waste manifest number;

(4) The container identification with the nationally tracked source.

(5) The date of disposal; and

(6) The method of disposal.

(f) The reports discussed in paragraphs (a) through (e) of this section must be submitted by the close of the next business day after the transaction. A single report may be submitted for multiple sources and transactions. The reports must be submitted to the National Source Tracking System by using:

(1) The on-line National Source Tracking System;

(2) Electronically using a computer-readable format;

(3) By facsimile;

(4) By mail to the address on the National Source Tracking Transaction Report Form (NRC Form 748); or

(5) By telephone with followup by facsimile or mail.

(g) Each licensee shall correct any error in previously filed reports or file a new report for any missed transaction within 5 business days of the discovery of the error or missed transaction. Each licensee shall reconcile the inventory of nationally tracked sources possessed by the licensee against that licensee's data in the National Source Tracking System. The reconciliation must be conducted during the month of January in each year. The reconciliation process must include resolving any discrepancies between the National Source Tracking System and the actual inventory by filing the reports identified by paragraphs (a) through (e) of this section. By January 31 of each year, each licensee must submit to the National Source Tracking System confirmation that the data in the National Source Tracking System is correct.

(h) Each licensee that possesses Category 1 nationally tracked sources shall report its initial inventory of Category 1 nationally tracked sources to the National Source Tracking System by March 15, 2007. Each licensee that possesses Category 2 nationally tracked sources shall report its initial inventory of Category 2 nationally tracked sources to the National Source Tracking System by March 30, 2007. The information may be submitted by using any

of the methods identified by paragraph (f)(1) through (f)(4) of this section. The initial inventory report must include the following information:

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

(2) The name of the individual preparing the report;

(3) The manufacturer, model, and serial number of each nationally tracked source or, if not available, other information to uniquely identify the source;

(4) The radioactive material in the sealed source;

(5) The initial or current source strength in becquerels (curies); and

(6) The date for which the source strength is reported.

Dated at Rockville, Maryland, this_____ day of_____, 2006.

For the Nuclear Regulatory Commission.

_____
Annette Vietti-Cook,
Secretary of the Commission.

Regulatory Analysis for the Final Rule on National Source Tracking of Sealed Sources - 10 CFR Parts 20, 32, and 150

U.S. Nuclear Regulatory Commission
Office of Nuclear Material Safety and Safeguards

March 10, 2006

EXECUTIVE SUMMARY

The U.S. Nuclear Regulatory Commission (NRC) is amending its regulations to implement a new program called the National Source Tracking System. Under this program, licensees will be required to report information on the manufacture, transfer, receipt, disassembly, and disposal of nationally tracked sources. This information will be used to support the National Source Tracking System and will provide NRC with a life cycle account for nationally tracked sources and, thus, improve accountability and controls over them.

This regulatory analysis evaluates the values and impacts associated with the two regulatory alternatives considered by NRC to address the tracking of sealed sources:

- *Option 1: No Action*. The no-action alternative is the baseline for this analysis. Because the Energy Policy Act of 2005 requires NRC to issue regulations for a source tracking system, the no action alternative in not a viable option.

- *Option 2: National Source Tracking System*. Under the National Source Tracking System alternative, NRC would establish the National Source Tracking System. Under this program, each licensee who manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source would be required to: (1) report its initial inventory of Category 1 and/or 2 nationally tracked sources; (2) complete and submit a National Source Tracking Transaction Report after each transaction; (3) correct any errors in previously filed National Source Tracking Transaction Reports within five business days of the discovery; and (4) reconcile and verify its inventory of nationally tracked sources on an annual basis. In addition, licensees who manufacture nationally tracked sources after the effective date of the rule would be required to assign a unique serial number to each nationally tracked source.

The primary function of Option 1 is to establish the baseline condition from which the incremental values and impacts associated with the National Source Tracking System are calculated.

NRC estimated the incremental costs to industry and NRC under Option 2. These costs were estimated for the years 2006 through 2016. All costs incurred in the future were calculated in 2006 dollars using discount rates of 7 and 3 percent. The results are presented in Table ES-1.

Table ES-1
Present Value of the Total Costs Under Option 2,
the National Source Tracking System Alternative: 2006 - 2016 [a]
(2006 dollars)

Discount Rate	Costs to Industry	Costs to NRC	Total Costs
7%	$3,600,000	$32,400,000	$36,000,000
3%	$3,900,000	$38,100,000	$42,100,000

[a] Table includes rounding error.

As shown in Table ES-1, the net present value under Option 2, using a 7 percent discount rate, is estimated to be a total cost of $36,000,000. Using a 3 percent discount rate, the net present value is estimated to be a total cost of $42,100,000.

NRC staff believes that the expected qualitative values contribute substantially to the benefits of the National Source Tracking System. These qualitative values include:

- *Improved Accountability and Control for Nationally Tracked Sources.* The National Source Tracking System is expected to result in improved accountability and control over nationally tracked sources. This is expected to improve public health (accident/event) and avert potential offsite property damage and costs by decreasing the risk of a security-related event involving nationally tracked sources.

- *Improved Understanding of the Location of Nationally Tracked Sources.* Information contained in the National Source Tracking System would improve the information available to NRC, as well as other government entities (e.g., Department of Homeland Security, Agreement States), concerning the locations of nationally tracked sources.

- *Improved Regulatory Efficiency.* The establishment of a national program to monitor the location of nationally tracked sources would improve regulatory efficiency by: (1) increasing accountability among all parties associated with a nationally tracked source transaction and (2) responding to a recommendation in the IAEA's Code of Conduct.

- *Enhanced Ability to Promote and Maintain the Common Defense and Security.* Information contained in the National Source Tracking System would allow NRC to better monitor the location of nationally tracked sources and, thus, improve accountability and controls over them. Consequently, the National Source Tracking System would enhance NRC's ability to maintain and promote the common defense and security.

- *Increased Public Confidence.* Information contained in the National Source Tracking System would allow NRC to better monitor the location of nationally tracked sources. This is expected to result in increased public confidence in NRC’s regulation of inventories of radioactive materials that could be used in the production of radiological dispersal devices (RDDs) and radiological exposure devices (REDs).

The Energy Policy Act of 2005 requires NRC to promulgate regulations establishing a national source tracking system by August 8, 2006. In addition, NRC believes that the incremental costs to licensees and NRC under Option 2 are justified because the requested actions and information are necessary to monitor the location of nationally tracked sources and, thus, promote and maintain the common defense and security.

TABLE OF CONTENTS

1. Introduction

The U.S. Nuclear Regulatory Commission (NRC) is amending its regulations to implement a new program called the National Source Tracking System. Under this program, licensees will be required to report information on the manufacture, transfer, receipt, disassembly, and disposal of nationally tracked sources. This information will be used to support the National Source Tracking System and will provide NRC with a life cycle account for nationally tracked sources and, thus, improve accountability and controls over them.

The purpose of this regulatory analysis is to evaluate the values and impacts associated with the National Source Tracking system. NRC considers the regulatory analysis process an integral part of its statutory mission to promote the common defense and security, to ensure adequate protection of public health and safety, and to protect the environment from civilian uses of byproduct, source, and special nuclear materials. This document presents background material, describes the objectives of the regulatory action, and evaluates the values and impacts of the regulatory alternatives.

1.1 Background

As a result of the terrorist attacks in the U.S. on September 11, 2001, NRC has undertaken a comprehensive review of nuclear material security requirements, with particular focus on radioactive material of concern. This radioactive material, including Cobalt-60, Cesium-137, Iridium-192, and Americium-24, has the potential to be used in a radiological dispersal device (RDD) or a radiological exposure device (RED) in the absence of proper security measures. NRC's review takes into consideration the changing domestic and international threat environments and related U.S. Government supported international initiatives in the nuclear security area, particularly activities conducted by the International Atomic Energy Agency (IAEA).

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

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

The U.S. Government has formally notified the Director General of the IAEA of its political commitment for the current Code of Conduct. Although the Code of Conduct does not have the stature of an international treaty, and its provisions are non-binding on IAEA member States, the U.S. Government has endorsed the Code of Conduct and is working toward implementation of its various provisions. The Commission is conducting this rulemaking to reflect those Code of Conduct recommendations that are consistent with NRC's responsibilities under the Atomic Energy Act, including the promotion of the common defense and security.

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

Efforts to improve controls over sealed sources face significant challenges, especially with regard to the need to secure the materials without discouraging their beneficial use in academic, medical, and industrial applications. Radioactive materials provide critical capabilities in the oil and gas, electrical power, construction, and food industries; are used to treat millions of patients each year in diagnostic and therapeutic procedures; are used in a variety of military applications; and are used in technology research and development involving academic, government, and private institutions. These materials are as diverse in geographical location as they are in functional use.

National source tracking is part of a comprehensive radioactive source control program for radioactive materials of greatest concern. Although neither a national source tracking system nor a source registry can ensure the physical protection of sources, they will provide greater source accountability. Thus, NRC believes that a national source tracking system, in conjunction with other activities, should result in improved security for radioactive sources. It is also required by the Energy Policy Act of 2005.

1.2 Objectives of the Regulatory Action

There is broad U.S. Government and international interest in tracking radioactive sources to improve accountability and control. Currently, there is no single U.S. source of information to verify the licensed users, locations, and quantities of these materials. Separate NRC and Agreement State systems contain information on licensees and the maximum amounts of materials they are authorized to possess but do not record actual sources.

To address this lack of information on actual material possessed, NRC, with the cooperation of

the Agreement States, began working on an interim database of risk-significant sources (Category 1 and Category 2). In November 2003, both NRC and Agreement State licensees were contacted and requested to provide some basic information on the sealed sources located at their facilities. Of the approximately 2,600 licensees contacted, over half of the licensees reported possessing Category 1 or Category 2 sealed sources. The interim database was updated in 2005 and is being updated for 2006. NRC plans to replace the interim database with the National Source Tracking System. While the interim database provides a snapshot in time, the National Source Tracking System is expected to provide information on an ongoing basis.

Development of the National Source Tracking System includes information technology (IT) development and maintenance activities. When completely operational, the National Source Tracking System will be a web-based system that will allow licensees to meet the reporting requirements on-line with ease. This rulemaking imposes requirements on both NRC and Agreement State licensees and establishes the regulatory foundation for the National Source Tracking System. The National Source Tracking System is being developed and will be implemented under NRC's statutory authority to promote the common defense and security.

To inform the development of the National Source Tracking System, NRC established an Interagency Coordinating Committee to provide guidance regarding interagency issues associated with the development, coordination, and implementation of the system. The Committee membership consists of representatives from various Federal agencies with an interest in source security and a representative from the Agreement States. The views of the Committee were included in the development of the requirements for the National Source Tracking System and this rulemaking.

2. Identification and Preliminary Analysis of Alternative Approaches

This regulatory analysis evaluates the values and impacts of complying with the Energy Policy Act of 2005 with regard to the establishment of a source tracking system.

2.1 Option 1: No Action

Option 1 is the baseline for this analysis. Because the Energy Policy Act of 2005 requires NRC to issue regulations for a source tracking system, the no action alternative in not a viable option.

2.2 Option 2: National Source Tracking System

Under Option 2, NRC would establish the National Source Tracking System. The final rule implements current United States policy for a National Source Tracking System for Category 1 and Category 2 sources. Under this program, each licensee who manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source would be required to:

- Report its initial inventory of Category 1 nationally tracked sources to the National Source Tracking System by March 15, 2007.

- Report its initial inventory of Category 2 nationally tracked sources to the National Source Tracking System by March 30, 2007

- Complete and submit a National Source Tracking Transaction Report (i.e., NRC Form 748) after each transaction

- Correct any errors in previously filed National Source Tracking Transaction Reports within five business days of the discovery

- Reconcile and verify the inventory of nationally tracked sources it possesses against the data in the National Source Tracking System on an annual basis

In addition, each licensee who manufactures a nationally tracked source after the effective date of the rule would be required to assign a unique serial number to each nationally tracked source.

NRC considered the inclusion of Category 3 sources in the National Source Tracking System. However, at the time of the proposed rule neither the Interagency Coordinating Committee, Steering Committee or Working Group recommended their inclusion. The proposed rule invited specific comment on the inclusion of Category 3 sources and sought information on the burden to licensees. The information was sought so an informed decision on the inclusion of Category 3 sources could be made at a later date. NRC does not have adequate information on the number of sources and the number of impacted licensees. If Category 3 sources were included in the National Source Tracking System, for consistency of treatment would they also need to be included in the import/export provisions and other security related requirements that rely on the Category 1 and Category 2 thresholds? Many Category 3 sources are possessed under general license; questions related to this also need to be addressed before a final decision is made. Additionally, the Category 3 sources do not pose the same risk as Category 1 and Category 2 sources. The Energy Policy Act of 2005 requires the formation of the interagency Radiation Source Protection and Security Task Force. This Task Force will be evaluating, among other things, whether modifications to the source tracking system should be made. The Interagency Coordinating Committee will also continue to look at the National Source Tracking System.

3. Analysis of Values and Impacts

The three subsections below describe the analysis conducted to identify and evaluate the values and impacts expected to result from the implementation of the National Source Tracking System. Subsection 3.1 identifies the attributes that the National Source Tracking System is expected to affect. Subsection 3.2 describes the methodology used to analyze the values and impacts associated with the National Source Tracking System. Subsection 3.3 discusses the results of the analysis.

3.1 Identification of Affected Attributes

This subsection identifies the attributes, within the public and private sectors, that the National Source Tracking System is expected to affect, using the list of potential attributes provided in Chapter 5 of NUREG/BR-0184, “Regulatory Analysis Technical Evaluation Handbook,” dated January 1997 and in Chapter 4 of NUREG/BR-0058, Rev. 5, “Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission,” dated September 2004. Each attribute listed was

evaluated. The basis for selecting those attributes expected to be affected by the National Source Tracking System is presented below.

The National Source Tracking System is expected to affect the following attributes:

- *Public Health (Accident/Event)*. The National Source Tracking System will require licensees to report information on the manufacture, transfer, receipt, and disposal of nationally tracked sources. This information provides a life cycle account for these sources. As a result, the regulatory action is expected to improve accountability and controls over them. This reduces the risk that terrorists may obtain and use radioactive materials in the production of RDDs and REDs and, therefore, has a positive effect on public health.

- *Offsite Property*. As stated above, licensees will be required to provide a life cycle account for nationally tracked sources. Improvement in the accountability and controls over these sources is expected to avert potential offsite property damage and costs (e.g., long-term relocation, emergency response) that may follow from a terrorist attack in which RDDs and/or REDs are used.

- *Industry Implementation*. The regulatory action will require licensees to report their initial inventory of Category 1 and 2 nationally tracked sources to the National Source Tracking System. Licensees who reported nationally tracked source information to the interim database will only need to verify or update their reported inventory information. Licensees who did not provide nationally tracked source information to the interim database will need to report their inventory information by the specified dates. As a result, licensees (i.e., industry) will incur one-time implementation costs under the regulatory action.

- *Industry Operation*. The regulatory action will require licensees to: (1) complete and submit a National Source Tracking Transaction Report after each transaction; (2) correct any errors in previously filed National Source Tracking Transaction Reports within five business days of the discovery; (3) reconcile and verify the inventories of nationally tracked sources they possess against the data in the National Source Tracking System on an annual basis; and (4) assign a unique serial number to each nationally tracked source they manufacture (if applicable). As a result, licensees (i.e., industry) will incur annual operating costs under the regulatory action.

- *NRC Implementation*. To implement the regulatory action, NRC will conduct IT development activities. Specifically, NRC will arrange to develop a web-based National Source Tracking System, as well as guidance on how to report information on nationally tracked source transactions to the National Source Tracking System.[1] NRC will also conduct training workshops. As a result, NRC will incur one-time implementation costs under the regulatory action.

- *NRC Operation*. Under the regulatory action, NRC staff will review nationally tracked

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

source information submitted to the National Source Tracking System and arrange for operation and maintenance activities on the web-based National Source Tracking System. NRC will also conduct inspections related to the system. As a result, NRC will incur annual operating costs under the regulatory action.

- *Other Government*. Under the regulatory action, other Federal agencies and State and local governments (e.g., Department of Homeland Security, Agreement States) will have access to and benefit from the information contained in the National Source Tracking System. This information may allow them to better monitor the location of nationally tracked sources and focus resources on higher risk licensees (e.g., based on the number of nationally tracked sources they possess). In addition, the information contained in the National Source Tracking System should improve coordination among the various agencies.

- *Improvements in Knowledge*. The regulatory action will require licensees to report information on the manufacture, transfer, receipt, disasembly, and disposal of nationally tracked sources. This information will allow NRC to better know the location of nationally tracked sources.

- *Regulatory Efficiency*. The regulatory action will improve regulatory efficiency by establishing a national source tracking program to monitor the location of nationally tracked sources. Consequently, there should be increased accountability among all parties associated with a nationally tracked source transaction. In addition, the regulatory action would improve regulatory efficiency by implementing applicable features of the IAEA's Code of Conduct.

- *Safeguards and Security Considerations*. The regulatory action will require licensees to provide a life cycle account for nationally tracked sources. This information will allow NRC to better monitor the location of nationally tracked sources and thus, improve accountability and controls over them. Consequently, the regulatory action will enhance NRC's ability to maintain and promote the common defense and security.

- *Other Considerations*. The regulatory action will require licensees to provide a life cycle account for nationally tracked sources. This information will allow NRC to better monitor the location of nationally tracked sources. As a result, the regulatory action may increase public confidence in NRC's regulation of inventories of radioactive materials that could be used in the production of RDDs and REDs.

The National Source Tracking System is *not* expected to affect the following attributes:

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

3.2 Methodology

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

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

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

3.2.1 Baseline for Analysis

The analysis measures the incremental values and impacts of the implementation and operation of the National Source Tracking System relative to a baseline (Option 1, the no-action alternative), which is how the world would be in the absence of the National Source Tracking System.

3.2.2 Assumptions

The following subsections discuss the assumptions used in the analysis.

3.2.2.1 Number of Licensees that Possess Nationally Tracked Sources

Based on data from NRC's interim database of nationally tracked sources and NRC staff's best judgment, NRC estimates that there will be 1,350 licensees that may possess Category 1 and/or 2 nationally tracked sources. Of the 1,350 licensees, 350 are assumed to be NRC licensees and 1,000 are assumed to be Agreement State licensees. These values provide an upper bound for cost estimates, the actual numbers are expected to be lower.

3.2.2.2 Number of Nationally Tracked Sources

Based on data in NRC's interim database of nationally tracked sources and NRC staff's best judgment, NRC estimates that, collectively, licensees possess approximately 75,000 Category 1 and/or 2 nationally tracked sources. The interim database contains information on about 3,600 of these sources[2].

3.2.2.3 Method of Submitting National Source Tracking Transaction Reports

[2] In providing nationally tracked source information for the interim database, licensees were allowed to treat irradiators and gamma knives as a single source to encourage reporting of some data. Each gamma knife actually has 201 individual sources and each irradiator has from a few sources to over 1,500 individual sources.

Based on best judgment, NRC anticipates that, of the 1,350 licenses with nationally tracked sources, about 75 percent (1,015 licensees) would report nationally tracked source transaction information using on-line forms, about 15 percent (200 licensees) using computer-readable format files, about 4.75 percent (64 licensees) by fax, about 4.75 percent (64 licensees) by mail, and about 0.5 percent (7 licensees) by telephone with followup by fax or mail. These assumptions are reflected in Table 1.

Table 1
Estimated Number of Licensees that Possess Nationally Tracked Sources, by Report Submission Method

Submission Method	Total Number of Licensees
On-line forms	1,015
Computer-readable format file	200
Fax	64
Mail	64
Telephone with followup by fax or mail	7
Total	1,350

3.2.2.4 Number of National Source Tracking Transaction Reports

Based on data in NRC's interim database of nationally tracked sources and NRC staff's best judgment, NRC estimates that, each year, licensees perform up to 73,050 nationally tracked source "transactions." NRC estimates that, of these 73,050 transactions, 15,000 are associated with the manufacture of new nationally tracked sources, 24,000 with the transfer of nationally tracked sources, 24,000 with the receipt of nationally tracked sources, 10,000 with the disassembly of nationally tracked sources, and 50 with the disposal of nationally tracked sources. These numbers are based on the assumption that gamma knife sources are replaced every five years, radiography sources are replaced every four months, and one tenth of the irradiator sources are exchanged every year. These assumptions are reflected in Table 2.

Table 2
Estimated Annual Number of Nationally Tracked Source Transactions

Type of Transaction	Number of Transactions
Manufacture	15,000
Transfer	24,000
Receipt	24,000
Disassemble	10,000
Disposal	50
Total	73,050

For each of the 73,050 transactions identified in Table 2, licensees would be required to complete and submit a National Source Tracking Transaction Report using on-line forms, computer-readable format files, fax, mail, or telephone with followup by fax or mail. NRC is uncertain about the number of National Source Tracking Transaction Reports that will be submitted each year for each type of transaction and submission method (e.g., manufacture/on-line forms, manufacture/fax). However, NRC anticipates that the majority of the reports will be submitted by manufacturers and distributors. These entities are expected to report their transaction information electronically using computer-readable format files, given the large volume of transactions they perform. For purposes of this analysis, NRC made the following simplifying assumptions:

- Manufacture:
  - -- Each year, licensees perform 15,000 transactions associated with the manufacture of new nationally tracked sources
  - -- All reports associated with the manufacture of new nationally tracked sources will be submitted using computer-readable format files
  - -- Each report will contain information on 100 transactions

- Transfer and receipt:
  - -- Each year, licensees perform 48,000 transactions associated with the transfer and receipt of nationally tracked sources
  - -- Reports associated with the transfer and receipt of nationally tracked sources will be submitted as follows:
    - 5,288 using on-line forms
    - 42,000 using computer-readable format files
    - 338 by fax
    - 338 by mail
    - 36 by telephone with followup by fax or mail
  - -- Each report submitted using computer-readable format files will contain information on 100 transactions; reports submitted using any other method will contain information on three transactions
  - -- The number of transfer reports equals the number of receipt reports

- Disassemble:
  - -- Each year, licensees perform 10,000 transactions associated with the disassembly of nationally tracked sources
  - -- All reports associated with the disassembly of nationally tracked sources will be submitted using computer-readable format files
  - -- Each report will contain information on 100 transactions

- Disposal:
  - -- Each year, licensees perform 50 transactions associated with the disposal of nationally tracked sources
  - -- All reports associated with the disposal of nationally tracked sources will be submitted using on-line forms
  - -- Each report will contain information on three transactions

These assumptions are reflected in Table 3.

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

Type of Transaction	Submission Method					Total
	On-Line Forms	Computer-Readable Format File	Fax	Mail	Telephone with Followup by Fax or Mail	
Manufacture	0	150	0	0	0	150
Transfer	882	210	56	56	6	1,210
Receipt	882	210	56	56	6	1,210
Disassemble	0	100	0	0	0	100
Disposal	17	0	0	0	0	17
Total	1,781	670	112	112	12	2,687

3.2.3 Analysis

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

- IT development/maintenance activities
- National Source Tracking System account set-up
- Initial inventory of nationally tracked sources
- National Source Tracking Transaction Reports
- Correction of previously filed National Source Tracking Transaction Reports
- Annual inventory reconciliation of nationally tracked sources
- Nationally tracked source unique serial numbers

The cost assumptions for each of the above impact categories are discussed in the following subsections. Note that all costs presented in this subsection are in 2006 dollars.

3.2.3.1 IT Development/Maintenance Activities

In implementing the regulatory action, NRC expects to perform IT development/maintenance activities. Among other things, these activities include development of the final rule, guidance documents, and licensee training; development, enhancement, and maintenance and operation of the web-based National Source Tracking System.

NRC estimates that, between 2006 and 2008, NRC will incur $11,700,000 to develop the National Source Tracking System. This value represents both NRC staff and contractor time and effort. NRC anticipates that, of this $11,700,000, $3,300,000 will be incurred in Fiscal Year (FY) 2006, and $4,300,000 in FY 2007 and $4,100,000 in FY 2008.[3] Once the system is developed, NRC estimates that approximately $2,700,000 a year will be expended for the maintenance and operation of the system, beginning in FY 2009.[4] This includes NRC and contractor effort.

3.2.3.2 National Source Tracking System Account Set-Up

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

NRC estimates that, on average, 0.5 hour (30 minutes) of licensee staff time will be required to establish an account with the National Source Tracking System. Using an estimated average labor rate of $87 per hour for licensee staff[5], the cost for establishing an account is estimated to be $43.50 per licensee (i.e., 0.5 hour x $87/hour). As shown in Table 1, NRC anticipates that, of the 1,350 licensees with nationally tracked sources, 1,215 (i.e., 1,015 + 200) would report transaction information electronically using on-line forms or computer-readable format files. Thus, industry's total cost for establishing accounts with the National Source Tracking System is estimated to be $52,853 (i.e., 1,215 licensees x $43.50/licensee).

Note that, for purposes of this analysis, NRC made the assumption that all licensees reporting

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[3] FY 2006 covers the period between October 1, 2005 and September 30, 2006. FY 2007 covers the period between October 1, 2006 and September 30, 2007. FY 2008 covers the period between October 1, 2007 and September 30, 2008.

[4] FY 2009 covers the period between October 1, 2008 and September 30, 2009.

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

nationally tracked source transaction information electronically would establish their accounts with the National Source Tracking System in 2007.

In addition, to account set-up, licensees planning to use the computer-readable format files will also expend some programing effort to establish the ability to report using this method. Some programing will be necessary to collect the information from current computer files. NRC estimates that, on average, 80 hours of licensee staff time will be required to conduct the necessary programming. Using an estimated average labor rate of $87 per hour for licensee staff, the cost of programing is estimated to be $6960 per licensee (i.e., 80 hours x $87/hour). As shown in Table 1, NRC estimates that 200 licensees will report transaction information electronically using computer-readable format files. Thus, industry's total programming cost is estimated to be $1,392,000 (i.e., 200 licensees x $6960/licensee). It is assumed that this effort would occur in 2007.

Licensees may also expend some effort on training. NRC will be sponsoring workshops for licensees and will also offer training via an on-line demonstration of the system. Each licensee is assumed to expend 4 hours per person to conduct the training and to train 2 individuals in use of the system. Using an average labor rate of $87 per hour for licensee staff, the cost of training is estimated to be $696 per licensee (i.e., 8 hours x $87/hour). Thus, industry's total training cost is estimated to be $939,600 (i.e., 1350 licensees x $696 per licensee). It is assumed that this effort would occur in 2007.

3.2.3.3 Initial Inventory of Nationally Tracked Sources

Under existing regulations, licensees are required to conduct an inventory of their sealed sources. The regulatory action will require licensees to report their initial inventory of Category 1 and 2 nationally tracked sources to the National Source Tracking System. Licensees that reported nationally tracked source information to the interim database will only need to verify or update their inventory information. Licensees that did not provide nationally tracked source information to the interim database will need to report their initial inventory of Category 1 nationally tracked sources to the National Source Tracking System by March 15, 2007, and their initial inventory of Category 2 nationally tracked sources by March 30, 2007.

NRC estimates that licensees will require, on average, 0.50 hour (30 minutes) to verify/update or report initial inventory information on their nationally tracked sources.[6] Using an estimated average labor rate of $87 per hour for licensee staff, the labor cost for verifying/updating or initially reporting this information is estimated to be $43.50 per licensee (i.e., 0.50 hour x $87/hour). As shown in Table 1, NRC estimates that 1,350 licensees will verify/update or initially report inventory information for nationally tracked sources. Thus, the labor cost to licensees is estimated to be $58,725 (i.e., 1,350 licensees x $43.50/licensee).

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

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

- *On-Line Forms and Computer-Readable Format Files.* NRC considers Internet access to be a standard business practice. Therefore, for purposes of this analysis, the cost associated with the purchase of Internet access services is not considered an incremental cost to licensees.

- *Fax.* NRC estimates that each of the 64 licensees submitting information by fax (see Table 1) will incur a materials cost of $0.15 for faxing the information to the National Source Tracking System.[7] Thus, the materials cost to licensees submitting information by fax is estimated to be $9.60 (i.e., 64 licensees x $0.15/licensee).

- *Mail.* NRC estimates that each of the 64 licensees submitting information by mail (see Table 1) will incur a materials cost of $3.64 for mailing the information to the National Source Tracking System.[8] Thus, the materials cost to licensees submitting information by mail is estimated to be $232.96 (i.e., 64 licensees x $3.64/licensee).

- *Telephone with Followup by Fax or Mail.* NRC estimates that each of the seven licensees submitting information by telephone with followup by fax or mail will incur a materials cost of $4.16 for making a telephone call and mailing the information to the National Source Tracking System.[9] Thus, the materials cost to licensees submitting information by telephone with followup by fax or mail is estimated to be $29.12 (i.e., 7 licensees x $4.16/licensee).

Based on the above, the materials cost to licensees is estimated to be $271.68 (i.e., $0 + $9.60 + $232.96 + $29.12).

In summary, NRC estimates that industry's total one-time cost for verifying/updating or initially reporting nationally tracked source inventory information would be $58,997 (i.e., $58,725 + $271.68). For purposes of this analysis, NRC assumes that all of this *one-time* industry implementation cost will be incurred in 2007.

3.2.3.4 National Source Tracking Transaction Reports

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

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

- *Reports Submitted Using On-Line Forms*. NRC estimates that, on average, 10 minutes

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[7] Based on the cost of a two-minute State-to-State telephone call.

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

[9] Includes a cost of $0.52 for making a seven-minute State-to-State telephone call and a cost of $3.64 for mailing the inventory information to the National Source Tracking System.

of licensee staff time will be required to complete and submit a National Source Tracking Transaction Report on-line. Using an estimated average labor rate of $87 per hour for licensee staff, the cost for conducting these activities is estimated to be $14.50 per report (i.e., [10 minutes/60 minutes] x $87/hour).[10]

As shown in Table 3, NRC estimates that licensees will complete and submit 1,781 reports on-line each year. Thus, the industry's total annual cost for completing and submitting National Source Tracking Transaction Reports on-line is estimated to be $25,825 (i.e., 1,781 reports x $14.50/report).

- *Reports Submitted Using a Computer-Readable Format File*. NRC estimates that, on average, five minutes of licensee staff time will be required to complete and submit a National Source Tracking Transaction Report electronically using a computer-readable format file. Using an estimated average labor rate of $87 per hour for licensee staff, the cost for conducting these activities is estimated to be $7.25 per report (i.e., [5 minutes/60 minutes] x $87/hour).[11]

  As shown in Table 3, NRC estimates that, each year, licensees would complete and submit 670 reports using computer-readable format files. Thus, the industry's total annual cost for completing and submitting National Source Tracking Transaction Reports electronically using computer-readable format files is estimated to be $4,858 (i.e., 670 reports x $7.25/report).

- *Reports Submitted by Fax*. NRC estimates that, on average, 0.25 hour (15 minutes) of licensee staff time will be required to complete and submit a National Source Tracking Transaction Report by fax. Using an estimated average labor rate of $87 per hour for licensee staff, the labor cost for conducting these activities is estimated to be $21.75 (i.e., 0.25 hours x $87/hour). In addition, NRC estimates that, on average, licensees would incur a materials cost of $0.15 for each report they fax to the National Source Tracking System.[12] Thus, the total cost for completing and submitting a report is estimated to be $21.90 (i.e., $21.75 + $0.15).

  NRC further estimates that, each year, licensees will complete and submit 112 reports by fax. Thus, the industry's total annual cost for completing and submitting National Source Tracking Transaction Reports by fax is estimated to be $2,453 (i.e., 112 reports x $21.90/report).

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[10] NRC considers Internet access to be a standard business practice. Therefore, for purposes of this analysis, the cost associated with the purchase of Internet access services is not considered an incremental cost to licensees.

[11] NRC considers Internet access to be a standard business practice. Therefore, for purposes of this analysis, the cost associated with the purchase of Internet access services is not considered an incremental cost to licensees.

[12] Based on the cost of a two-minute State-to-State telephone call.

- *Reports Submitted by Mail*. NRC estimates that, on average, 0.25 hour (15 minutes) of licensee staff time will be required to complete and submit a National Source Tracking Transaction Report by mail. Using an estimated average labor rate of $87 per hour for licensee staff, the labor cost for conducting these activities is estimated to be $21.75 (i.e., 0.25 hours x $87/hour). In addition, NRC estimates that, on average, licensees will incur a materials cost of $3.64 for each report they mail to the National Source Tracking System.[13] Thus, the total cost for completing and submitting a report is estimated to be $25.39 (i.e., $21.75 + $3.64).

  NRC further estimates that, each year, licensees will complete and submit 112 reports by mail. Thus, the industry's total annual cost for completing and submitting National Source Tracking Transaction Reports by mail is estimated to be $2,844 (i.e., 112 reports x $25.39/report).

- *Reports Submitted by Telephone with Followup by Fax or Mail*. NRC estimates that, on average, 0.30 hours (18 minutes) of licensee staff time will be required to complete and submit a National Source Tracking Transaction Report by telephone with followup by fax or mail.[14] Using an estimated average labor rate of $87 per hour for licensee staff, the labor cost for conducting these activities is estimated to be $26.10 (i.e., 0.30 hours x $87/hour). In addition, NRC estimates that, on average, licensees will incur a cost of $3.86 for each report they submit by telephone to the National Source Tracking System.[15] Thus, the total cost for completing and submitting a report is estimated to be $29.96 (i.e., $26.10 + $3.86).

  NRC further estimates that, each year, licensees will complete and submit 12 reports by telephone. Thus, the industry's total annual cost for completing and submitting National Source Tracking Transaction Reports by telephone with followup by fax or mail is estimated to be $360 (i.e., 12 reports x $29.96/report).

Based on the above, NRC estimates that industry's total annual cost for completing and submitting National Source Tracking Transaction Reports will be $36,338 (i.e., $25,825 + $4,858 + $2,453 + $2,844 + $360). For purposes of this analysis, NRC assumes that this *annual* industry operating cost will be incurred for the first time in 2007.

3.2.3.5 Correction of Previously Filed National Source Tracking Transaction Reports

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[13] Includes costs associated with mailing a five-ounce package by certified mail in a manila envelope ($1.29 for postage, $2.30 for the certified-mail fee, and $0.05 for a manila envelope).

[14] For purposes of this analysis, NRC assumes that licensees submitting information by telephone with followup by fax or mail would spend three minutes more than licensees submitting information by mail or fax. This estimate takes into account the additional time they will need to report the information by telephone.

[15] Includes a cost of $0.22 for making a three-minute State-to-State telephone call and a cost of $3.64 for mailing the National Source Tracking Transaction Report.

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

NRC estimates that, on average, 0.05 hour (3 minutes) of licensee staff time will be required to correct and re-submit a previously filed National Source Tracking Transaction Report on-line. Using an estimated average labor rate of $87 per hour for licensee staff, the cost for conducting these activities is estimated to be $4.35 per report (i.e., 0.05 hour x $87/hour).[16] As shown in Table 3, NRC estimates that, each year, licensees will submit 2,687 National Source Tracking Transaction Reports. Based on best judgment, NRC estimates that licensees will correct and re-submit one percent of these reports (i.e., 2,687 x 0.01 = 27 reports). Thus, the industry's total annual cost for correcting and re-submitting previously filed National Source Tracking Transaction Reports is estimated to be $117 (i.e., 26 reports x $4.35/report).

Note that, for purposes of this analysis, NRC assumes that this *annual* industry operating cost would be incurred for the first time in 2007.

3.2.3.6 Annual Inventory Reconciliation of Nationally Tracked Sources

Under existing regulations, licensees are required to conduct inventories of their sealed sources. The regulatory action will require each licensee to reconcile and verify its inventory of nationally tracked sources against the data in the National Source Tracking System. This verification would be conducted during the month of January each year. As part of the verification process, licensees will be required to resolve any discrepancies between the National Source Tracking System and their actual inventory by filing the necessary National Source Tracking Transaction Report(s).

NRC estimates that licensees will require, on average, one hour to reconcile inventory information on their nationally tracked sources.[17] Using an estimated average labor rate of $87 per hour for licensee staff, the labor cost for reconciling and documenting this information is estimated to be $87 per licensee (i.e., 1 hour x $87/hour). As shown in Table 1, NRC estimates that 1,350 licensees will reconcile and verify inventory information for nationally tracked sources. Thus, the labor cost to licensees is estimated to be $117,450 (i.e., 1,350 licensees x $87/licensee).

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

- *On-Line Forms and Computer-Readable Format Files.* NRC considers Internet access to be a standard business practice. Therefore, for purposes of this analysis, the cost

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

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

associated with the purchase of Internet access services is not considered an incremental cost to licensees.

- *Fax.* NRC estimates that each of the 64 licensees submitting information by fax (see Table 1) will incur a materials cost of $0.15 for faxing the information to the National Source Tracking System.[18] Thus, the materials cost to licensees submitting information by fax is estimated to be $9.60 (i.e., 64 licensees x $0.15/licensee).

- *Mail.* NRC estimates that each of the 64 licensees submitting information by mail (see Table 1) will incur a materials cost of $3.64 for mailing the information to the National Source Tracking System.[19] Thus, the materials cost to licensees submitting information by mail is estimated to be $232.96 (i.e., 64 licensees x $3.64/licensee).

- *Telephone with Followup by Fax or Mail.* NRC estimates that each of the seven licensees submitting information by telephone with followup by fax or mail will incur a materials cost of $4.16 for making a telephone call and mailing the information to the National Source Tracking System.[20] Thus, the materials cost to licensees submitting information by telephone with followup by fax or mail is estimated to be $29.12 (i.e., 7 licensees x $4.16/licensee).

Based on the above, the materials cost to licensees is estimated to be $271.68 (i.e., $0 + $9.60 + $232.96 + $29.12).

In summary, NRC estimates that industry's total annual cost for reconciling and verifying its inventory of nationally tracked sources will be $117,722 (i.e., $117,450 + $271.68). For purposes of this analysis, NRC assumes that this *annual* industry operating cost will be incurred for the first time in 2008.

3.2.3.7 Nationally Tracked Source Unique Serial Numbers

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

NRC estimates that, on average, two minutes of licensee staff time will be required to assign a unique serial number to a nationally tracked source. Using an estimated average labor rate of $87 per hour for licensee staff, the cost for assigning a serial number is estimated to be $2.90 per source (i.e., [2 minutes/60 minutes] x $87/hour). NRC estimates that 15,000 nationally tracked sources are manufactured each year. Thus, the industry's total *annual* cost for assigning unique serial numbers to nationally tracked sources is estimated to be $43,500 (i.e.,

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[18] Based on the cost of a two-minute State-to-State telephone call.

[19] Includes costs associated with mailing a five-ounce package by certified mail in a manila envelope ($1.29 for postage, $2.30 for the certified-mail fee, and $0.05 for a manila envelope).

[20] Includes a cost of $0.52 for making a seven-minute State-to-State telephone call and a cost of $3.64 for mailing the inventory information to the National Source Tracking System.

15,000 sources x $2.90/source), beginning in 2007.

3.2.3.8 Inspection Costs

NRC will conduct inspections of the National Source Tracking System reporting requirements. These inspections would be included as part of routine inspections for NRC licensees. For Agreement State licensees, NRC will either conduct the inspection or pay for the Agreement State to conduct the inspection through a Section 274i Agreement. The approximate NRC resources needed to support inspection and enforcement is $750,000 and 20 FTE for 2008 and $250,000 and 7 FTE for later years.

3.3 Results

Under the National Source Tracking System alternative (Option 2), NRC will require licensees to report information on the manufacture, transfer, receipt, disassembly, and disposal of nationally tracked sources.

Using the cost assumptions discussed in Section 3.2 of this document, NRC staff estimated the incremental costs to industry and NRC under Option 2. These costs were estimated for the years 2006 through 2016. All costs incurred in the future were calculated in 2006 dollars using discount rates of 7 and 3 percent. Discounting all costs to year 2006 adjusts for the fact that costs incurred at different points in time are not equivalent. The results are presented in Table 4.

As shown in Table 4, the net present value under Option 2, using a 7 percent discount rate, is estimated to be a total cost of $36,000,000. Using a 3 percent discount rate, the net present value is estimated to be a total cost of $42,100,000.

NRC staff believes that the expected qualitative values contribute substantially to the benefits of the National Source Tracking System. These qualitative values include:

- *Improved Security for Nationally Tracked Sources.* The National Source Tracking System is expected to result in improved accountability and controls over nationally tracked sources. This is expected to improve public health (accident/event) and avert potential offsite property damage and costs by decreasing the risk of a security-related event involving nationally tracked sources.

- *Improved Understanding of the Location of Nationally Tracked Sources.* Information contained in the National Source Tracking System will improve the information available to NRC, as well as other government entities (e.g., Department of Homeland Security, Agreement States), concerning the locations of nationally tracked sources.

- *Improved Regulatory Efficiency.* The establishment of a national program to monitor the location of nationally tracked sources would improve regulatory efficiency by: (1) increasing accountability among all parties associated with a nationally tracked source transaction, (2) responding to a recommendation in the IAEA's Code of Conduct, and (3) responding to the statutory mandate of the Energy Policy Act of 2005.

- *Enhanced Ability to Promote and Maintain the Common Defense and Security.* Information contained in the National Source Tracking System will allow NRC to better monitor the location of nationally tracked sources and, thus, improve accountability and controls over them. Consequently, the National Source Tracking System should enhance NRC's ability to maintain and promote the common defense and security.

- *Increased Public Confidence.* Information contained in the National Source Tracking System will allow NRC to better monitor the location of nationally tracked sources. This is expected to result in increased public confidence in NRC's regulation of inventories of radioactive materials that could be used in the production of RDDs and REDs.

4. Backfit Analysis

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

5. Decision Rationale

For the two regulatory alternatives identified, the values and impacts have been considered. Option 2, the National Source Tracking System alternative, was determined to be the preferred option because it is expected to: (1) enhance NRC's ability to promote and maintain the common defense and security, (2) improve understanding of the location of nationally tracked sources, (3) improve regulatory efficiency (by increasing accountability among all parties associated with a nationally tracked source transaction), (4) improve public health and safety, and (5) increase public confidence. NRC believes that the incremental costs to licensees and NRC under Option 2 are justified because the Energy Policy Act of 2005 requires NRC to issue regulations for a source tracking system.

Table 4
Present Value of the Costs Under the National Source Tracking System Alternative (Option 2): 2005 - 2016 [a]
(2005 dollars)

Category	7% Discount Rate			3% Discount Rate		
	Costs to Industry	Costs to NRC	Total Costs	Costs to Industry	Costs to NRC	Total Costs
IT Development/Maintenance Activities	$0	$24,981,811	$24,981,811	$0	$29,204,580	$29,204,580
National Source Tracking System Account Set-Up	$49,395	$0	$49,395	$51,314	$0	$51,314
Licensee Programming	$1,300,935	$0	$1,300,935	$1,351,456	$0	$1,351,456
Licensee Training	$878,131	$0	$878,131	$912,233	$0	$912,233
Initial Inventory of Nationally Tracked Sources	$55,137	$0	$55,137	$57,279	$0	$567,279
National Source Tracking Transaction Reports	$255,223	$0	$255,223	$309,971	$0	$309,971
Correction of Previously Filed National Source Tracking Transaction Reports	$822	$0	$822	$998	$0	$998
Annual Inventory Reconciliation of Nationally Tracked Sources	$716,810	$0	$716,810	$889,899	$0	$889,899
Nationally Tracked Source Unique Serial Numbers	$305,526	$0	$305,526	$371,064	$0	$371,064
Inspection Cost	$0	$7,492,276	$7,492,276	$0	$9,030,379	$9,030,379
Total	$3,561,978	$32,394,554	$35,956,532	$3,944,213	$38,139,097	$42,083,310

[a] Table includes rounding error.

6. Implementation

The regulatory action will be enacted through a Final Rule. No impediments to implementation of the recommended alternative have been identified. The Final Rule implements United States policy to have a National Source Tracking System for Category 1 and Category 2 sources.

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

NRC is currently in the process of developing the National Source Tracking System and expects to finalize its development by spring 2007 When completely operational, the National Source Tracking System will be a web-based system that will allow licensees to easily meet the reporting requirements.

24722

Submission of Federal Rules Under the Congressional Review Act

☐ President of the Senate ☐ Speaker of the House of Representatives ☑ GAO

Please fill the circles electronically or with black pen or #2 pencil.

1. Name of Department or Agency
U.S. Nuclear Regulatory Commission

2. Subdivision or Office
Nuclear Material Safety and Safeguards

3. Rule Title
National Source Tracking of Sealed Sources

4. Regulation Identifier Number (RIN) or Other Unique Identifier (if applicable)
RIN 3150-AH48

5. Major Rule ○ Non-major Rule ◉

6. Final Rule ◉ Other ○ _____

7. With respect to this rule, did your agency solicit public comments? Yes ◉ No ○ N/A ○

8. Priority of Regulation (fill in one)
◉ Economically Significant; or Significant; or Substantive, Non Significant
○ Routine and Frequent or Informational/Administrative/Other (Do not complete the other side of this form if filled in above.)

9. Effective Date (if applicable)

10. Concise Summary of Rule (fill in one or both) attached ○ stated in rule ◉

Submitted by: _____ (signature)

Name: **Rebecca Schmidt**

Title: **Director, Office of Congressional Affairs**

For Congressional Use Only:

Date Received: _____

Committee of Jurisdiction: _____

3/23/99

	Yes	No	N/A
A. With respect to this rule, did your agency prepare an analysis of costs and benefits?	◉	○	○
B. With respect to this rule, by the final rulemaking stage, did your agency			
1. certify that the rule would not have a significant economic impact on a substantial number of small entities under 5 U.S.C.§ 605(b)?	◉	○	○
2. prepare a final Regulatory Flexibility Analysis under 5 U.S.C. § 604(a)?	◉	○	○
C. With respect to this rule, did your agency prepare a written statement under § 202 of the Unfunded Mandates Reform Act of 1995?	○	○	◉
D. With respect to this rule, did your agency prepare an Environmental Assessment or an Environmental Impact Statement under the National Environmental Policy Actg (NEPA)?	○	◉	○
E. Does this rule contain a collection of information requiring OMB approval under the Paperwork Reduction Act of 1995?	◉	○	○
F. Did you discuss any of the following in the preamble to the rule?	◉	○	○
• E.O. 12612, Federalism	○	◉	○
• E.O. 126630, Government Actions and Interference with Constitutionally Protected Property Rights	○	○	◉
• E.O. 12866, Regulatory Planning and Review	○	◉	○
• E.O. 12875, Enhancing the Intergovernmental Partnership	○	◉	○
• E.O. 12988, Civil Justice Reform	○	◉	○
• E.O. 13045, Protection of Children from Environmental Health Risks and Safety Risks	○	◉	○
• Other statutes or executive orders discussed in the preamble concerning the rulemaking process (please specify) **Energy Policy Act of 2005**			

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• E.O. 12866, Regulatory Planning and Review	○	◉	○
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• E.O. 12988, Civil Justice Reform	○	◉	○
• E.O. 13045, Protection of Children from Environmental Health Risks and Safety Risks	○	◉	○

- Other statutes or executive orders discussed in the preamble concerning the rulemaking process (please specify)

Energy Policy Act of 2005