

NUCLEAR REGULATORY COMMISSION

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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 November 15, 2007, for Category 1 sources and November 30, 2007, for Category 2 sources.

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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 at a minimum Category 1

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

The work on the DOE/NRC joint report was done in parallel with the work on the Code of Conduct and the development of IAEA TECDOC-1344, "Categorization of Radioactive Sources." The IAEA published this categorization system for radioactive sources in August 2005 in its Safety Series as RS-G-1.9, Categorization of Radioactive Sources. The report, available on the IAEA 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 entering or exiting the DOE complex.

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 the DOE complex as appropriate.

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 applicable to source tracking and imposed by the Energy Policy Act of 2005. 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 Ci 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. DOE, however, is more likely to possess these isotopes, and therefore, it was determined that these isotopes 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 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 November 15, 2007, and all Category 2 sources by November 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. An example of accidental destruction includes sources destroyed during attempts to remove them from devices.

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 November 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 November 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 June 13, 2006 (71 FR 34024) for a 20-day public comment period. The comment period was extended to July 28, 2006 (71 FR 37862; July 3, 2006). Fourteen comment letters were received on the basis change. In addition, a letter from two members of Congress was placed in the rule docket. Comments on the basis change and the associated responses are addressed in Comments G.12 - G.19.

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 stereotactic 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. 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, reviewed the National Source Tracking System and suggested that the issue of including Category 3 sources in the system should be evaluated and a final decision made on the issue.

In this rulemaking, the Commission is not making a final determination on what additional sources should be included in the National Source Tracking System. This rulemaking addresses Category 1 and 2 sources on the date this rule becomes effective. If additional material is added to the National Source Tracking System, it will be done through subsequent rulemaking. In a June 9, 2006, Staff Requirements Memorandum, the Commission has directed the NRC staff to conduct a one-time survey of Category 3.5 sources (one-tenth of

Category 3) and develop a proposed rule to include Category 3 data in the National Source Tracking System.

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 versus 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 two 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.

Comment G.12: Six Agreement States expressed support for the change in basis to public health and safety. (In addition, two Agreement States suggested issuing the rule under a basis of public health and safety during the original comment period in 2005.) The six States supporting issuance of the rule under public health and safety and as a Compatibility Category "B" argued that: States are better positioned than NRC to assure licensee cooperation; the

States are better suited and able to perform this type of oversight than the NRC; the public health and safety basis would minimize the potential for the dual regulation of a State licensee; there would be less potential for licensee confusion; some licensees may be more comfortable and willing to respond when contacted by the State officials with whom they are familiar and have an established working relationship; National Source Tracking would not necessarily increase source security but it would increase source accountability, which is a function under health and safety; States are better able to react quickly when there may be discrepancies in the reported information than the NRC; States are able to inspect in a more timely and cost-effective manner than NRC when problems arise; National Source Tracking is a logical fit with the increased controls that States are already implementing; and Agreement States have demonstrated the ability to work cooperatively with the NRC on security initiatives under public health and safety. (NRC issued orders that required strengthening of the measures regarding the control over use and storage of Category 2 quantities of radioactive material. (70 FR 72128; December 1, 2005) Agreement States issued compatible legally binding requirements at the same time.)

One industry organization also supported the basis change and supported the use of a single database. One industry organization was neutral. One commenter did not object to the basis change.

Five Agreement States are opposed to the basis change. The opposing States argued: the State's ability to quickly implement health and safety requirements for the increased controls is not a reason to change the designation of the rule (common defense and security to

public health and safety) and does not mean States have the resources or desire to do so for national source tracking; lack of resources to implement the program (e.g., lack of trained experienced inspectors); concern over the additional burden from the future inclusion of Category 3 sources in the tracking system; Congress intended source tracking to be a measure to promote the national security and changing the basis would violate the express intent of Congress; the federal government is attempting to shift additional responsibilities to the States simultaneously as it is withdrawing funding of the grant support from the Department of Homeland Security; and tracking of sources is not a local or State issue but a national issue. One of the Agreement States asserted that the NRC's authority to issue rules to promote common defense and security and its authority to issue rules to protect public health and safety have distinct applicability and limitations attached, and if the functions are intertwined, Congress could not assign the one responsibility to the Agreement States and the other to the Commission.

One commenter stated that while there is certainly a nexus between safety and security, the motivation for the Energy Policy Act is the security of these materials. The commenter urged the Commission to reconsider its decision and return to a common defense and security basis which is necessary in order to faithfully implement Congressional intent.

Response: The NRC agrees that the National Source Tracking is a logical fit with the increased controls that States are implementing. A public health and safety basis is consistent with the framework for the increased controls established by the Commission and NRC continued cooperation with Agreement States to implement a national materials program. In

addition, implementation of the NSTS will not increase the physical security of sources; rather, it will improve the tracking of sources to support public health and safety. The NRC supports issuance of the final rule under its public health and safety authority. NRC will develop and will maintain a single National Source Tracking System. Agreement State licensees will report to the national system. The Agreement States will be responsible for issuing legally binding requirements to their licensees that will require reporting of the necessary data. The legally binding requirements will be identical to the rule requirements and will be issued such that they are effective at the same time as the rule.

The National Source Tracking rule solely concerns collecting data, submitting it to a national data base developed and maintained by the NRC, and ensuring the data are appropriately updated in a timely manner. As such, the National Source Tracking System fulfills the Congressional mandate in the Energy Policy Act that the NRC establish by regulation such a system for tracking radioactive sources. Issuing this rule under the NRC's authority to protect the public health and safety in no way diminishes NRC authority to take appropriate action, nor lowers the significance of NRC actions. In fact, the safety of the public is the main reason for implementing security measures for radioactive materials. NRC is very aware of the resource concerns expressed by the five Agreement States which oppose the basis change. NRC will work with all of the Agreement States to further verify the rule requirements, the implementation period and approach, understand resource impacts of system implementation, and identify and address implementation issues as they arise.

Comment G.13: One Agreement State argued that the switch of the basis for adoption of the rule does irreparable harm to the States by denying them meaningful opportunity for input in a rulemaking that will place direct demands upon State resources. The State asserted that the fact that only six States submitted comments on the proposed rule attests to the States' perception that the matter had little impact upon them. The State also asserts that the change in basis amounts to a substantive change in the rule and requires that the entire rule be reopened for comment. One commenter requested information on Agreement State interactions.

Response: The NRC disagrees with the commenter. The States have had many opportunities to provide input to the National Source Tracking System. Representatives of the States participated in the development of the requirements for the system and development of the rule. The rule and system have been discussed at the Organization of Agreement States annual meetings and the Conference of Radiation Control Program Directors annual meetings. The NRC disagrees that the change in basis warrants that the entire rule be reopened for comment. The basis change was initiated by comments received from several Agreement States and is consistent with the framework established for the increased controls.

Comment G.14: Two Agreement States, while supporting the basis change, recommended that NRC consider revising the security orders issued to certain manufacturer and distributor licensees to implement the source tracking reporting requirements. The commenters stated that this could reduce the regulatory burden for those Agreement States that have a large number of manufacturer and distributor licensees that routinely transfer large numbers of Category 1 and 2 sources.

Response: Because the final source tracking rule is being issued under the basis of public health and safety, the Agreement States will be responsible for issuance of legally binding requirements for their licensees that possess Category 1 or 2 sources, including State licensees that received NRC orders. NRC has chosen to impose the tracking system reporting requirements by rule rather than by orders. See also response to Comment G.12 concerning resources.

Comment G.15: One Agreement State disagreed with the statement that “the requirements are laid out in the rule and it should be a straightforward matter for States to develop the legally binding requirements.” Two States also disagreed with the estimate of approximately 1 hour for inspection. The States indicated that their experience with inspecting for the increased controls as part of routine inspections demonstrated that NRC underestimated the effort involved. One State indicated that NRC has not allowed for or provided adequate training opportunity for the State to conduct these inspections.

Response: The NRC staff disagrees with the comment. The rule does lay out the reporting requirements that Agreement States will need to impose on their licensees. NRC will work with the States to develop the legally binding requirements for State licensees. In reference to training, it is not clear if the commenter is referring to training related to inspections for the National Source Tracking or the increased controls. A Temporary Instruction will be issued for use by NRC inspectors; Agreement States will have access to the instruction and can also use it to conduct inspections. As for the time estimate required for the inspection, NRC staff believes one hour on average to be adequate to perform a simple check to make sure that

the licensee has accurately reported sources to the National Source Tracking System. NRC will also utilize existing mechanisms for communicating and working with the Agreement States to help ensure a consistent uniform national approach to implementing the rule. We will use an approach similar to the one we used with the increased controls, e.g., routine calls, electronic communications, formation of an NRC-State working group. Through these interactions, the NRC will continue to coordinate with the states to understand any issues with the impact of NSTS implementation on state resources.

Comment G.16: One commenter requested information on the budgetary needs for implementation of the National Source Tracking System and copies of correspondence. The commenter requested information on the cost for Agreement States to develop their own tracking systems and how they would coordinate transfers between licensees in different geographic locations.

Response: Information on the cost of the rulemaking is available in the Regulatory Analysis completed to support this rulemaking and relevant correspondence is available in ADAMS. Under this framework, NRC will develop and will maintain the tracking system; Agreement States will not be developing their own systems. All licensees will report to the national system. Agreement States are not expected to coordinate the tracking of sources when transfers to different states occur.

G.17: One commenter stated that transactions involving aggregation of sources whose activity level, if taken together, exceed the Category 2 threshold should be included because

the security and safety threats of such a transaction would be the same as that associated with a transaction involving a single Category 2 level source. The commenter further asked how, from a security and safety perspective, NRC could justify tracking an import of aggregated Category 2 sources until the sources reach the U.S. after which they might be essentially ignored if such aggregated sources are not included in the tracking system.

Response: The NSTS will not consider transactions involving the aggregation of sources. The System will be an item-level tracking system for individual sources. If aggregation were considered, the smaller sources would be entering and exiting the system. The system data would become unreliable as the source moved in and out of the system. Some licensees would be required to report information on Category 3 sources and some would not. It is important to note that the NSTS does not impose any additional security requirements on the sources. The security and control measures are imposed by Order or other legally binding requirements. Those security and control requirements do consider aggregation of sources. Additionally, imports of Category 1 and 2 radioactive material are not tracked under the import/export rule, but licensees are required to provide notification to the U.S. government of the estimated arrival date for imports.

G.18: One commenter stated that a February 26, 2006, report by the NRC Inspector General (IG) entitled "Audit of the Development of the National Source Tracking System (NSTS)" found that the proposed tracking system "may not account for all byproduct material that represents a risk to the common defense and security and public health and safety. Such risks could result in economic, psychological, and physical harm to the United States and

public.” The commenter requested information on whether the two recommendations from the report: 1) to conduct a comprehensive regulatory analysis for the NSTS that explores other viable options and 2) to validate the existing data in the Interim Database were followed prior to the Commission vote.

Response: The rule on National Source Tracking was originally developed for Category 1 and 2 sources. Data were not available to conduct a cost-benefit analysis of including additional sources in the tracking systems. As for validating data in the Interim Database, the staff did take some measures for improvement in the 2005 survey of licensees. The analysis of the 2005 data was available before the Commission vote.

G.19: One commenter requested information on Agreement State responsibility to share information when a source is missing, lost, or stolen. The commenter also requested information on coordination with Agreement States and U.S. Customs and Border Protection to confirm the legitimacy of imports of shipments of risk-significant sources. The commenter requested the complete timeline for the process of adding Category 3 sources to the tracking system, what analysis would be required, and information on Agreement State regulation of Category 3 sources.

Response: This rule does not change the requirements for reporting of lost, stolen or missing sources. The U.S. Customs and Border Protection program is not impacted by this rule, and the notification information is required by the import/export rule. Agreement States do not have authority to issue import or export licenses as that is reserved for the NRC. The inclusion of Category 3 sources is addressed in this section, item A. All Agreement States regulate Category 3 sources.

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 has been removed from the fee basis and 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 programming 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 and the Agreement States can take enforcement action. The system will have built-in features that will trigger an alarm for mismatched transactions. The system will not catch situations in which both sides of the transaction have failed to report; however, these transactions 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 through rulemaking; the NRC will obtain the system through a formal procurement process. Section L addresses the use of NMMSS for byproduct source tracking.

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 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-user's 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 November 15, 2007, and the inventory of Category 2 nationally tracked sources by November 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 3150-0202.

The burden to the public for the information collections in NRC Form 748 is estimated to average 10 minutes per response plus an annualized one-time burden of 80 hours per recordkeeper, the burden for the information collections in 10 CFR Part 20 is estimated to average 1 hour per response plus an annualize one-time burden of 8 hours per recordkeeper, and the burden for the information collections in 10 CFR Part 32 is estimated to average 45

hours per recordkeeper. This includes 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 F53), 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 3150-0202), 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 3150-0202.

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 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. 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. 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. 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. 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. 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. Such errors may be detected by a variety of methods such as administrative reviews or by physical inventories required by regulation. In addition, 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 November 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 November 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	Category 1	Category 2	Category 2
	(TBq)	(Ci)	(TBq)	(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 1st day of November, 2006.

For the Nuclear Regulatory Commission.

/s/

Annette Vietti Cook,
Secretary of the Commission.