OMB SUPPORTING STATEMENT FOR FINAL RULE, 10 CFR PARTS 20 AND 32 NATIONAL SOURCE TRACKING OF SEALED SOURCES

(3150-0014 and 3150-0001)

Description of the Information Collection

As a result of the terrorist attacks in the U.S. on September 11, 2001, the U.S. Nuclear Regulatory Commission (NRC) has undertaken a comprehensive review of nuclear material security requirements, with particular focus on radioactive material of concern. This material, including Cobalt-60, Cesium-137, Iridium-192, and Americium-241 isotopes, has the potential to be used in a radiological dispersal device (RDD) or a radiological exposure device (RED) in the absence of proper security measures. The NRC's review takes into consideration the changing domestic and international threat environments and related U.S. Government supported international initiatives in the nuclear security area, particularly activities conducted by the International Atomic Energy Agency (IAEA). In addition, the Energy Policy Act of 2005 requires the NRC to issue regulations establishing a mandatory tracking system for radiation sources in the United States.

Based on the findings of its review, the NRC is amending its regulations at 10 CFR Parts 20, 32, and 150 to implement a new program called the National Source Tracking System. Under this program, licensees will be required to report information on the manufacture, transfer, receipt, disassembly, and disposal of nationally tracked sources. This information will be used to maintain the National Source Tracking System and will provide the NRC with a life cycle account for the sources and, thus, improve accountability and controls over them.

Currently, there is no single U.S. source of information to verify the authorized users, locations, quantities, and movement of these materials. Separate, non-standard NRC and Agreement State systems track licensees and the maximum amounts of materials they are authorized to possess but do not record actual sources or their movements.

To address this lack of information on actual possessed material, the NRC, with the cooperation of the Agreement States, began working on an interim database of sealed sources. In November 2003, both NRC and Agreement State licensees were contacted and requested to provide some basic information on the Category 1 and 2 sealed sources located at their facilities under OMB clearances 3150-0029 and 3150-0011. Of the approximately 2,600 licensees contacted, 1,328 licensees reported possessing high-risk sealed sources at the Category 1 or Category 2 levels, which are the levels that the system will track. The NRC plans to replace the interim database with the National Source Tracking System. While the interim database provides a snapshot in time, the National Source Tracking System will provide information on an ongoing basis.

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

Under the final rule, licensees who manufacture, transfer, receive, disassemble, or dispose of nationally tracked sources will be required to complete and submit a National Source Tracking Transaction Report (NRC Form 748) after each transaction. Licensees will also be required to provide their initial inventory of nationally tracked sources and to annually verify and reconcile their inventories of nationally tracked sources in the National Source Tracking System. In addition, licensees who manufacture nationally tracked sources after the effective date of the rule will be required to assign a unique serial number to each nationally tracked source.

A. Justification

1. Need for and Practical Utility of the Collection of Information

<u>Section 20.2207(a)</u> requires manufacturers of any nationally tracked source to complete NRC Form 748. The report must include the source information such as make, model, serial number, radionuclides, activity, and manufacture date. The report also includes the licensee name, address, and license number and the name of the individual that prepares the report. This information is needed to monitor on a timely basis the location and manufacture of new nationally tracked sources. The burden to complete this form is included in the clearance package for new NRC Form 748, clearance number 3150-xxxx.

Section 20.2207(b) requires licensees to report the transfer of any nationally tracked source to another person on NRC Form 748. The report must include the source information such as the make, model, serial number, radionuclides, source strength, and the date recorded; the transfer information including the name, shipping address, and license number of the recipient; the shipping date; and estimated arrival date. The report also includes the licensee name, address, and license number and the name of the individual that prepares the report. If applicable, the report should include the Uniform Low-Level Radioactive Waste Manifest number and the container identification. This information is needed to monitor on a timely basis the location and transfer of the nationally tracked sources. The burden to complete this form is included in the clearance package for new NRC Form 748, clearance number 3150-xxxxx.

Section 20.2207(c) requires licensees to report the receipt of any nationally tracked source on NRC Form 748. The report must include the source information such as the make, model, serial number, radionuclides, source strength, and date recorded; the name and license number of the person that provided the source; and the receipt date. The report also includes the licensee name, address, and number and the name of the individual that prepares the report. If applicable the report should include the Uniform Low-Level Radioactive Waste Manifest number and the container identification. This information is needed to monitor on a timely basis the location and receipt of the nationally tracked sources. The burden to complete this form is included in the clearance package for new NRC Form 748, clearance number 3150-xxxx.

<u>Section 20.2207(d)</u> requires licensees to report the disassembly of any nationally tracked source on NRC Form 748. The report must include the source information such as the make, model, serial number, radionuclides, source strength, and date recorded; the name and license number of the person that provided the source; and the receipt date. The report also includes the licensee

name, address, and number and the name of the individual that prepares the report. This information is needed to monitor on a timely basis the status of the nationally tracked sources. The burden to complete this form is included in the clearance package for new NRC Form 748, clearance number 3150-xxxx.

<u>Section 20.2207(e)</u> requires licensees to report the disposal of any nationally tracked source on NRC Form 748. The report must include the Uniform Low-Level Radioactive Waste Manifest number, the container identification, the date of and method of disposal. The report also includes the licensee name, address, and number and the name of the individual that prepares the report. This information is needed to know the final dispensation of a nationally tracked source. The burden to complete this form is included in the clearance package for new NRC Form 748, clearance number 3150-xxxx.

Section 20.2207(g) requires licensees to correct errors in previously filed reports or file any missed transaction reports within 5 business days of the discovery. The section also requires licenses to reconcile and verify the inventory of nationally tracked sources possessed by the licensee against the licensee's data in the National Source Tracking System on an annual basis. This verification is necessary to maintain the accuracy and reliability of the system over time. The burden to correct errors and file missed transaction reports is included in the clearance package for new NRC Form 748, clearance number 3150-xxxx.

Section 20.2207(h) requires licensees to report their initial inventory of nationally tracked sources to the National Source Tracking System. Category 1 sources must be reported by March 15, 2007 and Category 2 sources must be reported by March 30, 2007. The initial report must include the source information such as make, model, serial number, radionuclides, source strength, and date for which the source strength is reported. The report also includes the licensee name, address, and number and the name of the individual that prepares the report. This information will populate the National Source Tracking System and form the baseline for the system. This is a one-time collection.

<u>Section 32.201</u> requires licensees who manufacture nationally tracked sources after the effective date of the rule to assign a unique serial number to each nationally tracked source. Manufacturers already do this; however, the rule will mandate it. In order to track the movement of sources, a unique way to identify the specific source is necessary. The National Source Tracking System will use the combination of the manufacturer, model, and the serial number to track the sources.

2. Agency Use of the Information

The NRC will use the information to identify licensees that possess nationally tracked sources so they can be contacted or inspected, to better understand and monitor the location and transfer of the sources, and to promote and maintain the common defense and security. The collection of the information is necessary to meet the U.S. Government commitment to the IAEA Code of Conduct and to meet the requirements of the Energy Policy Act of 2005.

3. Reduction of Burden Through Information Technology

There are no legal obstacles to reducing the burden associated with this information collection through the use of information technology. In fact, the NRC encourages licensees to use information technology when it would be beneficial to them. NRC issued a regulation on October 10, 2003 (68 FR 58792) consistent with the Government Paperwork Elimination Act, which allows its licensees, vendors, applicants, and members of the public the option to make submissions electronically via CD-ROM, e-mail, special web-based interfaces, or other means.

The rule contains provisions for the submission of nationally tracked source transaction information in electronic format (i.e., through the use of on-line forms or computer-readable format files). It is anticipated that 90 percent of the licensees that possess nationally tracked sources will submit their nationally tracked source transaction information electronically.

4. Effort to Identify Duplication and Use Similar Information

Some information on plutonium and thorium will be collected by both the Nuclear Materials Management Safeguards System (NMMSS) and the National Source Tracking System. The current regulations require reporting transfers, receipts, and inventory to NMMSS for one gram or more of plutonium (Pu) and any thorium (Th) that has foreign obligations. However, because NMMSS does not collect information at the item level, information (e.g., make, model, serial number) on sealed sources will not be reported to NMMSS. Therefore, the NRC will not be able to extract the information for the National Source Tracking System from NMMSS.

Conversely, the National Source Tracking System will contain information only on nationally tracked sources and not information on sources that are not considered sealed or on any bulk material that a licensee may possess. Therefore, the NRC will not be able to extract information from the National Source Tracking System to support NMMSS. Neither system will be able collect the needed information for the other system without modifications to the database and the regulations.

In practice, the NRC has found that Pu and Th nationally tracked 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 have indicated that they possess Pu or Th sources that will need to be reported to the National Source Tracking System. The NRC does not believe that the limited number of licensees and transactions likely to be affected by this dual reporting requirement will impose an unnecessary burden. The NMMSS and the National Source Tracking System will collect information on these isotopes but in different formats and with different levels of detail as needed by each system.

5. Effort to Reduce Small Business Burden

While some licensees who possess nationally tracked sources are small

businesses, the concerns associated with the safe and secure use of nationally tracked sources are the same for large and small entities. It is not possible to reduce the burden on small businesses by less frequent or less complete reporting while maintaining the required level of common defense and security.

6. <u>Consequences to Federal Program or Policy Activities if the Collection is Not Conducted or is Conducted Less Frequently</u>

If the information is not collected, the NRC will have no way to identify licensees that possess nationally tracked sources or monitor the location and movement of the sources.

Required reports will be collected and evaluated on a continuing basis as transactions and events occur. The schedule for collecting the information is the minimum frequency necessary to monitor the location and movement of nationally tracked sources from a security standpoint and ensure that the information in the National Source Tracking System is accurate and up-to-date.

7. <u>Circumstances Which Justify Variation from OMB Guidelines</u>

Contrary to OMB Guidelines in 5 CFR 1320.5(d)(2), sections 20.2207(a) through (e) and 150.18(a) through (e) require licensees to complete and submit a National Source Tracking Transaction Report by the close of the next business day after the transaction. This information collection frequency is necessary to monitor the current location and movement of nationally tracked sources from a security standpoint and ensure that the information in the National Source Tracking System is accurate and up-to-date.

8. <u>Consultations Outside the NRC</u>

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

Opportunity to comment on the proposed rule's information collection requirements was published in the *Federal Register* on August 8, 2005 (70 FR 45571). No specific comments on the information collection were received. Comments were received on the Regulatory Analysis prepared to support the proposed rule that impact the information collection burden. One commenter stated that regulatory analysis understated the cost and time necessary to comply with the rule, specifically, that approximately 80 hours will be needed to conduct some computer programming, another commenter also indicated that some effort was necessary to develop the process for electronic data downloads, including training and procedure development. The staff agreed that some

licensees will need time to develop commuter programs to handle to electronic data download. The 80-hour estimate suggested by the commenter has been used in the regulatory analysis and is reflected in the information collection burden for the new NRC Form 748 transaction report. Most licensees will not need to do any programming but will use the on-line option for providing input. The staff has also added a one-time training cost of 8 hours per licensee in this supporting statement to cover time for learning the system.

9. Payment or Gifts to Respondents

Not applicable.

10. Confidentiality of Information

The information reported to the National Source Tracking System will be Official Use Only - Security-Related Information, and licensees will only have access to their own information. The information will be withheld from public disclosure.

11. Justification for Sensitive Questions

This information collection does not contain sensitive questions.

12. Estimated Burden and Burden Hour Cost

The total burden increase for Parts 20 and 32 rulemaking is 5,850 hours for a total cost of \$1,152,450 (5,850 hours x \$197/hour). This supporting statement covers the burden for all information collections other than the one-time implementation and continuing burden for completing the new NRC Form 748, "National Source Tracking Transaction Report" as reflected in the attached tables.

The 5,850 hours are broken down as follows:

- Recurring burden 1,800 hours reporting
 - Section 20.2207(f) 1,350 hours [(350 NRC licensees @ 1 response per licensee x 1 hour per response) + (1,000 Agreement State licensees @ 1 response per licensee x 1 hour per response)]
 - Section 20.2207(g) 450 hours [(350 NRC licensees x 1 response every 3 years (.333) per licensee x 1 hour per response) + (1,000 Agreement State licensees x 1 response every 3 years (.333) x 1 hour per response)]
- One-time burden 3,600 hours recordkeeping
 - Section 20.2207 3,600 hours [(117 NRC recordkeepers x 8 hours per recordkeeper) + 333 Agreement

State Recordkeepers x 8 hours per recordkeeper)]

Part 32 burden - 450 hours new recordkeeping

Section 32.201 - 450 hours [(3 NRC recordkeepers x 45 hours per recordkeeper) + (7 Agreement State recordkeepers x 45 hours per recordkeeper)]

We estimate that a total of 2,260 responses (467 NRC licensees reporting + 120 NRC licensees recordkeeping + 1,333 Agreement State licensees reporting + 340 Agreement State recordkeeping) will be filed by 1,350 respondents (350 NRC licensees and 1,000 Agreement State licensees).

The burden and information collections for the new NRC Form 748 are captured in a separate supporting statement because this form will receive a new OMB clearance number.

13. Estimate of Other Additional Costs

The NRC estimates that licensees will experience an annual cost of about \$543 in faxing, mailing, and telephone call costs to provide the initial inventory information and conduct the annual reconciliation.

The NRC considers Internet access to be a standard business practice. Therefore, the cost associated with the purchase of Internet access services is not considered an incremental cost to licensees.

14. <u>Estimated Annualized Cost to the Federal Government</u>

All costs are attributed to operating the National Source Tracking System¹. Estimated operation and maintenance cost for the system is \$2,700,000 per year. This includes the cost of ADP, record holding, and clerical processing of NRC Form 748.

15. Reasons for Change in Burden

The final rule, "National Source Tracking of High-Risk Sealed Sources," establishes a National Source Tracking System to track sources containing radioactive material of concern. Part 20 adds requirements for NRC and Agreement State licensees to input the source data, correct errors and file any missed transaction reports within 5 business days, report the transfer of any sources, and verify the information in the database on an annual basis. Part 32 establishes a specific requirement for manufacturers to assign a unique serial number to each nationally tracked source. The new requirements would increase the burden in Part 20 by 5,400 hours, from 128,669 to 134,069 hours, and the number of responses by 2,250, from 5,019 to 7,269 responses. Part 32

¹Developmental costs for the National Source Tracking System are estimated to be \$11.7 million.

affects recordkeeping only and would increase the burden by 450 hours, from 135,741 to 136,191 hours, and the number of responses by 10, from 3,172 to 3,182 responses.

16. Publication for Statistical Use

The information requested will not be published for statistical use.

17. Reason for Not Displaying the Expiration Date

The requirement will be contained in a regulation. Amending the Code of Federal Regulations to display information that, in an annual publication, could become obsolete would be unduly burdensome and too difficult to keep current.

18. Exceptions to the Certification Statement

None.

B. Collection of Information Employing Statistical Methods

Not applicable.

Burden Tables

10 CFR Part 20 (3150-0014)

Annual Reporting Requirements for NRC Licensees

Annual Reporting Requirements for three Electrococ						
Section	No. Of	Rsps. Per	Total	Brdn per	Total Annual	Cost @
000	Rspndts	Respndt	Responses	Response	Burden Hours	\$197/Hr
20.2207(a), (b),					Burden	
(c), (d) and (e)					included in	
					OMB	
					Clearance for	
					NRC Form 748	
20.2207(f) for	350	1	350	1	350	68,950
annual						
reconciliation						
and verification						
20.2207(g)	350	.33	117	1	117	23,049
One- time						
annualized						
implementation						
burden						
Total Part 20		Not Applicable	467		467	91,999
NRC Licensee						
Reporting						

Recordkeeping Requirements for NRC Licensees

Section	Number of Recordkeepers	Burden Hrs. Per Recordkeeper	Total Annual Burden Hours	Cost @\$197/Hr.
20.2207 (one- time annualized implementation burden for training)	117	8	936	184,392
Total Part 20 NRC Licensee Recordkeeping	117	8	936	184,392

Total Part 20 (NRC) Rulemaking Burden: 1,403 hours (467 hours reporting + 936 annualized hours for one-time recordkeeping)

10 CFR Part 20 (3150-0014)

Annual Reporting Burden for Agreement State Licensees

Amadi Reporting Burden for Agreement otate Licensees						
Section	No. Of	Rsps. Per	Total	Brdn per	Total Annual	Cost @
Section	Rspndts	Respndt	Responses	Response	Burden Hours	\$197/Hr
20.2207(a), (b), (c), (d) and (e)					Burden included in OMB Clearance for NRC Form 748	
20.2207(f) for annual reconciliation and verification	1,000	1	1,000	1	1,000	197,000
20.2207(g) One-time annualized implementation burden	1,000	.33	333	1	333	65,601
Total Part 20 Reporting		Not Applicable	1,333		1,333	262,601

Recordkeeping Requirements for Agreement State Licensees

Section	Number of Recordkeepers	Burden Hrs. Per Recordkeeper	Total Annual Burden Hours	Cost @\$197/Hr.
20.2207 (one- time annualized implementation burden for training	333	8	2,664	524,808
Total for Part 20	333	8	2,664	524,808

Total Part 20 Agreement State

Rulemaking Burden: 3,997 hours (1,333 hours reporting + 2,664

annualized hours for one-time recordkeeping)

Total 10 CFR Part 20 Burden

Total Burden Hours: 5.400

> NRC 1,403 (467 reporting + 936 recordkeeping) 3,997 (1,333 reporting + 2,664 recordkeeping) Agreement States

Number of Respondents: 1,350

NRC 350 1,000 Agreement States

Number of Responses: 2,250

> NRC 584 (467 + 117 recordkeepers) 1,666 (1,333 + 333 recordkeepers) Agreement States

Total Part 20 Burden Cost: \$1,063,800 (\$354,600 reporting and \$709,200 recordkeeping)

10 CFR Part 32 (3150-0001)

Annual Recordkeeping Burden for NRC Licensees

Section	Number of Recordkeepers	Burden Hrs. Per Recordkeeper	Total Annual Burden Hours	Cost @\$197/Hr.
32.201	3	45	135	26,595
Total Part 32 NRC Licensee Recordkeeping	3	45	135	26,595

10 CFR Part 32 (3150-0001)

Annual Recordkeeping Burden for Agreement State Licensees

Section	Number of Recordkeepers	Burden Hrs. Per Recordkeeper	Total Annual Burden Hours	Cost @\$197/Hr.
32.201	7	45	315	62,055
Total Part 32 Agreement State Licensee Recordkeeping	7	45	315	62,055

10 CFR Part 32 Burden

Total Burden Hours: 450

NRC 135 Agreement States 315

Number of Recordkeepers: 10

NRC 3 Agreement States 7

Total Part 32 Burden Cost: \$88,650

Total Parts 20 & 32 Cost: \$1,152,450 (\$1,063,800 Part 20 + \$88,650 Part 32)