OMB SUPPORTING STATEMENT FOR PROPOSED RULE

10 CFR PARTS 20 AND 32 AND NRC FORM 748 EXPANSION OF THE NATIONAL SOURCE TRACKING SYSTEM (RIN 3150-AI29) REVISION

DESCRIPTION OF THE INFORMATION COLLECTION

The Final Rule that Established National Source Tracking System

On November 8, 2006, NRC published a final rule in the *Federal Register* (71 FR 65856) that established a national source tracking system (NSTS) for tracking nationally tracked sources. In that rule, the "nationally tracked source" is defined as IAEA Category 1 or 2 sources¹. The current implementation date for the NSTS is January 31, 2009.

The purpose of that rule was to provide improved accountability of sources which could, in the absence of proper security measures, potentially be used in a radiological dispersal device (RDD) or a radiological exposure device (RED). In the Federal Register notice, It was noted that a joint NRC and Department of Energy (DOE) analysis of potential health effects from use of sources in a RDD or a RED identified radionuclide "quantities of concern" to be in a range similar to the IAEA Category 2 threshold values. Therefore, to allow alignment between domestic and international efforts to increase safety and security of radioactive sources, NRC adopted the IAEA Category 2 values as thresholds in the NSTS.

Under that rule, licensees that possess IAEA Category 1 or 2 sources are required to report information, such as the manufacture, transfer, receipt, disassembly, and disposal of Category 1 or 2 sources to NSTS. Certain information is to be reported on NRC Form 748, "National Source Tracking System Transaction Report." The information reported will provide the NRC with a life cycle account for Category 1 or 2 sources and, thus, improve accountability and controls over them.

Information collection requirements for that final rule, including NRC Form 748, have been approved by OMB under 3150-0014, 3150-0001, and 3150-0202.

The Proposed Rule

This proposed action is designed to improve accountability and control of sources by expanding the definition of "nationally tracked source" to include Category 3 sources and those that are less than category 3 but equal to or greater than 1/10th of Category 3 (referred to as "1/10th of Category 3"). The same reporting and recordkeeping information required for Category 1 or 2

¹ The IAEA source categorization scheme includes five categories. Sources in Category 1 are considered to be the most 'dangerous' because they can pose a very high risk to human health if not managed safely and securely. At the lower end of the categorization system, sources in Category 5 are the least dangerous; however, even these sources could give rise to doses in excess of the dose limits if not properly controlled. Each of the Categories contain radioactive material in sealed sources in quantities that can be characterized as follows:

Category 1: equal to or greater than the Category 1 threshold;

Category 2: less than the Category 1 threshold but equal to or greater than the Category 2 threshold (which is 1/100th of Category 1);

Category 3: less than the Category 2 threshold but equal to or greater than the Category 3 threshold (1/10th of Category 2);

Category 4: less than the Category 3 threshold but equal to or greater than the Category 4 threshold (1/100th of Category 3).

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

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

sources would also be required for Category 3 or 1/10th of Category 3 sources. Expanding the scope of the NSTS would provide a single source of information for Category 1 through 1/10th of Category 3 sources.

The rationale for adding Category 3 and 1/10th of Category 3 sources into the NSTS is to improve accountability and control of these sources. It would help reduce the potential that a sufficient number of these sources could be aggregated to create the equivalent of a Category 2 source which could, in the absence of proper security measures, potentially be used in a RDD or a RED. The threshold of a Category 3 source is 1/10th of the threshold of a Category 2 source. This means that a groups of 10-12 sources, each slightly below the threshold of a Category 3 source (i.e., high-end of Category 4 source) could be aggregated to Category 2 quantity. These high-end Category 4 sources are relatively widespread in use in industry. Thus, this rule is designed to help reducing the potential for aggregation of sufficient number of Category 3 or 1/10th of Category 3 sources to Category 2 levels.

Current database systems contain information on the maximum amounts of radioactive materials licensees are authorized to possess. However, those systems do not record actual sources or their movements. To address this lack of information, the NRC is proposing to expand the NSTS to include Category 3 and 1/10th of Category 3 sources.

This proposed rule would also address concerns expressed by members of the U.S. Congress and the Government Accountability Office (GAO) regarding the aggregation of a large number of lower activity sources whose activity level, if taken together, could exceed Category 2 thresholds.

Proposed Amendments

This proposed rule would amend the following sections:

- 1. In 10 CFR 20.1003 and 32.2, add Categories 3 and 1/10th of Category 3 sources to the definition of "nationally tracked source,"
- 2. In 10 CFR 20.2207(h), add Categories 3 and 1/10th of Category 3 sources and specify that initial inventory be reported by July 31, 2009, and
- 3. In Appendix E to Part 20, add radioactivity values of Categories 3 and 1/10th of Category 3 sources to the Table.

Impact on Information Collections

The proposed changes in rule language, in themselves, would not affect information collection requirements. However, these changes would impact on information collection burdens in existing sections in Parts 20 and 32 and in existing NRC Form 748 because licensees that possess Category 3 or 1/10th of Category 3 sources would be subject to information collection requirements (same as licensees that possess Category 1 or 2 sources) under two existing sections 10 CFR 20.2207 and 32.201.

Under these sections, the licensees who possess Category 3 or 1/10th of Category 3 sources would be required to:

- 1. Submit National Source Tracking Transaction Reports (NRC Form 748) if they manufacture, transfer, receive, disassemble, or dispose of these sources (10 CFR 20.2207(a) through (e));
- 2. Submit corrections for errors (NRC Form 748) in previously filed reports, file any missed transaction reports, and annually verify/reconcile their inventories in the NSTS (10 CFR 20.2207(g));
- 3. Submit initial inventory of these sources (10 CFR 20.2207(h)); and
- 4. Assign a unique serial number to the source if they manufacture a Category 3 or 1/10th of Category 3 source (10 CFR 32.201).

This supporting statement addresses the information collection burdens that would be added to the existing sections 10 CFR 20.2207 and 32.201 and to existing NRC Form 748.

A. <u>JUSTIFICATION</u>

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

This proposed action is needed to improve accountability and control of Category 3 and 1/10th of Category 3 sources. It would help reduce the potential that a sufficient number of these sources could be aggregated to create the equivalent of a Category 2 source which could, in the absence of proper security measures, potentially be used in a RDD or a RED. Expanding the scope of the NSTS would provide a single source of information for Category 1 and 2 sources as well as Category 3 and 1/10th of Category 3 sources.

The information collections would provide a near real-time knowledge of source whereabouts and an ability to confirm an individual licensee's account of its sources. Reports would be evaluated on a continuing basis as transactions and other covered actions occur. The information is needed to improve the accountability and control of the nationally tracked sources, and to ensure that the information in the NSTS is accurate and up-to-date.

Brief descriptions of information collection requirements in sections 10 CFR 20.2207 and 32.201 are presented below:

Section 20.2207(a)

This section 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 and license number and the name of the individual that prepares the report.

Section 20.2207(b)

This section 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 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.

Section 20.2207(c)

This section 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 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.

Section 20.2207(d)

This section 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 disassembly date. The report also includes the licensee name and number and the name of the individual that prepares the report.

Section 20.2207(e)

This section 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 and number and the name of the individual that prepares the report.

Section 20.2207(g)

This section requires licensees to correct errors in previously filed reports (on NRC Form 748) or file any missed transaction reports within 5 business days of the discovery.

In addition, this section requires licenses to reconcile and verify the inventory of nationally tracked sources possessed by the licensee against the licensee's data in the NSTS on an annual basis.

Section 20.2207(h)

This section requires licensees to report their initial inventory of nationally tracked sources to the NSTS. The licensees must report initial inventory of Category 3 and 1/10th of Category 3 sources July 32, 2009. 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 and number and the name of the individual that prepares the report. This information would populate the NSTS and form the baseline for the system for the additional sources covered by this rulemaking. This is a one-time collection.

Section 32.201

This section requires licensees who manufacture Category 3 or 1/10th of Category 3 sources after the effective date of the rule to assign a unique serial number to each of these sources. Manufacturers already do this; however, the proposed rule would mandate it. In order to track the movement of sources, a unique way to identify the specific source is necessary. The expanded NSTS, for the additional sources covered by this rulemaking, would use the combination of the manufacturer, model, and the serial number to track the sources.

2. Agency Use of the Information

The NRC would use the information to identify licensees that possess Category 3 or 1/10th of Category 3 sources so they can be contacted or inspected, to better understand and monitor the location and transfer of the sources, and to improve accountability and control of these sources and protect public health and safety.

3. Reduction of Burden Through Information Technology

There are no legal obstacles to reducing the burden associated with this information collection. The NRC encourages respondents to use information technology when it would be beneficial to them. NRC issued a regulation on October 10, 2003 (68 FR 58791), 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 interface, or other means. It is estimated that approximately 90% of the potential responses are filed electronically.

4. Effort to Identify Duplication and Use Similar Information

No sources of similar information are available. There is no duplication of requirements. NRC has in place an ongoing program to examine all information collections with the goal of eliminating all duplication and/or unnecessary information collections.

Effort to Reduce Small Business Burden

While some licensees who possess Category 3 or 1/10th of Category 3 sources are small businesses, the concerns associated with the safe 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 protection of public health and safety.

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 would have no way to identify licensees that possessing Category 3 or 1/10th of Category 3 sources, or monitor the location and movement of the sources.

Required reports would be collected and evaluated on a continuing basis as transactions and other covered actions occur. The schedule for collecting the information is the minimum frequency necessary to monitor the location and movement of Category 3 or 1/10th of Category 3 sources, improve the accountability and control of these sources, and ensure that the information in the NSTS 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) 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 Category 3 or 1/10th Category 3 sources, and ensure that the information in the NSTS is accurate and up-to-date.

8. Consultations Outside the NRC

Concerns by members of the U.S. Congress and the Government Accountability Office (GAO) have been expressed regarding the aggregation of a large number of lower activity sources whose activity level, if taken together, could exceed Category 2 thresholds. These are discussed in two GAO audit reports on the security aspects of NRC's licensing process, GAO-06-940T (July 7, 2006) and GAO-07-1038T (July 12, 2007).

The opportunity for public comment on the information collection requirements has been published in the *Federal Register*.

9. Payment or Gifts to Respondents

Not applicable.

10. <u>Confidentiality of Information</u>

The information reported to the NSTS would be Official Use Only, and licensees would only have access to their own information. The information would be withheld from public disclosure.

Confidential and proprietary information is protected in accordance with NRC

regulations at 10 CFR 9.17(a) and 10 CFR 2.390(b).

11. <u>Justification for Sensitive Questions</u>

Not applicable.

12. Estimated Burden and Burden Hour Cost

As indicated in the Regulatory Analysis for this proposed rulemaking, there are approximately 700 NRC licensees and 2800 Agreement State licensees covered by this rulemaking. The burden associated with information collections is given in Table 1 for reporting burden in 10 CFR Part 20, Table 2 for reporting burden in NRC Form 748, Table 3 for recordkeeping burden in 10 CFR Part 20, and Table 4 for recordkeeping burden for 10 CFR Part 32.

A summary of estimated burden is presented below:

Total burden/cost:

16,821 hours (6,555 reporting + 10,266 recordkeeping)

\$4,339,895 (16,821.3 hours x \$258/hour)

Total respondents:

3,500 (700 NRC licensees; 2,800 Agreement State licensees)

Total responses:

20,912 (19,746 responses; 1,166 recordkeepers)

13. Estimate of Other Additional Costs

The NRC estimates that licensees would experience an annual materials cost of about \$1,742 in faxing, mailing, and telephone call costs to provide the initial inventory information; conduct the annual reconciliation; and report source transactions using NRC Form 748 (based on sections 3.2.3.3 through 3.2.3.5 of the draft Regulatory Analysis).

Based on the number of pages maintained for a typical clearance, the record=s storage cost has been determined to be equal to 0.0004 times the recordkeeping burden cost. Therefore, the annual storage cost for this clearance is estimated to be \$1,059 (10,266 hours X \$258/hour X 0.0004).

The total annualized materials cost would be \$2,801.

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 NSTS. Estimated operation and maintenance cost for expanding the NSTS for the additional sources covered by this rulemaking is \$ 7.7M per year for the first three years and \$7 M thereafter (based on section 3.2.3.1 of the draft Regulatory Analysis,). The first three year cost includes costs to NRC for credentialing of licensees as well as the costs of ADP, record holding, and clerical processing of NRC Form 748. Subsequently, the cost includes only the ADP, record holding, and clerical processing costs.

15. Reasons for Change in Burden

The proposed rule is expected to increase the burden by 16,821 hours, from the current 276,014 hours to 292,835 hours. The increased burden is a result of the expansion of the definition, "nationally tracked source" to include Category 3 and 1/10th of Category 3 sources. Approximately 3,500 licensees (700 NRC licensees and 2,800 Agreement State licensees) would be affected by this rule. The information is needed to improve the accountability and control of the nationally tracked sources.

16. Publication for Statistical Use

The information requested would not be published for statistical use.

17. Reason for Not Displaying the Expiration Date

The requirement would 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

Not applicable.

B. <u>COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS</u>

Not applicable.

Table 1

Annual Reporting Requirements for Part 20 (3150-0014)

A. For NRC Licensees*

Section	No. of Respon- dents	Responses per Respondent	Total Responses	Burden/ Response (Hrs)	Total Annual Burden Hours	Cost @ \$258/hr
20.2207(a), (b), (c), (d), (e) and (g): for report manufacture, transfer, receive, disassemble, disposal, and correct errors					Burden included in Table 2 - for NRC Form 748	
20.2207(g): for annual reconciliation/ verification	700	1	700	1	700	180,600
20.2207(h): for one time annualized initial inventory	700	0.333	233	0.5	116.5	30,057
Total – Part 20 Reporting	700		933		816.5	210,657

^{*} Based on Sections 3.2.3.3 and 3.2.3.4 of the draft Regulatory Analysis for this rulemaking.

B. For NRC and Agreement State Licensees

	No. of Respondents	Total Responses	Total Annual Burden Hours	Cost @ \$258/hr
NRC licensees	700	933	816.5	210,657
Agreement State licensees**	2,800	3,732	3266	842,628
Total – Part 20 Reporting	3,500	4,665	4,082.5	1,053,285

^{**} Values for Agreement State licensees are approximately 4 x values for NRC licensees

Table 2 Annual Reporting Requirements for Completing NRC Form 748 (3150-0202)

(By Method of Submittal)

A. For NRC Licensees*

Section	No. of Respon- dents	Responses per Respondent	Total Responses	Burden/ Response (Hrs)	Total Annual Burden Hours	Cost @ \$258/hr
On-line	700	3.9**	2,730	0.167	456	117,648
Computer- readable	700	0.26	182	0.083	15	3,870
Mail/fax	700	0.1	70	0.25	17.5	4,515
Phone	700	0.006	4	0.25	1	258
Corrections	700	0.043	30	0.167	5	1,290
Total - Form 748 Reporting	700		3,016		494.5	127,581

B. For NRC and Agreement State Licensees

	No. of Respondents	Total Responses	Total Annual Burden Hours	Cost @ \$258/hr
NRC licensees	700	3,016	494.5	127,581
Agreement State licensees***	2,800	12,065	1,978	510,324
Total – Part 20 Reporting	3,500	15,081	2,472.5	637,905

^{***} Values for Agreement State licensees are approximately 4 x values for NRC licensees

 ^{*} Based on Section 3.2.3.5 of the draft Regulatory Analysis for this rulemaking.
 ** This value is calculated from dividing the estimated total responses by the number of respondents.

Table 3

Recordkeeping Requirements for 10 CFR Part 20 (3150-0014)

For NRC and Agreement State Licensees*

Section	No. of Recordkeepers	Burden Hrs. per Recordkeeper	Total Annual Burden Hours	Cost @ \$258/hr
20.2207 One-time annualized burden for training	1,166 (annualized, 3,500/3)	8	9,333	2,408,000
20.2207 One-time annualized burden for programming	17 (manufacturers only, annualized, 50/3)	20	333	86,000
Total – Part 20 Recordkeeping	1,166**		9,666	2,494,000

- * Based on Section 3.2.3.2 of the draft Regulatory Analysis for this rulemaking.
- ** The numbers of recordkeepers in the second row (17) is a part of the recordkeepers in the first row (1,166). Thus, the total numbers of recordkeepers is 1,166.

Table 4 Recordkeeping Requirements for 10 CFR Part 32 (3150-0001)

For NRC and Agreement State Licensees*

Section	Number of Recordkeepers	Burden Hrs Per Recordkeeper	Total Annual Burden Hours	Cost @ \$258/hr
32.201 Assign serial numbers to affected sources	50 (manufacturers only)	12	600**	154,800
Total – Part 32	50	12	600	154,800

- * Based on Section 3.2.3.7 of the draft Regulatory Analysis for this rulemaking.
- ** Based on 2 min/source and 17,910 sources (6,233 Category 3 and 11,677 1/10th of Category 3).

TOTAL BURDEN: 16,821 hours (4,082.5 hours Part 20 reporting + 2,472.5 hours NRC Form 748 reporting + 9,666 hours Part 20 recordkeeping + 600 hours Part 32 recordkeeping)

TOTAL RESPONSES: 20,912 (4,665 for Part 20 reporting + 15,081 for NRC Form 748 reporting +1,166 recordkeepers)

TOTAL RESPONDENTS: 3,500 (700 NRC licensees + 2,800 Agreement State licensees)

: