Final Supporting Statement for
"Nuclear Material Events Database (NMED)"
for the Collection of Event Report, Response, Analyses, and Follow-up Data on Events Involving the Use of Atomic Energy Act (AEA) Radioactive Byproduct Material
(3150-0178)

Revision

Description of the Information Collection

The U.S. Nuclear Regulatory Commission (NRC) proposes to continue the automated collection of Agreement State licensee data on the occurrence of incidents and events involving the use and transportation of radioactive byproduct material, such as medical events, radiation overexposures, environmental releases, contamination, leaking sources, lost sources, equipment failure, etc. This information is submitted to the Agreement States by their licensees through Agreement State regulations that are compatible to NRC regulations, and that require the reporting of incidents and events involving the use of radioactive byproduct materials. In addition, NRC requests that the Agreement States report by telephone significant events that could pose a significant health, safety or security hazard to NRC within the next working day of notification by their licensee. (In accordance with established regulatory requirements, Agreement State licensees report significant events to the Agreement State within 24 hours.) These and other radioactive material events will be reported on a monthly basis using the automated system. Agreement States may also choose to submit reports in a standardized written format transmitted via electronic mail. NRC is requesting that the Agreement States provide information on the initial notification, response actions, and follow-up investigations. The reporting of material event information is now mandatory under compatibility policy for Agreement States (June 30, 1997, Commission Staff Requirements Memorandum for SECY 97-054, Final Recommendations on Policy Statement and Implementing Procedures for: "Statement of Principles and Policy for the Agreement State Program" and "Policy Statement on Adequacy and Compatibility of Agreement State Programs.")

A. JUSTIFICATION

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

The Commission is directed under the Atomic Energy Act of 1954 ("the Act") Sections 274, Sec. 2, Findings, Paragraphs D and E, to protect the public against the hazards of radiation. The Commission is authorized to study, inspect, and monitor, as necessary, to protect health and minimize any danger to life or property. In 1959, Section 274 of the Act was enacted to spell out a State's role and to provide a statutory basis under which the Federal government could relinquish to the States portions of its regulatory authority. The 1959 amendments made it possible for the State to license and regulate byproduct, source, and small quantities of special nuclear material. The mechanism for the transfer of NRC's authority to a State is an Agreement signed by the Governor of the State and the Chairman of NRC. These States are known as Agreement States. Pursuant to the 1954 "Act" and the Energy Reorganization Act of 1974, as amended, the NRC investigates significant events and abnormal occurrences in licensed facilities. The Energy Reorganization Act requires NRC to provide to Congress on an annual basis, information on significant events that meet the abnormal occurrence criteria. Pursuant to Section 274j of the Act, the

Commission evaluates Agreement State programs to ensure that each Agreement State has a program that is compatible with NRC's program and to ensure that the State's regulatory program is adequate to protect the public health and safety. In addition, Section 274g of the Act requires NRC to cooperate with Agreement States in the formulation of standards for protection against hazards of radiation. Due to the importance of operating experience as an essential element in the regulatory process for ensuring that licensed activities are conducted safely, the Commission made reporting of radioactive material events to NRC an item of compatibility for the Agreement States in June 1997. The information from incidents and events involving the use of radioactive material at medical, industrial and research facilities located in the Agreement States, is invaluable in assessing actual Agreement State regulatory experience. The analyses of events provides valuable information and may result in the identification and review of health and safety or security concerns.

Responsibility for regulating the 21,197 specifically licensed users of radioactive materials is shared between NRC and the 34 Agreement States. A State may regulate from as few as 100 licenses to over 2,000 licenses. Agreement State material licensees include about 5,858 medical licensees and about 12,000 other non-reactor licensees. Approximately 80 percent of the licensed users of radioactive material are regulated by the Agreement States. Therefore, we could expect a representative proportion of nuclear material event report data, including medical events, from Agreement State licensees. Agreement State licensees are required to report material events to Agreement State regulators under established compatible regulatory reporting requirements contained in the U.S. Code of Federal Regulations (10 CFR 20, 30, 31, 34, 35, 36, 39, 40 and 70).

The automated system, the Nuclear Material Events Database (NMED), was designed to improve the technical information content of event reports, increase consistency, improve ease of access and retrieval of event information, and reduce duplication of effort in processing by all parties involved. NMED has become a valuable analytical and statistical support tool. Although NRC encourages States to use a standardized electronic submittal, a number of Agreement States currently provide event reports in a word processing format or in the format of their own automated database system. NRC is requesting that all events be reported by the Agreement States on a monthly basis. The reports should be provided to NRC within approximately 30 days after receipt from their licensees. NRC requests that all events be reported using the NMED automated system, or a similar automated system or process, that results in electronic submittal of the information, or an electronic mail word processing file.

In addition, events that could pose a significant health and safety hazard will be reported by the Agreement States to the NRC Operations Center, within the next working day of notification by their licensee. (In accordance with compatible regulatory reporting requirements, licensees report significant events to an Agreement State within 24 hours or less.)

2. Agency Use of the Information

The NRC collection of Agreement State licensee data on incidents and events involving the use and transportation of radioactive byproduct material, such as medical events, radiation exposures, environmental releases, contamination, leaking sources, lost sources, equipment failure, etc., significantly aids in understanding material events and identifying actions necessary to improve the effectiveness of NRC and Agreement State regulatory programs. Information is collected and maintained on preliminary initial notification information, and event response, investigation results, analyses and follow-up activities. Some significant events (reportable within 24 hours or less) may meet the criteria for an abnormal occurrence. NRC is required to report abnormal occurrences to Congress on an annual basis.

Significant events, reported to the NRC Operations Center, are monitored by NRC. NRC monitors the Agreement State event response activities, and stands ready to offer Federal assistance. NRC is the official lead Federal agency (LFA) for radiological emergencies involving AEA material. As the LFA, NRC is responsible for coordination of the Federal response, including assistance from NRC or other agencies, e.g., Department of Homeland Security, Department of Energy, etc., as requested by the States. Agreement State staff may be requested to brief NRC managers on the status of significant event response and investigations.

NRC conducts an assessment of the periodic collection of event data provided from the individual Agreement States, both individually and collectively. The analyses of the initial notification, response actions, follow-up investigative information, and close-out of material events, provides valuable information and may result in the identification and review of safety concerns that could have public health, safety and security significance. NRC reviews radiation safety incident reports and assesses the information against other similar operating experiences at licensed facilities. These assessments can provide important information to NRC, Agreement States, and material licensees regarding generic or recurring problems, as well as safe operational details and procedures. Specific task forces or working groups may be established to analyze problems and provide lessons learned. These assessments may also identify generic implications which would indicate a need for NRC to assess any changes necessary to nuclear material policies or regulations. This information is also used during formal periodic reviews of an Agreement State radiation control program to assess the adequacy of their programs. The NRC also provides feedback to industry, the regulated community and others, in the form of technical reports, safety notices, training programs, video tapes on medical and industrial safety training, etc., on lessons learned in order to improve safety. Event data analysis information, generated from the NMED database, has become a valuable support tool in our continued efforts to identify and address specific and generic safety-related issues.

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 58792), consistent with the Government Paperwork Elimination Act, which allows its licensee, vendors, applicants, and members of the public the options to make submissions electronically via CD-ROM, e-mail, special Web-based interface, or other means.

4. Efforts 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 collection with the goal of eliminating all duplication and/or unnecessary information collections.

5. Effort to Reduce Small Business Burden

This information is requested only from Agreement State regulatory authorities.

6. Consequences to Federal Program or Policy Activities if the Collection is not Conducted or is Conducted Less Frequently

Collecting information on a less frequent basis could impact public health, safety, and security, would greatly reduce the usefulness of the assessments of nuclear material events that have occurred in the Agreement States, and would impact our responsibility to report abnormal occurrences to the Congress and the public in a timely manner. It would also impact our responsibility to provide an annual performance report to Congress based on Strategic Plan performance goals and nuclear material event target metric data, as required under the Government Performance Results Act (GPRA). Under GPRA, NRC provides information on the results of regulatory activities designed to protect the public health and safety and the environment, and protect against radiological sabotage and theft or diversion of special nuclear materials based on strategic goals and performance measures as required in NUREG-1100, Budget Estimates and Performance Plan by Fiscal Year. The performance measures metric data contained in the report, is based on all reportable NRC licensee and Agreement State material event report data. The NRC requests that Agreement States report by telephone information on events that could pose a significant health, safety or security hazard to the NRC Operations Center within the next working day of notification to the Agreement State by an Agreement State licensee. All other events are reported on a monthly basis. Additional follow-up information on significant events is requested to be provided as it is collected by the States. Some significant events meet the criteria of an abnormal occurrence and are included in NUREG-0090, the NRC annual abnormal occurrence report to Congress, required by the Energy Reorganization Act of 1974.

7. Circumstances Which Justify Variation from OMB Guidelines

Information on events that could pose a significant health, safety or security hazard is requested from Agreement States, within the next working day of notification by their licensee so that NRC can identify immediately any health, safety or security hazard to the public, and offer assistance to the Agreement State in responding to the event.

8. Consultations Outside the NRC

Opportunity for public comment was published in the *Federal Register* (71FR25861) on May 2, 2006. No comments were received.

9. Payment or Gift to Respondents

Not applicable.

10. Confidentiality of the Information

Proprietary information is only generated in a small percentage of Agreement State collections. However, this information will be handled in accordance with NRC regulations in 10 CFR 2.390.

11. Justification for Sensitive Questions

No sensitive information is requested.

12. Estimated Burden and Burden Hour Cost

Agreement State Regulatory Authority: Through formal Agreements with the Governor of a State, the NRC relinquishes regulatory authority to the State. As the entity with regulatory authority, Agreement States, through regulations that are compatible to NRC regulations, require their licensees to report events including medical events, involving the use of radioactive byproduct, source, and special nuclear material. The Agreement States Radiation Control Program, as the entity with regulatory authority, shares the responsibility and burden of collecting nuclear material event information from Agreement State licensees and reporting this information to NRC. Therefore, the Agreement State licensee's burden to report nuclear material event information to the Agreement State, and the Agreement State's burden to collect this information, exist absent NRC's request for Agreement State participation in the electronic reporting of medical events and other incidents and events. The burden is covered in a separate OMB approval (3150-0029), for licensee reporting and Agreement State review.

The information is collected as follows: Agreement State licensees report information to the State regulator and the States in turn will enter event information from their licensees into a local version of NMED. NRC requests that all events be reported in a standardized format, using the NMED software or a similar automated system or process, that results in electronic submittal of the information, or an electronic word processing file. A list of the fields or elements that would be used to collect medical event, incident and event information, is enclosed with this supporting statement. Currently, 27 of the 34 Agreement States are using the NMED software to prepare and send data transfer files to the contractor responsible for maintaining the database. This translates to a current percentage of approximately 70% for Agreement State use of the software. The remaining seven States use other methods of reporting such as faxing or emailing a word processed document to the NRC Headquarters Operations Center or Office of Nuclear Material Safety and Safeguards (NMSS)

where NRC personnel enter the information into the NMED.

The estimated burden on the Agreement States is presented below and in table format.

a. The staff estimates that the contractor responsible for NMED, receives approximately 711 initial material event notifications, this includes initial notifications for significant events. The staff estimates that the time associated for an Agreement State to process and enter material event information received from a licensee into NMED is about 1.0 hour per event. This estimate is based on a range of .5 -1.5 hours per event - where a minimum of .5 hours may be needed to input a complete event report at the time of the initial event report or an outer range of 1.5 hours may be needed for more complex events wherein updates are needed at least once after the initial event report until closure of the event.

   711 event reports x 1.0 hour = 711 burden hours

b. In addition to the above, the Agreement States report significant events (events reportable within the next working day of notification by their licensee) by telephone to the NRC Headquarters Operations Center. These significant events that occur could pose a significant health, security and safety hazard. Based on experience, the State may orally report ongoing response and follow-up activities from 1-4 times, based on the type of event and safety significance of the event. Staff estimates that 30 of the 711 events rise to the level of significant events, each of which would require up to 1.5 additional hours to provide an initial oral report and follow-up safety assessment investigation information.

   1.5 hours/report X 30 significant reports = 45 burden hours

   The total burden for Agreement States is (711 + 45) = 756 hours

   The total cost for Agreement States is (756 x $197) = $148,932

c. The estimated reporting burden for the Agreement States in table format:

Information Collection	No. of Respondents	Responses Per Respondent	Total Number of Responses	Burden Per Response	Total Annual Burden Hours	Total Burden Cost
Material Event Reports (All)	34	20.9	711	1	711	$140,067
Subset: Material Significant Event Follow-up/Monitoring Activities*	30	1	30	1.5	45	$8,865
Totals	34	--------	741	------	756	$148,932

* Monitoring of significant event response activities through NRC Headquarters Operations Center.

13. Estimate of Other Additional Costs

None

14. Estimated Annualized Cost to the Federal Government

Based on experience, the staff estimates the following annualized cost estimates (1) to review and assess material event notifications, (2) monitor significant event response activities, (3) review follow-up investigative reports, (4) conduct safety assessments and analyses of both individual and collective Agreement State event information, and (5) code and maintain the collection of event information in NMED:

a. The annual cost from NRC Regional, State and Tribal Programs and NMSS staff involved in reviewing Agreement State event responses, follow-up and closeout information (resulting in 2-4 follow-up event reports for one occurrence and 1-2 follow-ups for less significant events) is estimated to be $492,500. This cost is based on a reported estimate of 5-15 hours per week, from the aforementioned offices, resulting in an combined estimate of 50 hours per week for 50 weeks per year. It is estimated that 2,500 staff hours per year will be attributed to event analyses for trends, generic implications, and requests for clarification.

2,500 staff hours X $197/hour = $492,500

b. Staff estimates the following additional annualized costs to the Federal government based on approximately 30 of the 711 events rising to the level of significant event. Staff estimates it would take approximately 3 hours for processing for these significant events by the NRC Headquarters Operations Center, and monitoring response and follow-up activities, resulting in 90 staff hours for a cost of $17,730.

3 hours X 30 significant events
= 90 staff hours
90 staff hours X $197/hour
= $17,730

c. The NMED contractor performs coding (data sorting and manipulation), data entry, record review for completeness of information, and requests for additional information, as necessary for the estimated 711 events which require approximately 2.2 hours per event at a cost of $226,809.

Contractor Cost:

711 events X 2.2 hour/event
= 1,564.2 hours (contractor)
1,5642.2 hours X $145/hour
= $226,809

Total NRC Staff Hours
= 2,590 hours (2,500 + 90 hours)
Total NRC Staff Cost
= $510,230 ($492,500 +$17,730)
Total NRC Cost (including contractor fees) = $737,039 ($510,230 + $226,809)

15. Reason for Change in Burden or Cost

The overall burden hours for the Agreement States has decreased by 484 hours from 1,240 to 756. The 756 burden hours are based on an annual average of the number of reported events and associated event updates, as reported by the NMED contractor for fiscal years 2002, 2003, 2004, and 2005 and the increase of two Agreement States. The time required to respond to the information collection has been re-estimated and decreased from 2.0 hours to 1.0 hour based on increased Agreement State operational familiarity with the NMED software; decreased time associated with evaluating response activities and requests for Federal assistance; and increased familiarity with reporting requirements. This decrease in burden hours is based on information gathered from Agreement States and the NMED contractor responsible for data sorting, data entry, record review for completeness of information, and request from Agreement States for additional information, as necessary. The cost for professional staff increased from $152 to $197 per hour.

16. Publication for Statistical Use

This information will not be published for statistical use.

17. Reason for Not Displaying the Expiration Date

Not applicable. The expiration date is displayed. The database software displays the OMB clearance, burden estimate, expiration date and public

protection statement as required.

18. Exceptions to the Certification Statement

Not applicable.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHOD

Not applicable.

DATA ENTRY INFORMATION FOR

NUCLEAR MATERIAL EVENTS DATABASE (NMED)
EVENT REPORT INVOLVING USE OF NUCLEAR MATERIAL
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The Nuclear Material Events Database (NMED) contains the official NRC collection of information on all non-commercial power reactor incidents and events, including medical events, that are required to be reported by the regulated community of licensees to NRC and the Agreements States, through NRC and compatible Agreement State regulations. The following 2 page list contains the NMED data entry elements necessary to support the collection of consistent information in a standardized format for all nuclear material incidents and events. Many of the items require only one keystroke for entry. Information has been pre-coded into a master list. The user scrolls through a pick list to the appropriate item and makes a choice. The codes have been developed to provide standardization and consistency in information, ease of retrieval, and to provide a three or four keystroke entry for lengthy information.

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GENERAL INFORMATION
(*For all Events*)

A. ORIGINAL ITEM NO (State ID\YR\No.)
B. EVENT CLASS (Code)
C. EVENT DATE
D. DISCOVERY- DATE REPORTED TO STATE
E. DATE OF THIS REPORT
F. EVENT CAUSE (Code)
G. LICENSEE NAME, CITY AND STATE, ZIP CODE (Code)
H. LICENSE NO.
J. SITE OF EVENT
K. PROGRAM CODE (License Type)
L. LICENSE NO. OF SITE
M. WERE OTHER PARTIES INVOLVED?
IF SO, IDENTIFY (Provide Name\City\State):
N. RECIPROCITY (Code)
O. REPORTABLE EVENT (Y\N):
NRC /__/ AS /__/
P. AEA (Y\N)
Q. ABNORMAL OCCURRENCE (Y\N)
R. INVESTIGATION (Y\N)
S. CONSULTANT (Y\N)
T. EVENT DESCRIPTION (Code)
U. CAUSE DESCRIPTION
V. CONTRIBUTING FACTOR (Code)
W. CORRECTIVE ACTION (Code)
X. REPORTING REQUIREMENT

a. CLASS EVENT TYPE (Code)
b. AGREEMENT STATE COMPATIBLE REGULATION

SPECIFIC INFORMATION BASED ON TYPE OF EVENT

1. *RELEASE OF MATERIAL*
(Where applicable).

a. EVENT CLASS (Code)
b. ISOTOPE (Code)
c. ACTIVITY (Ci) (Code)
d. CONSEQUENCE (Code)
e. RADIONUCLIDE

2. *MEDICAL EVENT INFORMATION* (Where applicable**)**

ISOTOPE, ACTIVITY AND DOSAGE: (i.e., 10 mCi of Iodine-131; 40 rad of Cs-137; 200 Ci of Iodine Hippurate)

a. INTENDED DOSE (Code)

Millicuries
Radiopharmacy
Radionuclide

b. ACTUAL DOSE (Code)

Millicuries
Isotope
Chemical Form
Study\Procedure

c. %OVERTREATMENT
d. %UNDERTREATMENT
e. CONSEQUENCES
f. FAMILY DOSE (Rem)
g. FETAL DOSE (Rem)
h. DOSE NEWBORN (Rem)
i ORGAN (Code)
j. EFFECT ON PATIENT(S)
k. WHO ADMINISTERED
l. DIAGNOSTIC OR THERAPEUTIC (D\T)
m. TREATMENT PLAN AND SCHEDULE--INTENDED AND ACTUAL (Include fractionations, where applicable)
n. NO. OF PATIENTS

o. PATIENT\RESPONSIBLE RELATIVE NOTIFIED (Y\N)
p. REFERRING PHYSICIAN NOTIFIED (Y\N)
q. DEMOGRAPHICS

3. *OVEREXPOSURE DATA* (Where applicable**)**

DATA ENTRY INFO. Cont.

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4. *EQUIPMENT INFO*. (Enter applicable data for all equipment in use during event--hardware\software) Choose from code list for a,b,c,d:

a. SYSTEM ID #
b. MANUFACTURER\SHIPPER
c. MODEL NO.
d. SERIAL\ID NO.
e. ISOTOPE ACTIVITY (Ci) (Code)
f. CONSEQUENCE

a. NO. OF PERSONS INVOLVED
b. DOSE RECEIVED (rem)
c. RADIATION SOURCE
d. BODY PART RECEIVING DOSE

5. *ABSTRACT* (Provide clear concise chronological statement in the form of a mini executive summary of the important facts concerning the event. This element is appended to as follow up information is added or when the licensee makes any corrections. It is not deleted and then rewritten as new information is obtained. Include direct cause, any new material, any retractions, licensee corrective actions, consultant statements, civil penalties, significant enforcement actions taken by State.)