

DRAFT OMB 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

(OMB CLEARANCE NO. 3150-0178)

EXTENSION

Description of the Information Collection

The U.S. Nuclear Regulatory Commission (NRC) proposes to continue the collection of data from the Agreement States on incidents and events involving the use and transportation of radioactive byproduct material. Such incidents and events include the medical uses of radioactive material, over exposures to radioactive material, environmental releases of radioactive material, radioactive contamination, leaking radioactive sources, lost radioactive sources, and equipment failure involving the use of radioactive material. The Agreement States report this information to the NRC on behalf of their licensees in accordance with NRC's 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.")

NRC requests that the Agreement States report by telephone to the NRC within 24 hours of notification from their licensee, those events which are considered to pose a significant health, safety or security hazard as defined in NRC regulations. Also, in addition to the 24 hour notification, Agreement States must submit a written report within 30 days of making the telephone report, which includes information on the event, actions taken in response to the event, and the results of any follow-up investigations. For those events that do not require a 24 hour notification, but are required to be reported in accordance with NRC regulations, Agreement States must submit a report in writing or electronically to the NRC describing the event, actions taken in response to the event, and the results of any follow-up investigations.

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 provide a statutory basis under which the Federal government could relinquish to the States portions of its regulatory authority, and to denote the role of any State for which part of NRC's authority would be relinquished. The 1959 amendments made it possible for the State to license and regulate the following categories of radioactive material: 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 the NRC. This signed

agreement designates a State as an "Agreement State." Pursuant to "the Act" and the Energy Reorganization Act of 1974, as amended, the NRC is required to examine higher significant events and abnormal occurrences at licensed facilities. Additionally, the Energy Reorganization Act requires NRC to provide to Congress on an annual basis, information on events that meet the abnormal occurrence criteria.

Pursuant to Section 274j of the Act, the Commission evaluates each Agreement State's regulatory program to ensure that each program is compatible with NRC's program and 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 formation of standards for protection against hazards of radiation. Because operating experience is an essential element in the regulatory process for determining 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 for assessing actual Agreement State regulatory experience, and also valuable for the identification and review of health and safety or security concerns.

Responsibility for regulating approximately 22,000 specifically licensed users of radioactive materials is shared between NRC and the 37 Agreement States. An Agreement State may regulate as few as 50 licensees to over 1,000 licensees. Agreement State radioactive material licensees include about 19,000 licensees, which equates to approximately 80 percent of the licensees that use radioactive material in the United States. Therefore, we could expect a proportionate number of nuclear material event report data from Agreement State licensees. Agreement State licensees are required to report nuclear material events to Agreement State regulators under established compatible regulatory reporting requirements contained in the U.S. Code of Federal Regulations (e.g., 10 CFR 20, 30, 31, 34, 35, 36, 39, 40 and 70).

The Nuclear Material Events Database (NMED), is a database that was designed to track nuclear material event information, increase consistency of reported event information, 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.

NRC requires the Agreement States to provide the required event information to the NRC by letter or electronically. The NRC encourages the Agreement States to provide the reports electronically. The reports are generally submitted directly to the appropriate NRC contact (e.g., NMED Contractor) for entry into NMED. A number of Agreement States currently provide event reports in a word processing format or in the format of their own automated database system. The Agreement States may provide an electronic report by using the local NMED Agreement State software, which may be downloaded from the NMED website, or by submitting the electronic file via the NMED website data upload function. Submitting an electronic file by e-mail is also allowed but is not preferred unless the Agreement State is responding to a question from the NRC or the NMED contractor.

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 significantly aids in understanding the nature of nuclear material events for the identification of actions necessary to improve the effectiveness of NRC and Agreement State regulatory programs. Data are collected and maintained on the initial notification of the event, the response to the event, the investigation results, and the analyses and follow-up activities. With regard to analysis and follow-up activities, 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 modify nuclear material policies or regulations, and/or assess the adequacy of the Agreement States' radiation control programs. The NRC also uses this information to provide feedback to industry, the regulated community and others, in the form of technical reports, safety notices, training programs, etc., on lessons learned that can improve safety. Some higher 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.

NRC monitors the Agreement State event response activities, and offers Federal assistance, as requested by the Agreement States. Under the National Response Framework (NRF), NRC is the coordinating agency for domestic incident management for incidents involving nuclear materials or facilities licensed by the NRC or Agreement States. As the coordinating agency, NRC may request assistance from other agencies (e.g., Department of Homeland Security, Department of Energy, etc.), which could also include the Agreement States.

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. It is estimated that approximately 99% of the potential responses are provided electronically.

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. No small businesses are affected.

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 the NRC's responsibility to report abnormal occurrences to the Congress and the public in a timely manner. It would also impact the agency's 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, the 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. One of the performance measures contained in the report is based on all reportable NRC licensee and Agreement State nuclear material event report data.

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 24 hours 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 on the information collection requirements for this clearance package has been published in the *Federal Register*.

9. Payment or Gift to Respondents

Not applicable.

10. Confidentiality of the Information

Confidential and proprietary information is not normally requested, and is generated in only a small number of cases. Confidential and proprietary information is protected in accordance with NRC regulations at 10 CFR 9.17(a) and 10 CFR 2.390(b).

11. Justification for Sensitive Questions

No sensitive information is required.

12. Estimated Burden and Burden Hour Cost

Agreement State Regulatory Authority: Through a formal Agreement with the Governor of a State, the NRC relinquishes regulatory authority to the State. The Agreement State Radiation Control Program, as the entity with regulatory authority, incurs 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 is to the Agreement State, and the Agreement State's burden to collect this information exists absent NRC's request for Agreement State participation in reporting the events to NRC. This burden is covered in a separate OMB approval (3150-0029), for licensee reporting and Agreement State review. The burden described in this OMB supporting statement only refers to the burden Agreement States incur when reporting event information to the NRC.

The estimated burden for the 37 Agreement States is presented below.

Based on the most recent three years of data from NMED, the staff estimates that the contractor responsible for NMED receives approximately 471 initial nuclear material event notifications/reports annually.

- a. *Events of routine significance.* Of the 471 nuclear material event notifications, the NRC estimates that 445 will be events of routine significance. The staff estimates that for events of routine significance, the time associated for an Agreement State to prepare and provide nuclear material event information to the NRC averages 1.5 hours per event. This estimate is based on a range of 0.75 to 2.25 hours per event - where a minimum of 0.75 hours may be needed to prepare a complete event report at the time of the initial event or an outer range of 2.25 hours may be needed for events requiring 1 – 2 updates after the initial event report.

Note that the estimated burden of 1.5 hours per event is an increase from the last submission to OMB, based on staff experience. The previous estimate for events of routine significance was 1 hour per event.

The estimated burden for Agreement States to provide information regarding nuclear material events of routine significance is 667.5 hours (445 events x 1.5 hrs/event) at a cost of \$182,895 (667.5 hrs x \$274/hour).

- b. *Events of higher significance.* Of the 471 nuclear material event notifications, an estimated 26 will be events of higher significance that pose a significant health, safety or security hazard (e.g., events that meet the abnormal occurrence criteria). Based on experience, for these events the Agreement State may orally and in writing (e.g., electronically) report ongoing response and follow-up activities from 2 to 5 times, based on the type of event and safety significance of the event. Staff estimates that events at this level of significance require about 3.0 hours to provide an initial report and the follow-up safety assessment investigation information. (Note that this is an increase from the previous estimate of 2 hours.)

The estimated burden for Agreement States to provide information regarding nuclear materials events of higher significance is 78 hours (26 events x 3 hrs/event) at a cost of \$21,372 (78 hours x \$274/hour).

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

AGREEMENT STATE BURDEN						
Information Collection	No. of Respondents	Responses Per Respondent	Total Number of Responses	Burden Per Response	Total Annual Burden Hours	Total Burden Cost at \$274/hr
Nuclear Material Event Report (Routine Significance)	37	12.03	445	1.5	667.5	\$182,895
Nuclear Material Event Report (Higher Significance)	37	0.7	26	3.0	78	\$21,372
Totals	37	-----	471	-----	745.5	\$204,267

13. Estimate of Other Additional Costs

There are no additional costs.

14. Estimated Annualized Cost to the Federal Government

Based on experience, the staff estimates the following annualized cost estimates (1) to review and assess nuclear 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 is provided below.

- a. *Events of routine significance.* Three NRC Regional Offices and the Office of Federal and State Materials and Environmental Management Programs (FSME) staff each spend an estimated 10 hours per week for 50 weeks per year reviewing Agreement State event responses, follow-up and closeout information. This results in an estimated cost of \$548,000 (4 offices x 10 hours per week x 50 weeks per year x \$274/hour). These 2,000 staff hours will be attributed to event analyses for trends, generic implications, and requests for clarification.

- b. *Events of higher significance.* For 26 events of higher significance, the staff estimates it would take approximately 6 hours for processing by the NRC Headquarters Operations Center and monitoring response and follow-up activities by FSME and NRC Regional Offices. This results in an estimated cost of \$42,744 (26 events x 6 hrs/event x \$274/hr).
- 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 471 events which require approximately 2.3 hours per Agreement State event at a cost of \$238,326 (471 events x 2.3 hrs/event x \$220/hour).

The following table provides the estimated costs to the Federal government for Agreement State reporting of events:

Costs to the Federal Government		
Information Collection	Annual Hours	Total Burden Cost ¹
Nuclear Material Events (Routine Significance)	2,000	\$548,000
Nuclear Material Events (Higher Significance)	156	\$42,744
NMED Contractor	1,083.3	\$238,326
Total	3,239.3	\$829,070

15. Reason for Change in Burden or Cost

The overall burden hours for the Agreement States have increased by 56.5 hours from 689 to 745.5. The number of estimated responses (reported events) has decreased from 669 to 471.

The estimated number of reported events is based on an annual average of the number of reported events, as reported by the NMED contractor, for fiscal years 2009 through 2011. The NRC staff expects to receive a similar number of reports annually during the next clearance cycle.

¹ NRC hours are calculated at the agency's fee rate of \$274/hr, whereas the contractor's hours are calculated at a rate of \$220/hr.

Although there was a decrease in the number of Agreement State nuclear material events, the NRC staff increased the estimated amount of time to prepare and provide the event information, resulting in an overall increase in burden. In the current submission, the NRC has increased the estimated burden to report an event of routine significance from 1 hour to 1.5 hours, and the estimated burden to report an event of higher significance from 2 hours to 3 hours. The burden estimate was increased based on NRC staff experience. In recent years, the staff has seen that an increasing number of events require submission of additional follow-up information and therefore require more time for the Agreement State to report.

Costs have increased due to an increase in the fee rate from \$238/hr to \$274/hr.

Finally, it should be noted that due to the reduced number of events and some changes to NRC's processing of events, the estimated hours and cost to the Federal government has decreased.

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 procedure used by the Agreement States for reporting events (SA-300, "Reporting Material Events") 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

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 Agreement 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.

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 µCi 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)

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

DATA ENTRY INFO. Cont.



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

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.)