

Draft 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 NRC proposes to continue the automated collection of Agreement State licensee data on the occurrence of incidents and events involving the use 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 Atomic Energy 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 21,400 specifically licensed users of radioactive materials is shared between NRC and the 32 Agreement States. A State may regulate from as few as 100 licenses to over 2,000 licenses. Agreement State material licensees include about 4,200 medical licensees and about 12,200 other nonreactor licensees. Approximately 77 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.

The automated system 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 on a monthly basis upon receipt from their licensee as required by 10 CFR 35.3045. 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 established regulatory requirements, licensees report significant events to an Agreement State within 24 hours.)

2. Agency Use of the Information

The NRC collection of Agreement State licensee data on incidents and events involving the use 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 Headquarters 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., FEMA, DOE, 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. Statistical 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

NRC incorporates the regulatory reporting requirements and risk factors into the event reporting process, for timely event notification, monitoring event response activities, and the collection and assessment of follow-up investigative information. NRC has worked with and continues to work with the Agreement States to develop and refine the NMED database system and event reporting guidance to provide the necessary information through the most efficient and cost effective method. The national electronic database system provides the Agreement States with online access to nuclear material event information from

NRC and Agreement State licensees. The current percentage of information collected electronically decreased from approximately 65% to 60%. Attachment A contains a list of the fields or elements that would be used to collect incident and event information including medical events.

4. Efforts to Identify Duplication and Use Similar Information

The Information Requirements Control Automated System (IRCAS) was searched and no duplication was found. There is no similar information available to the NRC. The information provided through the subject electronic database is not available from any other source other than Agreement States.

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). 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. 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. 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 strategic goals and performance measures as required under GPRA, in NUREG-1100, Budget Estimates and Performance Plan by Fiscal Year. The performance measures metric data contained in the report, is based on NRC licensee and Agreement State 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 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

The opportunity for public comments on the information collections had been published in the *Federal Register*.

The Agreement States are provided the opportunity to comment on revisions to NRC event reporting guidance documents. Any comments are factored into the final guidance document.

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 2.790.

11. Justification for Sensitive Questions

No sensitive information is requested.

12. Estimated Burden and Burden Hour Cost

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

Information Collection	No. of Respondents	Responses Per Respondent	Total Number of Responses	Burden Per Response	Total Annual Burden Hours	Total Burden Cost
Material Events Reports	32	12.5	400	2	800	\$121,600
Follow-up Reports	32	6.25	200	2	400	\$60,800
Significant Events Report	32	.63	20	2	40	\$6,080
Totals			620		1,240	\$188,480

13. Estimate of Other Additional Costs

None

14. Estimated Annualized Cost to the Federal Government

The annual cost for the NRC staff involved in reviewing significant event response activities provided by the Agreement States which has resulted in 2-4 follow-up event reports for one occurrence and 1-2 follow-ups for less significant events is estimated to be 280 staff hours (240 for normal events and 40 for significant events) at a cost of \$42,560. The estimated time to follow-up on the 400 events reports is estimated at .60 hours and for the 200 significant reports it is estimated at 2 hours. The NMED contractor perform coding and data entry duties which require approximately 2.2 hours per report at a cost of \$132,000 for professional staff and \$3,250 for clerical staff.

0.60 hour/event X 400 event reports	= 240 hours
240 staff hours X \$152/hr	= \$36,480
2 hours X 20 significant events	= 40 staff hours
40 staff hours X \$152/hr	= \$6,080
600 event reports X 2.2 hr/report	= 1,320 hours (contractor)
1,320 hours X \$100/hr	= \$132,000 (professional)
50 hours X \$65/hr	= \$3,250 (clerical)
Total Contractor Cost:	= \$135,220
Total Staff Hours = 280 hours (240 + 40 hours)	
Total Staff Cost = \$42,560 (\$36,480 + \$6,080)	
Total NRC Cost = \$177,780 (\$135,220 + \$42,560)	

These costs are fully recovered through license fees charged to NRC licensees pursuant to 10 CFR Part 170 and/or 171.

15. Reason for Change in Burden or Cost

The overall burden has increased by 295 hours from 945 to 1,240 hours due to an increase in the number of requests for additional clarifying information, increased demands for information reported under GPRA, and the increase of one additional Agreement State. Although the burden increased, the number of reports decreased by 300, from 900 to 600 reports due to the change in calculating the number of event reports reportable under the compatible Agreement State regulations, which previously included voluntary reports. The time required to respond to the information collection has been re-estimated and increased from 1 hour to 2 hours based on the increased need for additional information and more substantive information associated with assessing whether or not reportable events are generic and require further agency action. The cost for professional staff increased from \$90 to \$152 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 METHODS

DATA ENTRY INFORMATION FOR NUCLEAR MATERIAL EVENTS DATABASE (NMED) EVENT REPORT INVOLVING USE OF NUCLEAR MATERIAL

ATTACHMENT A

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 μ 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)

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

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

DATA ENTRY INFO. Cont.

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.)