

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)

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.")

The 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 AEA) 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 AEA 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 AEA 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 AEA, 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 AEA 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 18,100 specifically licensed users of radioactive materials is shared between NRC and the 41 current Agreement States¹. An Agreement State may regulate as few as 14 licensees to over 1,700 licensees. Agreement States currently oversee approximately 16,600 radioactive material licensees. Agreement State licensees are required to report nuclear material events to Agreement State regulators under established compatible regulatory reporting requirements contained in the Title 10 of the *Code of Federal Regulations* (10 CFR) (e.g., 10 CFR 20, 30, 31, 34, 35, 36, 39, 40 and 70).

The Nuclear Materials 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. The NMED has become a valuable analytical and statistical support tool.

¹ There are currently 39 Agreement States, overseeing approximately 16,000 licensees. Connecticut and Indiana submitted letters of intent to become Agreement States and are on track to become Agreement States by 2025 and 2026, respectively. (NRC Information Digest ML23047A371, page xiv). Since current schedules project them to become an Agreement States within this next 3-year OMB clearance period, 41 Agreement States will be used, along with 16,600 Agreement State Licensees for a conservative estimate.

The 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. The NRC is required to report abnormal occurrences to Congress on an annual basis.

The 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

The NRC has issued [*Reference Materials for Electronic Submissions*](#) which provides direction for the electronic transmission and submittal of documents to the NRC. Electronic transmission and submittal of documents can be accomplished via the following avenues: the Electronic Information Exchange (EIE) process, which is available from the NRC's "Electronic Submittals" Web page, by Optical Storage Media (OSM) (e.g., CD-ROM, DVD), by facsimile or by e-mail. It is estimated that approximately 99 percent of the responses are filed

electronically.

4. Efforts to Identify Duplication and Use Similar Information

No sources of similar information are available. There is no duplication of requirements.

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

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Opportunity for public comment on the information collection requirements for this clearance package was published in the *Federal Register* on April 28, 2025 (90 FR 17627). A total of four individuals were also contacted via e-mail regarding this opportunity for comment. The individuals represented the Agreement State programs that interact with the NMED system on a routine basis. No comments were received in responses to these consultations or 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. This burden is covered in a separate the 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 41 Agreement States is presented below.

Based on the most recent 3 years of data from NMED, the staff estimates that the contractor responsible for NMED receives approximately 444 initial nuclear material event notifications/reports annually from Agreement States. Historically, events occurring in Connecticut and Indiana number approximately 4 and 6 events per year, respectively. The State of Connecticut was already captured as part of the previous OMB clearance. Therefore, as a result of the addition of the State of Indiana as an Agreement State, the number of estimated events will increase by six for an estimate of 450 initial nuclear material event notifications/reports annually from Agreement States and the number of respondents will increase from 40 to 41.

- a. *Events of routine significance.* Of the 450 nuclear material event notifications, the NRC estimates that 420 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.

The estimated burden for Agreement States to provide information regarding nuclear material events of routine significance is 630 hours (420 events x 1.5 hours per event) at a cost of \$199,710 (630 hours x \$317 per hour).

- b. *Events of higher significance.* Of the 450 nuclear material event notifications, an estimated 30 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 two to five 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.

The estimated burden for Agreement States to provide information regarding nuclear materials events of higher significance is 90 hours (30 events x 3 hours per event) at a cost of \$28,530 (90 hours x \$317 per hour).

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

AGREEMENT STATE NUCLEAR MATERIAL EVENT REPORTING BURDEN						
Information Collection	No. of Respondents	Responses Per Respondent	Total Number of Responses	Burden Per Response	Total Annual Burden Hours	Total Burden Cost at \$317/hr
Nuclear Material Event Report (Routine Significance)	41 ¹	10.24	420	1.5	630	\$199,710
Nuclear Material Event Report (Higher Significance)	41 ¹	0.73	30	3.0	90	\$28,530
Totals	41 ¹	-----	450	-----	720	\$228,240

1. The State of Connecticut and the State of Indiana are currently pursuing an Agreement with the NRC. Since current schedules project them to become an Agreement States within this next 3-year OMB clearance period, 41 Agreement States will be used, along with 16,600 Agreement State Licensees for a conservative estimate. Note that the calculated responses per respondent in this table drops slightly as a result of the addition of Connecticut and Indiana, which historically have few events per year.

The \$317 hourly rate used in the burden estimates is based on the NRC's fee for hourly rates as noted in 10 CFR 170.20 "Average cost per professional staff-hour."

13. Estimate of Other Additional Costs

There are no additional costs.

14. Estimated Annualized Cost to the Federal Government

The staff has developed estimates of annualized costs to the Federal Government related to the conduct of this collection of information. These estimates are based on staff experience and subject matter expertise and include the burden needed to review, analyze, and process the collected information and any relevant operational expenses.

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 Nuclear Material Safety and Safeguards (NMSS) 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 \$634,000 (4 offices x 10 hours per week x 50 weeks per year x \$317 per 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 30 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 NMSS and NRC Regional Offices. This results in an estimated cost of \$57,060 (30 events x 6 hours per event x \$317 per hour).
- 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 450 events which require approximately 2.3 hours per Agreement State event at a cost of \$328,095 (450 events x 2.3 hours per event x \$317 per 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
Nuclear Material Events (Routine Significance)	2,000	\$634,000
Nuclear Material Events (Higher Significance)	180	\$57,060
NMED Contractor	1,035	\$328,095
Total	3,215	\$1,019,155

15. Reason for Change in Burden or Cost

COMPARISON OF CURRENT VS. PREVIOUS ESTIMATES		
	Previous OMB Clearance	Current OMB Clearance
Responses (estimated)	452	450
Total Burden to Agreement States (estimated hrs)	723	720
Fee Rate	\$288/hr	\$317/hr
Total Burden to Agreement States (estimated cost)	\$208,203	\$228,420

The number of estimated responses (reported events) has decreased from 452 to 450, based on a decrease in the number of events reported over the most recent 3-year period, compared to the previous 3-year period.

The overall burden hours for the Agreement States have decreased from 723 to 720, based on a decrease in the number of events reported over the most recent 3-year period, compared to the previous 3-year period.

The estimated costs have increased due to an increase in the fee rate from \$288 per hour to \$317 per hour.

16. Publication for Statistical Use

This information will not be published for statistical use.

17. Reason for Not Displaying the Expiration Date

The expiration date is displayed. The NMED website displays the OMB clearance control number, burden estimate, expiration date and public protection statement as required.

In addition, the procedure used by the Agreement States for reporting events (SA-300, "Reporting Material Events") displays the OMB clearance control number and public protection statement. The SA-300 is available in Agencywide Document Access and Management System under Accession No. ML22251A239.

18. Exceptions to the Certification Statement

Not applicable.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Not applicable.

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

NMED contains the official NRC collection of information on all non-commercial power reactor incidents and events, including medical events, which 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 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.

Minimum Required Event Information

General

- Narrative event description (e.g., Event circumstances and details including source radionuclide and activity) Provide clear concise chronological statement in the form of a mini executive summary of the important facts concerning the event. Include direct cause, any new material, any retractions, licensee corrective actions, consultant statements, civil penalties, significant enforcement actions taken by State.
- Report identification number
- Event date and notification date
- Licensee name, license number, and address
- Whether the event is NRC reportable and the applicable reporting requirement
- Cause and corrective actions (Agreement State and licensees' actions)
- Notifications: local law enforcement, FBI, and other States, as needed
- Indicate if there are any generic implications (i.e., generic issues or concerns)

Source/Radioactive Material

- Isotope and activity
- Manufacturer
- Model and serial number
- Leak test results, if applicable

Device/Associate Equipment

- For equipment/device involved, indicate the manufacturer, model, and serial number
- Provide clear description of any equipment problems.

Release of Licensed Material or Contamination

- Release type (air or water)
- Contamination (person or surface)
- Isotope and activity released

Medical Event

- Procedure administered, dose intended, and actual dose administered
- Isotope and activity administered, target organ
- Whether the patient and referring physician were notified

Overexposure

- Radiation source and activity
- Exposure dose and exposure type (e.g., whole body, extremity, etc.)

Transportation

- Type of transport
- Identity of shipper
- Package type and ID number (if available)