

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 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 19,300 specifically licensed users of radioactive materials is shared between NRC and the 38 current Agreement States¹. An Agreement State may regulate as few as 50 licensees to over 1,700 licensees. Agreement States currently oversee approximately 16,500 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 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.

¹ The State of Vermont is currently pursuing an Agreement with the NRC. Since current schedules project it to become an Agreement State within this next 3-year OMB clearance period, 39 Agreement States will be used, along with 16,600 Agreement State Licensees for a conservative estimate.

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

The NRC has issued [Guidance for Electronic Submissions to the NRC](#) 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% 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 September 10, 2018 (83 FR 45695). No comments were received. A total of seven individuals were also contacted via email regarding this opportunity for comment. They were as follows: Arizona Radiation Regulatory Agency; Alabama Department of Public Health- Office of Radiation Control; Colorado Department of Public Health and Environment; Florida Department of Health- Bureau of Radiation Control; Iowa Department of Public Health- Bureau of Radiological Health; New Jersey Department of Environmental Protection- Division of Energy Security

and Sustainability; and Washington Department of Health- Office of Radiation Protection. No responses were received in response to the public consultations.

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 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 39 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 450 initial nuclear material event notifications/reports annually.

- 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 hrs/event) at a cost of \$165,690 (630 hrs x \$263/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 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.

The estimated burden for Agreement States to provide information regarding nuclear materials events of higher significance is 90 hours (30 events x 3 hrs/event) at a cost of \$23,670 (90 hours x \$263/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 \$263/hr
Nuclear Material Event Report (Routine Significance)	39 ¹	10.77	420	1.5	630	\$169,690
Nuclear Material Event Report (Higher Significance)	39 ¹	0.77	30	3.0	90	\$23,670
Totals	39 ¹	-----	450	-----	720	\$189,360

1. The States of Vermont is currently pursuing an Agreement with the NRC. Since current schedules project it to become an Agreement State within this next 3-year OMB clearance period, 39 Agreement States will be used, along with 16,600 Agreement State Licensees for a conservative estimate

The \$263 hourly rate used in the burden estimate is based on the Nuclear Regulatory Commission's fee for hourly rates as noted in 10 CFR 170.20 "Average cost per professional staff-hour." For more information on the basis of this rate, see the *Federal Register* notice at: 82 FR 30682; June 30, 2017.

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 \$526,000 (4 offices x 10 hours per week x 50 weeks per year x \$263/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 \$47,340 (30 events x 6 hours/event x \$263/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 \$262,890 (450 events x 2.3 hours/event x \$254/hour²).

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 ³
Nuclear Material Events (Routine Significance)	2,000	\$526,000

² \$254 per hour was used based on the current contract costs for this project.

³ NRC hours are calculated at the agency's fee rate of \$263/hr, whereas the contractor's hours are calculated at a rate of \$254/hour.

Nuclear Material Events (Higher Significance)	180	\$47,340
NMED Contractor	1,035	\$262,890
Total	3,215	\$836,230

15. Reason for Change in Burden or Cost

COMPARISON OF CURRENT VS. PREVIOUS ESTIMATES		
	Previous OMB Clearance	Current OMB Clearance
Responses (estimated)	506	450
Total Burden (estimated hrs)	804	720
Fee Rate	\$268 /hr	\$263 /hr
Total Burden (estimated cost)	\$215,472	\$189,360

The overall burden hours for the Agreement States have decreased by 84 hours from 804 to 720. The number of estimated responses (reported events) has decreased from 506 to 450.

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 2015 through 2017. The NRC staff expects to receive a similar number of reports annually during the next clearance cycle.

Costs have decreased due to a decrease in the fee rate from \$268/hr to \$263/hr.

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. The SA-300 is available in ADAMS under Accession No. ML13053A346.

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

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, 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 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

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.)