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)
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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 18,600 specifically licensed users of radioactive materials is shared between NRC and the 40 current Agreement States[1]. 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 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. The NMED has become a valuable analytical and statistical support tool.

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 Web site, or by submitting the electronic file via the NMED Web site data

[1] The State of Connecticut 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, 40 Agreement States will be used, along with 16,600 Agreement State Licensees for a conservative estimate.

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 *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 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

Opportunity for public comment on the information collection requirements for this clearance package was published In the *Federal Register* on November 19, 2021 (86 FR 64,964). A total of six individuals were also contacted via e-mail regarding this opportunity for comment. The individuals represented the Agreement State programs, whom interact with the NMED system on a daily 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 40 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 452 initial nuclear material event notifications/reports annually. The number estimated events will increase to 452 as a result of the addition of the State of Connecticut as an Agreement State. This will increase the number of respondents from 39 to 40. Historically, Connecticut reports a very small number of events per year (1.67 events/year), so the number of events per year was increased by 2.

a. *Events of routine significance.* Of the 452 nuclear material event notifications, the NRC estimates that 422 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 633 hours (422 events x 1.5 hrs/event) at a cost of $182,304 (633 hrs x $288/hour).

b. *Events of higher significance*. Of the 452 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 $25,920 (90 hours x $288/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 $288/hr |
| Nuclear Material Event Report (Routine Significance) | 40[1] | 10.5 | 422 | 1.5 | 633 | $182,304 |
| Nuclear Material Event Report (Higher Significance) | 40[1] | 0.75 | 30 | 3.0 | 90 | $25,920 |
| Totals | 40[1] | -------- | 452 | ------ | 723 | $208,224 |

1. The State of Connecticut 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, 40 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, which historically averages less than two events per year.

The $288 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." For more information on the basis of this rate, see the Revision of Fee Schedules; Fee Recovery for Fiscal Year 2021 (86 FR 32146, June 17, 2021).

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 $576,000 (4 offices x 10 hours per week x 50 weeks per year x $288/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 $51,840 (30 events x 6 hours/event x $288/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 452 events which require approximately 2.3 hours per Agreement State event at a cost of $299,405 (452 events x 2.3 hours/event x $288/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 | $576,000 |

| | | |
|---|---|---|
| Nuclear Material Events (Higher Significance) | 180 | $51,840 |
| NMED Contractor | 1,040 | $299,405 |
| Total | 3,215 | $927,245 |

15. Reason for Change in Burden or Cost

| COMPARISON OF CURRENT VS. PREVIOUS ESTIMATES | | |
|---|---|---|
| | Previous OMB Clearance | Current OMB Clearance |
| Responses (estimated) | 450 | 452 |
| Total Burden (estimated hrs) | 720 | 723 |
| Fee Rate | $263 /hr | $288 /hr |
| Total Burden (estimated cost) | $189,360 | $208,203 |

The overall burden hours for the Agreement States has increased to 723. The number of estimated responses (reported events) has increased to 452.

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 2018 through 2020. The NRC staff expects events per year to return to pre-COVID levels within the next 3-year period but has no certainty on the exact timeframe for that. As a result, the NRC is using a conservative estimate of the same number of events per year as estimated during the previous as 3-year period, and which is consistent with the number of events per year received prior to the start of COVID (450 events/year). The addition of the State of Connecticut will add a small number of events per year (2 events/year) to this estimate, resulting in a total estimate of 452 events/year.

Costs have increased due to an increase in the fee rate from $263/hr to $288/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 Agencywide Document Access and Management System 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 Agreements States, through NRC and compatible Agreement State regulations. The following two -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, were 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.)