[7590-01-P]

NUCLEAR REGULATORY COMMISSION

Documents Containing Reporting or Recordkeeping Requirements: Notice of Pending Submittal to the Office of Management and Budget (OMB) Review

AGENCY: U. S. Nuclear Regulatory Commission (NRC)

ACTION: Notice of pending NRC action to submit an information collection request to OMB and solicitation of public comment.

SUMMARY: The NRC is preparing a submittal to OMB for review of continued approval of information collections under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

Information pertaining to the requirement to be submitted:

1. The title of the information collection: Nuclear Material Events Database (NMED).

2. Current OMB approval number: 3150-0178

3. How often the collection is required: Agreement States are requested to report events to NRC electronically or by hard copy within one month of notification from an Agreement State licensee that an incident or event involving the industrial, commercial and/or academic use of radioactive byproduct materials, or the use of radioactive materials for medical diagnosis, therapy, or research has occurred. In addition, Agreement States are requested to report events that may pose a significant health and safety hazard to the NRC Headquarters Operations Officer within the next working day of notification by an Agreement State licensee.

4. Who is required or asked to report: Current Agreement States and any State receiving Agreement State status in the future.

5. The number of annual respondents: 29

6. The number of hours needed annually to complete the requirement or request: 705 hours (an average of approximately one hour per response) for all existing Agreement States reporting; any new Agreement State would add approximately 25 reports per year or 25 burden hours.

7. Abstract: NRC regulations require NRC licensees to report incidents and events involving the use of radioactive byproduct material, and source material, such as those involving a radiation overexposure, a leaking or contaminated sealed source, release of excessive contamination of radioactive material, lost or stolen radioactive material, equipment failures, and abandoned well logging sources. Medical misadministrations are required to be reported in accordance with 10 CFR 35.33. Agreement State licensees are also required to report these events and medical misadministrations to their individual Agreement State regulatory authorities under compatible Agreement State regulations. NRC is requesting that the Agreement States voluntarily submit summary information on events and medical misadministrations involving the use of nuclear materials regulated pursuant to the Atomic Energy Act, in a uniform electronic format, for assessment and identification of any facility/site specific or generic safety concerns that could have the potential to impact public health and safety; and to evaluate actions necessary to prevent their occurrence at the same or other facilities.

Submit, by (insert date 60 days after publication in the FR), comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?
2. Is the burden estimate accurate?
3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?
4. How can the burden of the information collection be minimized, including the use of automated collection techniques or other forms of information technology?

A copy of the draft supporting statement may be viewed free of charge at the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC. Members of the public who are in the Washington, DC, area can access this document via modem on the Public Document Room Bulletin Board (NRC's Advanced Copy Document Library) NRC subsystem at FedWorld, 703-321-3339. Members of the public who are located outside of the Washington, DC, area can dial FedWorld, 1-800-303-9672, or use the FedWorld Internet address:

fedworld.gov(Telnet). If assistance is needed in accessing the document, please contact the FedWorld help desk at 703-487-4608. Additional assistance in locating the document is available from the NRC Public Document Room, nationally at 1-800-397-4209, or within the Washington, DC, area at 202-634-3273.

Comments and questions about the information collection requirements may be directed to the NRC Clearance Officer, Brenda Jo Shelton, U.S. Nuclear Regulatory Commission, T-6 F33, Washington, DC. 20555-0001, or by telephone at (301) 415-7233, or by Internet electronic mail at BJS1@NRC.GOV.

Dated at Rockville, Maryland, this ____ day of _____, 1996.

For the Nuclear Regulatory Commission

_____

Gerald F. Cranford
Designated Senior Official
for Information Resources Management

fedworld.gov(Telnet). If assistance is needed in accessing the document, please contact the FedWorld help desk at 703-487-4608. Additional assistance in locating the document is available from the NRC Public Document Room, nationally at 1-800-397-4209, or within the Washington, DC, area at 202-634-3273.

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Dated at Rockville, Maryland, this _____day of _____, 1996.

For the Nuclear Regulatory Commission

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Gerald F. Cranford
Designated Senior Official
for Information Resources Management

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OFFICE	OSP	OSP:DDG	OSP:D	IRM	OGC	IRM:D
NAME	PMLarkins:kk	PHLohaus	RLBangart	BJShelton	GFehst	GFCranford
DATE	12/12/96	12/16/96	12/18/96	12/18/96	12/ /96	12/ /96

Designated Original
PDR
Bill Shay

SUPPORTING STATEMENT FOR
Proposed NRC "Nuclear Material Events Database (NMED)"
for the Collection of
Event and Medical Misadministration Reports
(3150-0178)
Revision Request

Description of the information Collection

The Agreement States have been requested to voluntarily participate in an automated collection of Agreement State licensee data on the occurrence of incidents and events involving the use of radioactive byproduct material, such as medical misadministrations, 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. Previously this information was collected annually from the Agreement States on NRC Forms 565 and 566. In addition, significant events that could pose a significant health and safety hazard are requested to be orally reported by the Agreement States 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 events will be reported on a monthly basis using the automated system, which will replace the use of NRC Forms 565 and 566. Agreement States may also choose to submit the report in written form by using a copy of the NMED data screen.

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. 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. 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

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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. The information from medical misadministrations and event reports is invaluable in assessing actual Agreement State regulatory experiences.

Responsibility for regulating the 22,000 specifically licensed users of radioactive materials is shared between NRC and the 29 Agreement States. States regulate from as few as 100 licenses to over 2,000 licenses. Agreement State material licensees include about 4000 medical licensees and about 11,000 other nonreactor licensees. Approximately 65-70 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 misadministation events, from Agreement State licensees. The reported information will significantly aid in understanding material events and identifying actions necessary to improve the effectiveness of NRC and Agreement State regulatory programs.

In 1994 and 1995, all 29 Agreement States provided information on material events in various formats from very limited to very detailed information in technical content and substance. To improve the technical information content of event reports, ensure consistency, improve ease of access and retrieval of event information, and reduce duplication of effort in processing and rekeying information by all parties involved, we are requesting that this information be collected in a standardized format, through electronic transmission into the Nuclear Material Events Database (NMED). The NMED data entry elements have been expanded over those identified in NRC Forms 565 and 566 to respond to General Accounting Office and Congressional recommendations to provide a complete national set of data that is adequate to perform long-term trend analyses of what occurred, direct and indirect causes, possible precursors, identify any site specific or generic issues and any effects (long and short-term) as a result of the event, as well as the health and safety significance. The automated NMED system will replace NRC Form 565, Event Report, and NRC Form 566, Medical Misadministrations. All events will be reported on a monthly basis, primarily using the new automated system.

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 periodic collection of event data from the individual Agreement States will be assessed both individually and collectively to identify any safety concerns that could have the potential to reduce assurance that the health and safety of the public are adequately protected. Some significant events may meet the criteria for an abnormal occurrence. NRC is required to report abnormal occurrences to Congress on an annual basis. When incidents related to radiation safety have occurred at material licensees' facilities, the NRC reviews the incident report and assesses the information against other similar operating experiences. These assessments can provide important information to NRC, Agreement States, and other 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 in the conduct of the Agreement State Program or any revisions to nuclear material regulations. This information is also used during formal periodic reviews of an Agreement State radiation control program to assess the adequacy of their program to assure the protection of public health and safety. The NRC also provides feedback to industry, the regulated community and others, in the form of technical reports, training programs, video tapes on medical and industrial safety training, etc., on lessons learned in order to improve safety.

3. Reduction of Burden Through Information Technology

NRC has worked with the Agreement States through several workshops to develop an efficient and cost effective method for providing the necessary information. The goal of this joint effort has been to develop an events database system that meets the needs of both the NRC and the Agreement States. The national electronic database system will provide the Agreement States with online access to nuclear material event information from NRC and Agreement State licensees. The current percentage of information collected electronically is approximately 30%. Attachment A contains a list of the fields or elements that would be used to collect medical misadministration and incident and event information.

4. Efforts to Identify Duplication and to 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 voluntary information is requested only from Agreement State regulatory authorities.

6. Consequences to Federal Program Activities if the Collection is not Conducted or is Conducted Less Frequently

Information on events that could pose a significant health and safety hazard is requested to be orally reported to the NRC Operations Center within the next working day of notification to the Agreement State by an Agreement State licensee. (Under established regulatory requirements, Agreement State licensees will report significant events to the Agreement State within 24 hours.) 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. Information on events that do not pose a significant health and safety hazard are collected within one month or 30 days after notification to the Agreement States by a licensee. Collecting information on a less frequent basis could impact public health and safety, 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.

7. Circumstances Which Justify Variation from OMB Guidelines

Information on events that could pose a significant health and safety hazard is requested from Agreement States within the next working day of notification by their licensee so that NRC can identify immediately any health and safety hazard to the public, and offer assistance to the Agreement State in responding to the event. (Under established regulatory requirements these events will be reported by a licensee to the Agreement State within 24 hours or less)

8. Consultation Outside the NRC

In 1993, 1994, and 1995, the Agreement States were consulted and participated in the identification of information to be collected for the Nuclear Material Events Database system.

9. Confidentiality of 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.

10. Justification for Sensitive Questions

No sensitive information is requested.

11. Estimate of Other Additional Costs

None

12. Estimated Annualized Cost to the Federal Government

The following cost is estimated to be incurred by the government in the automated processing, coding and information storage activities related to these events and misadministration.

The staff estimates that it would take a contractor an average of about 233 hours per year to review an estimated 700 events and misadministrations forwarded annually by the Agreement States to NRC or 1/3 hour per report. Automating this effort reduces the government burden from 250 hours to 233 hours. The annual cost to the government is estimated as follows:

233 Hours X $120 an hour = $27,960 (professional effort)
50 Hours X $45 an hour = 2,250 (clerical effort)

TOTAL COST: $30,210.
Contractor Cost)

Events that occur that could pose a significant health and safety hazard will be orally reported by an Agreement State to the NRC Operations Center within the next working day of notification by their licensee. The staff estimates that they may receive and process approximately 20 such significant events, each of which would require approximately 2 hours of staff time.

2 hours X 20 significant events = 40 staff hours
40 staff hours X $120.00 an hour = $4,800.

TOTAL COST: $4,800.
(Staff Cost)

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

13. Estimate of Industry Burden

The requested information is collected in the following manner.

Agreement State licensees report information to the States and the States in turn will summarize event information received from their licensees and voluntarily enter this information into an electronic "Nuclear Material Event Database (NMED)," on a monthly basis. They will electronically transmit the information to NRC or send it to NRC via PC diskette. Some small Agreement State

programs with less than 100 licensees may provide NMED event reports in written form using a hard copy of the NMED data screen. Events do not occur with any particular frequency; therefore, a particular State may report 3-4 events during one month and may not report any information for the following two months.

Through formal Agreements with the Governor of a State the NRC relinquishes regulatory authority to the State. As the entity with regulatory authority, Agreement States, through regulations that are compatible to NRC regulations, require their licensees to report events and medical misadministrations involving the use of radioactive byproduct material. Additionally, as the entity with regulatory authority, the Agreement State radiation control program, generally under the State Department of Health, shoulders the responsibility and burden of collecting nuclear material event information from Agreement State licensees and voluntarily reports this information to NRC. Therefore, the Agreement State licensee's burden to report nuclear material event information to the Agreement State, and the Agreement State's burden to collect this information, exists absent NRC's request for voluntary Agreement State participation in the electronic reporting of medical misadministration and other incidents and events, and the burden is covered in separate OMB approvals for licensee reporting and Agreement State overview.

The staff estimates that the States receive from their licensees about 700 material event reports annually, and it will take about 3/4 (.75) hour for the Agreement State to process the event information received from their licensees.

29 States X 24 Reports/State = 700 X .75 hour = 525 burden hours

The previous OMB clearance for NRC Forms 565 and 566 estimated the burden to be 1050 hours. The change from written to electronic reporting reduces the estimated burden to 700 burden hours.

Based on historical data and experience during the first four months of a trial program using the NMED system, the additional burden to the Agreement States to enter the event information and electronically transmit it to NRC via the NMED system will be as follows:

29 States X 24 reports/State X .25 hour = 175 burden hours

In addition to the above, the Agreement States voluntarily report events that occur that could pose a significant health and safety hazard orally to the NRC Operations Center within the next working day of notification by their licensees. The staff estimates that they may report between 12 and 20 significant events, each of which would require between 5 and 15 minutes to report (15 min./rpt. x 20 rpts. = 5 burden hours).

The total burden for Agreement State licensees and Agreement States is (525 + 175 + 5) = 705 total burden hours.

14. Reason for Change in Burden

The burden is estimated to decrease from 1050 hours to 700 hours due to the use of an automated, rather than manual, system to collect the data.

15. Publication for Statistical Use

This information will not be published for statistical use.

16. Reason for Not Displaying the Expiration Date

Not applicable. The expiration date is displayed. The database software displays the OMB clearance number, burden estimate, expiration date and public protection statement as required.

17. Exceptions to the Certification Statement

Not applicable.

18. Payment or a Gift to Respondents

Three Agreement States were provided one 386 Personal Computer each, from NRC retired equipment, through a government to government transfer. The three Agreement States had indicated that they would not be able to participate in the electronic collection of event information due to insufficient equipment.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

The collection of information does not employ statistical methods.

Attachment:
As stated

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 misadministration, that 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 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. FOLLOW UP RPT NO.
(01, 02, etc.)
C. LICENSEE NAME, CITY AND STATE, ZIP CODE (Code)
D. LICENSE NO.
E. PROGRAM CODE (License Type)
F. SITE OF EVENT
G. STATE OF EVENT
H. LICENSE NO. OF SITE
I. WERE OTHER PARTIES INVOLVED?
IF SO, IDENTIFY (Provide Name\City\State):
J. RECIPROCITY (Code)
K. REPORTABLE EVENT (Y\N):
NRC ___ AS ___
L. AEA (Y\N)
M. DATE OF EVENT
N. TIME OF EVENT
O. TIME ZONE
P. DATE RPTED TO STATE
Q. TIME REPORTED
R. CONSULTANT (Y\N)
S. ABNORMAL OCCURRENCE (Y\N)
T. DATE OF THIS REPORT
U. INVESTIGATION (Y\N)
V. EVENT DESCRIPTION (Code)
W. CAUSE DESCRIPTION (Code)
X. CONTRIBUTING FACTOR (Code)
Y. PRECIPITATING FACTOR (Code)
Z. CORRECTIVE ACTION (Code)
A1. REPORTING REQUIREMENT

a. CLASS EVENT TYPE (Code)
b. NRC 10 CFR (Code)
c. AGREEMENT STATE COMPATIBLE REGULATION

SPECIFIC INFORMATION BASED ON TYPE OF EVENT

1. **RELEASE OF MATERIAL**
(Where applicable).

a. TYPE OF RELEASE (Code)
b. ISOTOPE (Code)
c. ACTIVITY (Ci) (Code)

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
Isotope
Chemical Form

b. ACTUAL DOSE (Code)

Millicuries
Isotope
Chemical Form
Study\Procedure

c. %OVERTREATMENT
d. %UNDERTREATMENT
e. FAMILY DOSE
f. FETAL DOSE
g. DOSE NEWBORN
h. ORGAN (Code)
i. EFFECT ON PATIENT(S)
j. WHO ADMINISTERED
k. DIAGNOSTIC OR THERAPEUTIC (D\T)
l. TREATMENT PLAN AND SCHEDULE--INTENDED AND ACTUAL (Include fractionations, where applicable)
m. NO. OF PATIENTS
n. PATIENT\RESPONSIBLE RELATIVE NOTIFIED (Y\N)
o. REFERRING PHYSICIAN NOTIFIED (Y\N)
p. DEMOGRAPHICS

3. **OVEREXPOSURE DATA** (Where applicable)

a. NO. OF PERSONS INVOLVED
b. DOSE RECEIVED (rem)
c. RADIATION SOURCE

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 TYPE
b. MANUFACTURER\SHIPPER
c. MODEL NO.
d. SERIAL\ID NO.
e. MANUFACT. DATE
f. ISOTOPE ACTIVITY (Ci) (Code)
g. ASSAY DATE
h. LEAK TEST RESULT (μCi)
i. SOURCE CHANGE DATE

4. EQUIPMENT INFO. CONT.

j. PROBLEM (Enter data when equipment may have contributed to the event).

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.)

December 11, 1996