PDR

Standard Form 83
(Rev. September 1983)

# Request for OMB Review

**Important**

Read instructions before completing form. Do not use the same SF 83 to request both an Executive Order 12291 review and approval under the Paperwork Reduction Act.

Answer all questions in Part I. If this request is for review under E.O. 12291, complete Part II and sign the regulatory certification. If this request is for approval under the Paperwork Reduction Act and 5 CFR 1320, skip Part II, complete Part III and sign the paperwork certification.

Send three copies of this form, the material to be reviewed, and for paperwork—three copies of the supporting statement, to:

Office of Information and Regulatory Affairs
Office of Management and Budget
Attention: Docket Library, Room 3201
Washington, DC 20503

## PART I.—Complete This Part for All Requests.

1. Department/agency and Bureau/office originating request

U.S. Nuclear Regulatory Commission

2. Agency code

3 1 5 0

3. Name of person who can best answer questions regarding this request

Pat Larkins

Telephone number

( 301 ) 504-2309

4. Title of information collection or rulemaking

NRC Forms 565 and 566, Event and Medical Misadministration Reports

5. Legal authority for information collection or rule *(cite United States Code, Public Law, or Executive Order)*

42 USC 2201(o) or

6. Affected public *(check all that apply)*

1 ☐ Individuals or households
2 ☒ State or local governments
3 ☐ Farms
4 ☒ Businesses or other for-profit
5 ☐ Federal agencies or employees
6 ☐ Non-profit institutions
7 ☒ Small businesses or organizations

## PART II.—Complete This Part Only if the Request is for OMB Review Under Executive Order 12291

7. Regulation Identifier Number (RIN)

___ ___ ___ ___ ___ ___ ___ ___ ___, or, None assigned ☐

8. Type of submission *(check one in each category)*

***Classification***
1 ☐ Major
2 ☐ Nonmajor

***Stage of development***
1 ☐ Proposed or draft
2 ☐ Final or interim final, with prior proposal
3 ☐ Final or interim final, without prior proposal

***Type of review requested***
1 ☐ Standard
2 ☐ Pending
3 ☐ Emergency
4 ☐ Statutory or judicial deadline

9. CFR section affected

___ CFR ___

10. Does this regulation contain reporting or recordkeeping requirements that require OMB approval under the Paperwork Reduction Act and 5 CFR 1320? ☐ Yes ☐ No

11. If a major rule, is there a regulatory impact analysis attached? 1 ☐ Yes 2 ☐ No
If "No," did OMB waive the analysis? 3 ☐ Yes 4 ☐ No

**Certification for Regulatory Submissions**

In submitting this request for OMB review, the authorized regulatory contact and the program official certify that the requirements of E.O. 12291 and any applicable policy directives have been complied with.

Signature of program official — Date

Signature of authorized regulatory contact — Date

12. *(OMB use only)*

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PART III — Complete This Part Only if the Request is for Approval of a Collection of Information Under the Paperwork Reduction Act and 5 CFR 1320.

13. Abstract (describe needs, uses and affected public in 50 words or less) "Radiation Exposure, Radioactive Materials, Radiation Safety"

Agreement State licensees, as a matter of compatibility, are required to report misadministration and events involving personnel overexposures or lost, stolen, abandoned or damaged radioactive material to their respective agreement states. NRC is requesting voluntary submittal of this data to NRC in a uniform summary format.

14. Type of information collection (check only one)

*Information collections not contained in rules*

1 [X] Regular submission
2 [ ] Emergency submission (certification attached)

*Information collections contained in rules*

3 [ ] Existing regulation (no change proposed)
4 [ ] Notice of proposed rulemaking (NPRM)
5 [ ] Final NPRM was previously published
6 Final or interim final without prior NPRM
A [ ] Regular submission
B [ ] Emergency submission (certification attached)

7. Enter date of expected or actual Federal Register publication at this stage of rulemaking (month, day, year) _____

15. Type of review requested (check only one)

1 [X] New collection
2 [ ] Revision of a currently approved collection
3 [ ] Extension of the expiration date of a currently approved collection without any change in the substance or in the method of collection
4 [ ] Reinstatement of a previously approved collection for which approval has expired
5 [ ] Existing collection in use without an OMB control number

16. Agency report form number(s) (include standard/optional form number(s))

NRC Forms 565 and 566

17. Annual reporting or disclosure burden

| | |
|---|---|
| 1 Number of respondents | 29 |
| 2 Number of responses per respondent | 25 |
| 3 Total annual responses (line 1 times line 2) | 700 |
| 4 Hours per response | 1.54 |
| 5 Total hours (line 3 times line 4) | 1,050 |

18. Annual recordkeeping burden

| | |
|---|---|
| 1 Number of recordkeepers | |
| 2 Annual hours per recordkeeper | |
| 3 Total recordkeeping hours (line 1 times line 2) | |
| 4 Recordkeeping retention period | years |

19. Total annual burden

| | |
|---|---|
| 1 Requested (line 17-5 plus line 18-3) | 1,050 |
| 2 In current OMB inventory | 0 |
| 3 Difference (line 1 less line 2) | + 1,050 |
| *Explanation of difference* | |
| 4 Program change | + 1,050 |
| 5 Adjustment | |

20. Current (most recent) OMB control number or comment number

21. Requested expiration date

3 years from approval

22. Purpose of information collection (check as many as apply)

1 [ ] Application for benefits
2 [X] Program evaluation
3 [ ] General purpose statistics
4 [X] Regulatory or compliance
5 [ ] Program planning or management
6 [ ] Research
7 [ ] Audit

23. Frequency of recordkeeping or reporting (check all that apply)

1 [ ] Recordkeeping

***Reporting***

2 [ ] On occasion
3 [ ] Weekly
4 [ ] Monthly
5 [ ] Quarterly
6 [ ] Semi-annually
7 [X] Annually
8 [ ] Biennially
9 [ ] Other (describe) _____

24. Respondents' obligation to comply (check the strongest obligation that applies)

1 [X] Voluntary
2 [ ] Required to obtain or retain a benefit
3 [ ] Mandatory

25. Are the respondents primarily educational agencies or institutions or is the primary purpose of the collection related to Federal education programs? [ ] Yes [X] No

26. Does the agency use sampling to select respondents or does the agency recommend or prescribe the use of sampling or statistical analysis by respondents? [ ] Yes [X] No

27. Regulatory authority for the information collection

10 CFR 20, 34, 35, and 39 , or _____ FR _____ , or Other (specify) _____

**Paperwork Certification**

In submitting this request for OMB approval, the agency head, the senior official or an authorized representative, certifies that the requirements of 5 CFR 1320, the Privacy Act, statistical standards or directives, and any other applicable information policy directives have been complied with.

Signature of program official — Date

Signature of agency head, the senior official or an authorized representative — Date

Gerald F. Cranford, DSO for Information Resources Management — 9/11/94

* U.S. Government Printing Office: 1990-270-914/10134

SUPPORTING STATEMENT FOR
Proposed NRC Forms: 565, and 566
"Event and Misadministration Reports"
(3150- )

Description of the information Collection

The Agreement States have been requested to voluntarily submit on proposed NRC Forms 565, and 566, respectively, licensee data on the occurrence of medical misadministration events and other material events having safety significance, such as, radiation overexposures, leaking sources, lost sources, etc., on an annual basis. This information is submitted to the Agreement States by their licensees and is forwarded to the NRC. Previously, some Agreement States have submitted this information to the NRC on an annual basis, while others submit these reports on an indeterminate frequency. In most cases, Agreement States receive reports from their licensees immediately following any event or misadministration having potential safety significance.

A. JUSTIFICATION

1. Need for the Collection of Information.

The Atomic Energy Act of 1954 ("the Act") Sections 274 Paragraphs D and J, require the Nuclear Regulatory Commission (as successor to the Atomic Energy Commission) to perform evaluations of an Agreement States' program to ensure that the State has regulations that are compatible with NRC's regulations and to ensure that the State's regulatory program is adequate to protect the public health and safety. In addition to these Section D and J evaluations, Section G of the Act requires NRC and the Agreement States to cooperate and share information and lessons learned from State and Federal regulating experiences. The information from misadministrations and event reports is valuable in assessing actual Agreement State regulatory experiences. When incidents related to radiation safety matters have occurred at material licensees' facilities, the NRC has reviewed these incidents and assessed the information against other similar operating experiences. These assessments can provide important information to NRC, Agreement States, and other material licensees regarding safe operational details and procedures.

Agreement State material licensees include about 4000 medical licensees and about 11,000 other nonreactor licensees. Although NRC has been evaluating medical misadministrations and other events reported by NRC licensees, these data represent only 30 to 40 percent of the data available nationwide. Agreement State misadministration and event report data will significantly aid in understanding material events and the actions necessary to prevent them.

In 1991, 16 of the 28 Agreement States provided data to the NRC. In 1992, all 29 agreement States provided information on material events. This information is being requested on forms to clearly indicate the information required by the regulations in a standard easily completed format.

2. Agency Use of the Information

The event reports and misadministrations submitted to the NRC by the Agreement States will be assessed both individually and collectively to identify any safety concerns which have the potential to seriously impact the health and safety of the public. These assessments by NRC would also identify generic implications which indicate a need for NRC to assess any changes needed in the conduct of its Agreement State Program.

3. Reduction of Burden Through Information Technology

The NRC has no objection to the use of information technologies that would reduce the burden associated with this information collection. Discussions are currently underway with the Agreement States to determine the most efficient and cost effective method for providing the necessary information.

4. Efforts to Identify Duplication

The Information Requirements Control Automated System (IRCAS) was searched and no duplication was found.

5. Efforts to Use Similar Information

There is no similar information available to the NRC. The information provided on the subject forms is not available from any other source other than Agreement States.

6. Effort to Reduce Small Business Burden

The majority of licensees who use byproduct materials are small businesses. Since the health and safety consequences of the improper handling or use of radioactive byproduct materials are the same for large and small entities, it is not possible to reduce the burden on small businesses by less frequent or less complete reporting.

7. Consequences of Less Frequent Collections

Collecting information on less than an annual frequency could greatly reduce the usefulness of the needed Agreement State assessments.

8. Circumstances Which Justify Variation from OMB Guidelines

None

9. Consultation Outside the NRC

In 1991 the NRC Agreement States were consulted and participated in the identification of information to be collected on these forms.

10. 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 at 10 CFR 2.790 regarding the handling of proprietary information.

11. Justification for Sensitive Questions

No sensitive information is requested.

12. Estimated Annualized Cost to the Federal Government

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

The staff estimates that it would take an average of about 250 hours to review an estimated 700 events and misadministrations forwarded annually by the Agreement States to NRC. This is approximately 1/3 hour per form. However, the use of the forms will expedite the review and reduce the evaluation time for the submitted data by half. The estimated burden is therefore 250 hours and the cost to the NRC to process 700 event reports at $132/hr is:

250 hours x $132.00/hour = $33,000.

The NRC is required by law to fully recover the cost associated with the regulation of nuclear power. These costs are fully recovered through fee assessments to NRC licensees pursuant to 10 CFR Part 171.

13. Estimate of Industry Burden

The requested information is collected in the following way:

Agreement State licensees report information to the States and the States in turn will use the forms to summarize event information received from their licensees. The summarized information contained on the event reporting form is then submitted to NRC. In this case, the primary or major burden for preparing event reporting information rests with the Agreement State. However, the burden of verbal reporting by the Agreement State licensee exists absent NRC's request for use of the misadministration and event reporting forms. The staff estimates that the States will receive from their licensees about 700 material event reports and it will take about an hour each to fill out the applicable NRC forms.

The estimated burden to Agreement State licensees will be:

700 event reports x approximately 1/2 hour per verbal report = 325 burden hours.

The burden to the Agreement States will be as follows:

29 States x 25 reports/State x 1 hour = 725 burden hours.

The total burden for Agreement State licensees and Agreement States is 1050 burden hours (325 + 725 hours).

14. Reason for change in Burden

This is a newly cleared collection.

15. Publication for statistical Use

This information will not be published for statistical use.

B. Collections of Information Employing Statistical Methods

The collection of information does not employ statistical methods.

NRC FORM 565 (12-93)

U. S. NUCLEAR REGULATORY COMMISSION

# EVENT REPORT

APPROVED BY OMB: NO. 3150-
EXPIRES

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST: HOURS. THIS INFORMATION IS NEEDED TO ASSESS MATERIALS EVENTS AND EVALUATE ACTIONS NECESSARY TO PREVENT THEIR RECURRENCE. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (MNBB 7714), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555-0001, AND TO THE PAPERWORK REDUCTION PROJECT (3150- ), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.

| LICENSEE | CITY AND STATE | ORIGINAL ITEM NUMBER |
|---|---|---|
| | | |
| TYPE OF LICENSE *(i.e., Field Radiography, Private Practice Medical, etc.)* | LICENSE NUMBER | THIS ITEM NUMBER |
| | | |

| ABNORMAL OCCURRENCE | FOLLOW-UP REPORT | ISOTOPE | TYPE OF ISOTOPE | DATE OF EVENT |
|---|---|---|---|---|
| ☐ YES<br>☐ NO | ☐ YES | | ☐ AEA MATERIAL<br>☐ ACCELERATOR PRODUCED<br>☐ NORM | DATE OF THIS REPORT |

AMOUNT OF RADIOACTIVE MATERIAL *(If amount of material is below exempt quantity, do not complete this form)*

| | | | |
|---|---|---|---|
| ☐ < 1 MILLICI | ☐ 100 MILLICI - < 1 CI | ☐ 10 CI - 100 CI | ☐ UNKNOWN |
| ☐ 1 MILLICI - < 100 MILLICI | ☐ 1 CI - < 10 CI | ☐ > 100 CI | |

EVENTS INVOLVING OVEREXPOSURE

| NUMBER OF OVEREXPOSURES | TYPE OF INDIVIDUAL | EVENT LOCATION | DOSE TO | DOSE | RAD | REM |
|---|---|---|---|---|---|---|
| | | | ☐ WHOLE BODY | | | |
| SOURCE OF RADIATION | ☐ EMPLOYEE | ☐ RESTRICTED AREA | ☐ LENS OF EYE | | | |
| ☐ EXTERNAL | ☐ MINOR EMPLOYEE | ☐ UNRESTRICTED AREA | ☐ EXTREMITY | | | |
| ☐ INTERNAL | ☐ EMBRYO/FETUS | ☐ CONTROLLED AREA | ☐ SKIN | | | |
| ☐ BOTH | ☐ PUBLIC | | ☐ ORGAN | | | |

☐ LEAKING SOURCE

☐ LOST OR STOLEN MATERIAL

| EVENT | EVENT LOCATION | PROBABLE DISPOSITION | |
|---|---|---|---|
| ☐ LOST | ☐ FIXED SITE | ☐ WELL LOGGING RECOVERED SOURCE | ☐ UNKNOWN |
| ☐ FOUND | ☐ TEMPORARY JOB SITE | ☐ WELL LOGGING IRRETRIEVABLE SOURCE | ☐ OTHER *(Specify)* |
| ☐ THEFT | ☐ LICENSED VEHICLE | ☐ COMMERCIAL WASTE | |
| ☐ THEFT, WITH FORCE | ☐ COMMERCIAL CARRIER | ☐ INCINERATOR | |
| | ☐ OTHER *(Specify)* | ☐ SCRAP METAL | |

☐ RELEASE OF MATERIALS

| FORM | EVENT | LOCATION |
|---|---|---|
| ☐ SOLID | ☐ SPILL | ☐ RESTRICTRED AREA |
| ☐ LIQUID | ☐ TRANSPORTATION | ☐ UNRESTRICTED AREA |
| ☐ GAS | ☐ OTHER *(Specify)* | ☐ CONTROLLED AREA |

☐ EVENTS INVOLVING FACILITIES

| | | |
|---|---|---|
| ☐ FIRE | ☐ SPILL | ☐ OTHER *(Specify)* |
| ☐ DAMAGE TO DEVICE | ☐ > 24-HOUR DENIAL OF ACCESS | |
| ☐ EXPLOSION | ☐ DAMAGE TO SAFETY EQUIPMENT | |

☐ EVENTS INVOLVING GAUGES

| TYPE | EVENT |
|---|---|
| ☐ GENERAL LICENSE | ☐ SHUTTER |
| ☐ EXEMPT | ☐ MOISTURE/DENSITY GAUGE DAMAGE |
| ☐ SPECIAL LICENSE | ☐ LOST/STOLEN |
| ☐ FIXED | ☐ OTHER *(Specify)* |
| ☐ PORTABLE | |

☐ EVENTS INVOLVING RADIOGRAPHY

| LOCATION | EVENT |
|---|---|
| ☐ FIXED | ☐ SOURCE DISCONNECT |
| ☐ TEMPORARY JOB SITE | ☐ SOURCE NOT RETURNED TO FULLY SHIELDED POSITION |
| | ☐ CABLE FAILURE |
| | ☐ FAILURE TO FOLLOW PROCEDURES |

| ☐ EVENT INVOLVING AN IRRADIATOR | MANUFACTURER | MODEL | SERIAL NUMBER |
|---|---|---|---|
| ☐ EVENTS INVOLVING TELETHERAPY | | | |

ABSTRACT *(Include the cause of the event(s) and licensee corrective action. May be continued on the reverse side)*

NRC FORM 5E6 (12-93)

U. S. NUCLEAR REGULATORY COMMISSION

# MEDICAL MISADMINISTRATION

APPROVED BY OMB: NO. 3150-
EXPIRES

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST: HOURS. THIS INFORMATION IS NEEDED TO ASSESS MISADMINISTRATIONS AND EVALUATE ACTIONS NECESSARY TO PREVENT THEIR RECURRENCE. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (MNBB 7714), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555-0001, AND TO THE PAPERWORK REDUCTION PROJECT (3150- ), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.

| LICENSEE | CITY AND STATE | ORIGINAL ITEM NUMBER |
|---|---|---|
| TYPE OF LICENSE *(e.g., Broad Scope, Private Practice Medical, etc.)* | LICENSE NUMBER | THIS ITEM NUMBER |
| ABNORMAL OCCURRENCE: ☐ YES ☐ NO | FOLLOW-UP REPORT: ☐ YES ☐ NO | THE PATIENT WAS NOTIFIED: ☐ YES ☐ NO | DATE OF EVENT / DATE OF THIS REPORT |

☐ SODIUM IODINE, I-125 OR I-131, > 30 MICROCURIES

- ☐ WRONG PATIENT
- ☐ WRONG RADIOPHARMACEUTICAL
- ☐ ADMINISTERED DOSE DIFFERS FROM PRESCRIBED DOSE BY > 20% AND DIFFERENCE EXCEEDS 30 MICROCURIES

☐ THERAPEUTIC RADIOPHARMACEUTICAL DOSE, OTHER THAN I-125 OR I-131

- ☐ WRONG PATIENT
- ☐ WRONG RADIOPHARMACEUTICAL
- ☐ WRONG ROUTE OF ADMINISTRATION
- ☐ ADMINISTERED DOSE DIFFERS FROM PRESCRIBED DOSE BY > 20%

☐ STEREOTACTIC RADIOSURGERY (GAMMAKNIFE)

- ☐ WRONG PATIENT
- ☐ WRONG TREATMENT SITE
- ☐ ADMINISTERED DOSE DIFFERS FROM PRESCRIBED DOSE BY MORE THAN 10%

☐ TELETHERAPY

- ☐ WRONG PATIENT
- ☐ WRONG MODE OF TREATMENT
- ☐ WRONG TREATMENT SITE
- ☐ ADMINISTERED DOSE DIFFERS FROM PRESCRIBED DOSE BY MORE THAN 10% IF THERE ARE 3 OR FEWER FRACTIONS PRESCRIBED; OR WHEN WEEKLY CALCULATED ADMINISTERED DOSE EXCEEDS PRESCRIBED DOSE BY > 30%; OR WHEN CALCULATED TOTAL ADMINISTERED DOSE DIFFERS FROM PRESCRIBED DOSE BY > 20%

☐ BRACHYTHERAPY

- ☐ WRONG PATIENT
- ☐ WRONG RADIOISOTOPE
- ☐ WRONG TREATMENT SITE
- ☐ LEAKING SOURCE
- ☐ ONE OR MORE SOURCES NOT REMOVED AT END OF TREATMENT
- ☐ CALCULATED ADMINISTERED DOSE DIFFERS FROM PRESCRIBED DOSE BY > 20%

☐ DIAGNOSTIC RADIOPHARMACEUTICAL DOSE, OTHER THAN QUANTITIES THAT EXCEED 30 MICROCURIES OF I-125 OR I-131, OR BOTH, WHEN THE PATIENT DOSE EXCEEDS 5 REM EFFECTIVE DOSE EQUIVALENT OR 50 REM ORGAN DOSE AND INVOLVES:

- ☐ WRONG PATIENT
- ☐ WRONG RADIOPHARMACEUTICAL
- ☐ WRONG ROUTE OF ADMINISTRATION
- ☐ ADMINISTERED DOSE DIFFERS FROM PRESCRIBED DOSAGE

ABSTRACT *(Include the cause of the misadministration, contributing factors, and licensee corrective action. May be continued on the reverse side.)*

[7590-01]

NUCLEAR REGULATORY COMMISSION

Documents Containing Reporting or Recordkeeping Requirements: Office of Management and Budget (OMB) Review

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of the OMB review of information collection.

SUMMARY: The Nuclear Regulatory Commission has recently submitted to the Office of Management and Budget (OMB) for review the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

1. Type of submission, new, revision or extension: New.

2. The title of the information collection: Event Report; Medical Misadministration Report.

3. The form number if applicable: NRC Forms 565 and 566.

4. How often the collection is required: Annually.

5. Who will be required or asked to report: All Agreement States. There are currently 29 Agreement States who have signed Section 274(b) agreements with the NRC. This would also be applicable to any State receiving Agreement State status in the future.

6. An estimate of the number of responses: 700 per year total for both forms.

7. An estimate of the total number of hours needed annually to complete the requirement or request: 1050 hours (1.5 hours per response) for existing Agreement States which assumes that all of the Agreement States report each year; any new Agreement State would add approximately 25 reports per year or 38 burden hours.

8. An indication of whether Section 3504(h) Pub. L. 96-511 applies: Not applicable.

9. Abstract: NRC licensees are required to report events such as those involving a personnel overexposure, a leaking or contaminated sealed source, release of excessive contaminations of radioactive material, lost or stolen radioactive materials and abandoned well logging sources. Misadministrations are required to be reported in accordance with 10 CFR 35.33. Agreement State licensees as a matter of compatibility are also required to report these events and misadministrations to their individual Agreement States where radioactive material is used. NRC is requesting voluntary submittal of summary event and misadministration data from the Agreement States in a uniform format to assess materials events to identify any safety concerns that could have the

potential to impact public health and safety and to evaluate actions necessary to prevent their occurrence.



Comments and questions should be directed to the OMB reviewer:

Troy Hillier
Office of Information and Regulatory Affairs (3150- )
NEOB-3019
Office of Management and Budget
Washington, D.C. 20503

Comments may also be communicated by telephone at (202) 395-3084.
The NRC Clearance Officer is Brenda Jo. Shelton, (301) 492-8132.

Dated at Bethesda, Maryland, this 11th day of January 1994.

For the Nuclear Regulatory Commission

Gerald F. Cranford
Designated Senior Official for
Information Resources Management