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

James H. Myers

Telephone number

(301) 492-0637

4. Title of information collection or rulemaking

10 CFR Part 35 - Medical Use of Byproduct Material

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)*

PART III.—Compiete 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 Safety, Radioactive Materials, Nuclear Medicine"
10 CFR Part 35 contains requirements that apply to NRC licensees who are authorized to administer byproduct material or its radiation to humans for medical care. The information in the required reports and records is used by the NRC to make licensing and regulatory decisions to ensure protection of the public health and safety.

14. Type of information collection *(check only one)*

Information collections not contained in rules

1 ☐ 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 ☐ 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))*

Not applicable

17. Annual reporting or disclosure burden

1 Number of respondents	2,400
2 Number of responses per respondent	3,509.6
3 Total annual responses *(line 1 times line 2)*	8,422,955
4 Hours per response	.002
5 Total hours *(line 3 times line 4)*	18,788

18. Annual recordkeeping burden

1 Number of recordkeepers	2,400
2 Annual hours per recordkeeper	118.4
3 Total recordkeeping hours *(line 1 times line 2)*	284,156
4 Recordkeeping retention period	3 years to duration of license years

19. Total annual burden

1 Requested *(line 17-5 plus line 18-3)*	302,944
2 In current OMB inventory	419,929
3 Difference *(line 1 less line 2)*	- 116,985
Explanation of difference	
4 Program change	
5 Adjustment	- 116,985

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

3150-0010

21. Requested expiration date

3 years from approval date

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

1 ☐ Application for benefits
2 ☐ Program evaluation
3 ☐ General purpose statistics
4 ☒ 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 ☐ Annually
8 ☐ Biennially
9 ☒ Other *(describe)* Renewals every 5 years

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

1 ☐ 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 ☒ 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 ☒ No

27. Regulatory authority for the information collection

10 CFR Part 35 ; 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

Joyce A. Amenta, Sisignated Senior Official for Information Resources Management — Joyce Amenta — 10/10/89

☆ GPO : 1984 O - 453-776

SUPPORTING STATEMENT
FOR
10 CFR PART 35
MEDICAL USE OF BYPRODUCT MATERIAL
AND
NRC FORM 473
DIAGNOSTIC MISADMINISTRATION REPORT

Background

10 CFR Part 35, Medical Use of Byproduct Material, contains requirements that apply to Nuclear Regulatory Commission (NRC) licensees who are authorized to administer byproduct material or its radiation to humans for medical diagnosis and therapy. NRC Form 473 is used by NRC medical licensees to report diagnostic misadministrations of radiopharmaceuticals as required by 10 CFR Section 35.33.

Justification

Part of NRC's function is to license and regulate the use of byproduct materials in order to assure protection of the public health and safety. The NRC requires licensees to perform certain tasks to ensure fulfillment of their obligations. The records required in this part are the least burdensome way for licensees to demonstrate compliance. Occasionally, safety matters are of such significance that others need to be aware of information in order to perform their jobs or work in a safe manner. In these cases, reports are required.

Need for and Practical Utility of the Information Collection

Sections 35.12 (b) and (c) of 10 CFR Part 35 require that applicants submit a completed NRC Form 313. The form elicits an orderly description of the applicant's complete radiation safety program. Requests for amendments and license renewals may be submitted in letter format. This report is needed to assure

NRC that the applicant has programs in place adequate to protect health and minimize danger to life and property before NRC can authorize receipt of radioactive material. NRC Form 313 has previously been cleared under OMB No. 3150-0120, which should be referred to for additional supporting information, as well as burden and cost data.

Section 35.13 of 10 CFR Part 35 requires that licensees apply for and receive a license amendment before using material not allowed by the license, before adding to or changing key individuals, before receiving more material than allowed by the license, or before changing the location of use or mailing address. The triggering events are critical indicators of a potential for change in the licensee's ability to control radiation dose to workers and the public, or the NRC's ability to contact the licensee or conduct an inspection of the licensee's program. The information is needed so that the staff can determine whether the licensee has individuals with adequate training and experience to safely use radioactive material and the facilities and equipment needed to assure protection of public health and safety.

Section 35.14 of 10 CFR Part 35 requires that licensees notify the NRC within 30 days if a key worker ends his association with the licensee. This prompt report is needed because if the licensee no longer has a complete staff, the collective training and experience of the remaining staff may no longer be sufficient to ensure safety. This report will trigger a check of the licensee's file to determine whether the licensee's remaining users are qualified to receive and use material safely.

Section 35.20 requires licensees to have a written program to keep radiation dose as low as reasonably achievable. The program must be written to provide clear statements of authority, responsibility, and technical requirements.

Section 35.21(b)(2) of 10 CFR Part 35 requires that the licensee establish and implement the written policy and procedures that were submitted as part of the application. The policy and procedures are needed so that the staff can review them and make a determination that the applicant can meet the requirements of the Atomic Energy Act and the Commission's regulations. The procedures must be implemented in order to provide for protection of the public health and safety.

The burden is included in the burden for the application, NRC Form 313, OMB No. 3150-0120.

Sections 35.22(a)(4) and (5) of 10 CFR Part 35 require that medical institution licensees retain a copy of Radiation Safety Committee meeting minutes for the duration of the license, and prescribe the information required in the minutes. This record is needed to show continuing management oversight of the radiation safety program.

Section 35.23(b) of 10 CFR Part 35 requires that licensees provide a written statement of authority, duties, responsibilities, and radiation safety activities for the Radiation Safety Officer and Radiation Safety Committee. The statement is needed so that managers and key users know their responsibilities. The statement must be retained for the duration of the license.

Section 35.27(a) of 10 CFR Part 35 requires that licensees provide written permission to visiting authorized users to work under the license. Section 35.27(c) requires licensees to retain a copy of an NRC or Agreement State license identifying the visitor as an authorized user. This permission and record are needed to show that licensee management has permitted this work, and that a regulatory agency has reviewed and approved the visitor's training and experience.

Section 35.29(b) of 10 CFR Part 35 requires that mobile nuclear medicine service licensees keep a letter of permission signed by the management of each client. This record is needed to show that client management has permitted this work.

Section 35.31(b) of 10 CFR Part 35 requires that licensees make a record of minor radiation safety program changes. This record is needed to show what radiation safety factors were considered before implementing the change, and also provides a record of where within the licensee's facility radioactive materials were received, used, and stored.

Section 35.33(a) of 10 CFR Part 35 requires that the licensee notify by telephone the appropriate NRC regional office in case of a therapy

misadministration within 24 hours after discovering the misadministration. This prompt notification is necessary because a therapy misadministration may present a clear and present radiation hazard to members of the public that might be mitigated by NRC assistance. The licensee is also required to notify the referring physician and the patient or a responsible relative (or guardian) of the patient unless contraindicated by factors known to the referring physician. These reports are needed so that adequate care can be provided for the patient.

Section 35.33(b) of 10 CFR Part 35 requires that a licensee file a written report to NRC within 15 days after telephoning an initial therapy misadministration report. This report is needed so that NRC can determine whether there might be generic implications in the incident which would require notification of all licensees. The licensee is allowed 15 days to submit the report so that it can review and analyze the event and provide NRC with a complete history of the event. NRC requires submission of the report within 15 days so that it can promptly notify other licensees of a generic problem.

Section 35.33(c) of 10 CFR Part 35 requires that the Radiation Safety Officer investigate the cause of diagnostic misadministrations and make a record for NRC review. The licensee must also notify the referring physician and the NRC Regional Office in writing on NRC Form 473 within 15 days. These written records are needed to determine what kinds of errors precipitate diagnostic misadministrations, and also provide an indicator of the licensee's management control of the radiation safety program.

Section 35.33(d) of 10 CFR Part 35 requires licensees to retain a record of each misadministration for 10 years. Misadministration events occur infrequently, and records must be retained for a sufficiently long time to evaluate the effectiveness of the licensee's corrective actions.

Section 35.50(b)(4) of 10 CFR Part 35 requires that licensees make a record of a geometry dependence test for the dose calibrator. This record is needed to demonstrate the relationship between volume configurations of the radiopharmaceutical and the accuracy of the reading given by the dose calibrator.

Section 35.50(e) of 10 CFR Part 35 requires that licensees retain a record of checks and tests of dose calibrator performance. This record is needed to show that the dose calibrator is functioning correctly and is capable of accurately measuring radiopharmaceutical dosages.

Section 35.51(a)(3) requires that the licensee note on a survey instrument the apparent exposure rate from a dedicated check source at the time of instrument calibration. This information is needed so the licensee can check the survey instrument for proper operation before making measurements. The burden is included in the burden estimate for Section 35.51(d).

Section 35.51(d) of 10 CFR Part 35 requires that licensees retain a record of survey instrument calibrations. This record is needed to show that survey instruments were calibrated and operational.

Section 35.53(c) of 10 CFR Part 35 requires that licensees retain a record of each radiopharmaceutical dosage measurement. This record is needed to show that licensees are maintaining control of the use of radiopharmaceuticals.

Section 35.59(a) of 10 CFR Part 35 requires that licensees maintain written instructions for the safe use of sealed sources and brachytherapy sources. These instructions are needed so that individuals who are handling sources can determine the specific safety measures appropriate for each kind of source used.

Section 35.59(d) of 10 CFR Part 35 requires that licensees retain a record of sealed source leak tests. This record is needed to show that the leak test was done at the appropriate time, and that the test showed that the source was not leaking.

Section 35.59(e)(2) requires that licensees file a report with the NRC within five days if leakage of a sealed source is detected. This report is needed so that NRC can make a determination as to whether other licensees who have similar sealed sources should take special precautions. NRC allows the licensee 5 days to submit the report so that it can review and analyze the source and the leakage measurement. NRC requires submission of the report

within 5 days so that it can promptly notify other licensees if it appears there may be a generic problem.

Section 35.59(g) of 10 CFR Part 35 requires that licensees make a record of sealed source and brachytherapy source inventory. This inventory is needed to show that possession of sealed sources did not exceed the amount authorized by the license. The five-year recordkeeping requirement will help to assure continued control over these sources that are only occasionally used.

Section 35.59(i) of 10 CFR Part 35 requires that licensees make a record of radiation surveys of areas where sealed sources and brachytherapy sources are stored. This record is needed to show that adequate radiation shielding has been provided for such sources, and that dose rates in contiguous areas are within allowed levels.

Section 35.60(b) of 10 CFR Part 35 requires that licensees label each syringe or syringe radiation shield as to its contents. This label is needed because review of misadministration reports has indicated that in many cases misadministrations are caused by inadvertent transposition of syringes.

Section 35.61(b) of 10 CFR Part 35 requires that licensees label vial radiation shields with the identity of the radiopharmaceutical contained. NRC review of several misadministration reports indicates that many misadministrations occur when technicians draw a dosage from the wrong vial of radioactive material. Labels will help to reduce the chance of this happening.

Sections 35.70(d) and (g) of 10 CFR Part 35 require that the licensee establish action levels for radiation surveys. The action levels provide the individual who makes a radiation survey with information on what levels are expected and what levels require investigation. The sections also require that the licensee immediately notify the Radiation Safety Officer if excessive levels are detected during a survey. This report is needed so that the Radiation Safety Officer can take appropriate remedial action. The Radiation Safety officer is the one individual onsite who is qualified to determine what action is needed to ensure worker and public health and safety, and whether that action is needed immediately or can be delayed.

Section 35.70(h) of 10 CFR Part 35 requires that licensees retain a record of radiation surveys. The record is needed to show that the required surveys were made.

Section 35.80(f) of 10 CFR Part 35 requires that mobile nuclear medicine service licensees make a record of radiation surveys. The record is needed to show that the required surveys were made.

Section 35.92(b) of 10 CFR Part 35 requires that licensees make a record of disposal of waste that was decayed in storage. The record is needed to show that materials were decayed for the proper length of time and that a proper survey of each waste container was made prior to disposal.

Section 35.204(c) of 10 CFR Part 35 requires that licensees retain a record of molybdenum-99 concentration in radiopharmaceuticals. This record is needed to show that the concentration measurement was made and that the maximum molybdenum-99 concentration level was not exceeded.

Section 35.205(d) requires that the licensee post a time period of evacuation in areas where aerosols and gases are used. In case of a spill, this provides notice to workers of how much time air handling equipment needs to reduce the air concentration to permissible limits. The licensee must retain a record of the calculations used to determine the evacuation time for the duration of the license.

Section 35.310(b) of 10 CFR Part 35 requires that licensees retain a record of radiation safety instruction given to personnel who care for radiopharmaceutical therapy patients. This record is needed to show that the training was given.

Sections 35.315(a)(2) and 35.415(a)(2) require that the licensee post radiopharmaceutical therapy and brachytherapy patient room doors with a "Radioactive Materials" sign. This provides notice to hospital workers and the public that there is radioactivity in the room. The section also requires that the licensee note in the patient's chart how long visitors may stay in the

patient's room. This is the most convenient way to provide this information to nurses, who are usually responsible for enforcing visiting rules.

Sections 35.315(a)(4) and 35.415(a)(4) require that licensees make a record of dose rates around radiopharmaceutical treatment and implant treatment rooms. This record is needed to show that members of the public are not exposed to excessive levels of radiation.

Section 35.315(a)(8) of 10 CFR Part 35 requires that licensees make a record of the thyroid burden measurement of each individual who helped prepare or administer a therapeutic dosage of iodine-131. This record is needed to show that workers were not exposed to excessive levels of iodine-131.

Sections 35.315(b) and 35.415(b) of 10 CFR Part 35 require that the licensee promptly notify the Radiation Safety Officer if the radiopharmaceutical therapy or brachytherapy patient dies or has a medical emergency. This report is needed so that the Radiation Safety Officer can take whatever actions are necessary to prevent a spread of radioactive contamination or loss of brachytherapy sources. The Radiation Safety Officer is the one individual onsite who is qualified to determine what action is needed to ensure worker and public health and safety, and whether that action is needed immediately or can be delayed.

Section 35.404(b) of 10 CFR Part 35 requires that licensees retain a record of the radiation survey of each patient who was treated with temporary implant sources. The record is needed to show that the survey was made.

Section 35.406(b) of 10 CFR Part 35 requires that licensees make a record of brachytherapy source use. This record is needed so that, if a brachytherapy source is misplaced, the licensee knows where to look for it.

Section 35.406(c) of 10 CFR Part 35 requires that licensees make a record of radiation surveys of patients after implanting sources. This record is needed to show that the survey was made.

Section 35.406(d) requires that the licensee retain a record of the use of brachytherapy sources and special safety surveys. This record is needed to

show that the licensee is providing adequate control for these sources. The record burden is included in the burden estimate for Sections 35.406(b) and (c).

Section 35.410(a) of 10 CFR Part 35 requires that licensees provide written radiation safety instruction for personnel caring for implant therapy patients. This instruction is needed so that these personnel may study and refer to it while caring for the patient.

Section 35.410(b) of 10 CFR Part 35 requires that licensees retain a record of training for personnel who care for implant patients. This record is needed to show that the training was given.

Section 35.606 of 10 CFR Part 35 requires that licensees apply for and receive a license amendment before making certain changes in the teletherapy program. This license amendment process is necessary because the licensee might consider making changes that would cause radiation levels in restricted and unrestricted areas to exceed permissible levels.

Section 35.610(a) of 10 CFR Part 35 requires that licensees post written instructions for individuals who operate teletherapy units. These instructions are needed to remind workers of proper operating procedures.

Section 35.610(c) of 10 CFR Part 35 requires that licensees make a record of training for individuals who operate teletherapy units. This record is needed to show that the training was given.

Section 35.615(d)(4) of 10 CFR Part 35 requires that licensees retain a record of the teletherapy room radiation monitoring device function check. This record is needed to show that the check was made.

Section 35.630(c) of 10 CFR Part 35 requires that licensees retain a record of each calibration, intercomparison, and comparison of teletherapy dosimetry equipment. These records are needed to show that measurements of radiation teletherapy doses were made with instruments capable of making accurate measurements.

Section 35.632(g) of 10 CFR Part 35 requires that licensees retain a record of teletherapy unit calibration. This record is needed to show that the calibrations were done and that licensees did not inadvertently administer incorrect radiation doses to patients.

Section 35.634(c) of 10 CFR Part 35 requires that the qualified teletherapy calibration expert report the results of teletherapy unit spot-checks promptly to the licensee. This assures the licensee that the results of each spot-check have been reviewed by an expert. The licensee must keep a copy of each report to assure that the review has been made.

Section 35.634(f) of 10 CFR Part 35 requires that licensees retain a record of spot-checks. This record is needed to show that the required checks were made.

Section 35.636(c) of 10 CFR Part 35 requires that licensees retain a record of safety checks for teletherapy facilities. This record is needed to show that the checks were made.

Section 35.641(c) of 10 CFR Part 35 requires that licensees retain a record of radiation measurements after installing a source in a teletherapy unit. These records provide assurance that the source is properly installed within the teletherapy unit, and that dose rates outside the teletherapy room are within permissible limits.

Section 35.643(a)(3) of 10 CFR Part 35 requires that licensees amend a report made to NRC pursuant to Section 35.645 to include additional survey information if changes in an installation as approved by NRC were necessary. The additional information in the report provides assurance to NRC that dose rates in restricted and unrestricted areas are within permissible limits. The 30-day submission requirement is contained in Section 35.645.

Section 35.643(b) of 10 CFR Part 35 requires that licensees request a license amendment if radiation levels in unrestricted areas are above permitted levels. This report will trigger an indepth NRC review of safety considerations before it allows a licensee to operate the unit. The 30-day submission requirement is contained in Section 35.645.

Section 35.645 of 10 CFR Part 35 requires that licensees mail a copy of teletherapy source installation records to the NRC. This record is needed to show that dose rates in restricted and unrestricted areas are within permissible levels. The submission must be made within 30 days after the completion of the action that initiated the record requirement. The 30-day requirement is imposed because of the especially high dose rates that can be found around teletherapy units.

Section 35.647(c) of 10 CFR Part 35 requires that licensees keep a record of teletherapy unit inspection and servicing. This record is needed to show that the required work was done.

Reduction of Burden Through Information Technology

There are no legal obstacles to reducing the burden associated with this information collection. However, because of the types of information and the infrequency of submission, the applications and reports do not lend themselves readily to the use of automated information technology for submission.

Effort to Identify Duplication

The Information Requirements Control Automated System (IRCAS) was searched to determine duplication. None was found. In general, information required by NRC in applications, reports, or records concerning the transfer, receipt, possession, or use of byproduct material does not duplicate other Federal information collection requirements and is not available from any source other than applicants or licensees. Portions of the needed information might also be contained in other information submittals to NRC or other Federal agencies. However, duplication, if any, is slight, and the collection of this information by use of specified forms and other required reports and records is the most effective and least burdensome means of obtaining the information.

Effort to Use Similar Information

There is no similar information available to the NRC.

Effort to Reduce Small Business Burden

The majority of licensees who use byproduct material are small businesses. Since the health and safety consequences of improper handling or use of

radioactive byproduct material 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, recordkeeping, or accounting and control procedures.

Consequences of Less Frequent Collection

Required reports are collected and evaluated on a continuing basis as events occur. Applications for new licenses and amendments are submitted only once. Applications for renewal of licenses are submitted every five years. Information submitted in previous applications may be referenced without being resubmitted. The schedule for collecting the information is the minimum frequency necessary to assure that licensees will continue to conduct programs in a manner that will assure adequate protection of the public health and safety.

Circumstances Which Justify Variation from OMB Guidelines

Contrary to the OMB Guidelines in 5 CFR 1320.6(f), Section 35.14 requires that licensees notify the NRC within 30 days if a key worker ends his association with the licensee. This prompt report is needed because if the licensee no longer has a complete staff, the collective training and experience of the remaining staff may no longer be sufficient to ensure safety. This report will trigger a check of the licensee's file to determine whether the remaining key users are qualified to receive and use material safely.

Section 35.33(a) requires that the licensee notify by telephone the appropriate NRC regional office in case of a therapy misadministration within 24 hours after discovering the misadministration. This prompt notification is necessary because a therapy misadministration may present a clear and present radiation hazard to a member of the public that might be mitigated by NRC assistance. The licensee is also required to notify the referring physician and the patient or a responsible relative (or guardian) of the patient unles contraindicated by factors known to the referring physician.. These reports are needed so that adequate care may be provided for the patient.

Section 35.33(b) requires that a licensee file a written report to NRC within 15 days after telephoning an initial therapy misadministration report. This report is needed so that NRC can determine whether there might be generic

implications in the incident which indicate a need to notify all licensees. NRC allows the licensee 15 days to submit the report so that it can review and analyze what has happened and provide NRC with a complete history of the event. NRC requires submission of the report within 15 days so that it can promptly notify other licensees if it appears the precipitating event might be generic.

Section 35.33(c) requires that the Radiation Safety Officer investigate the cause of diagnostic misadministrations and make a record for NRC review. The licensee must also notify the referring physician and the NRC Regional Office in writing on NRC Form 473 within 15 days. These written records are needed to determine what kinds of actions precipitate misadministrations, and also provide an indicator of the licensee's management control of the radiation safety program.

Section 35.59(e)(2) requires that licensees file a report with the NRC within five days if leakage of a sealed source is detected. This report is needed so that NRC can make a determination as to whether other licensees who have similar sealed sources should take special precautions. NRC allows the licensee 5 days to submit the report so that it can review and analyze the source and the leakage measurement. NRC requires submission of the report within 5 days so that it can promptly notify other licensees if it appears there may be a generic problem.

Section 35.645 requires that licensees mail a copy of teletherapy source installation records to the NRC. This record is needed to show that dose rates in restricted and unrestricted areas are within permissible levels. The submission must be made within 30 days after the completion of the action that initiated the record requirement. The 30-day requirement is imposed because of the especially high dose rates that can be found around teletherapy units.

Consultations Outside the Agency

Several experts in the use of radioactive material for patient care were asked to comment on the technical content, including the information collection requirements, of the proposed regulation. They were representatives of: Food and Drug Administration, American Association of Physicists in Medicine, Health Physics Society, Society of Nuclear Medicine, and the American College of

Radiology. The comments received were considered in promulgating the final rule. There have been no consultations outside the agency since the promulgation of the revised rule.

Confidentiality

None, except for proprietary information.

Sensitive Questions

None.

Number and Type of Respondents

These requirements will affect approximately 2400 licensees and applicants. About 2200 of the licensees are hospitals, and about 200 of the licensees are physicians in private practice.

Estimate of Compliance Burden

Reporting Requirements

Section	No. of Licensee Responses Annually	Licensee Staff Hours Per Submittal	Total Annual Licensee Burden (Hours)
35.12(b)	See OMB Clearance No. 3150-0120		
35.12(c)	See OMB Clearance No. 3150-0120		
35.13	1300	3	3900
35.14	200	0.5	100
35.27(a)(1)	300	0.5	150
35.27(a)(2)	300	0.5	150
35.33(a)	5	1	5
35.33(b)	5	10	50
35.33(c)	See NRC Form 473 (below), OMB Clearance No. 3150-0140		
35.59(e)	1	2	2
35.60(b)	7.0×10^{6}	5.55×10^{-4}	3885
35.61(b)	1.4×10^{6}	4.16×10^{-3}	5824
35.70(d)	2400	0.02	48
35.70(g)	2400	0.02	48
35.315(b)	1	1	1
35.315(a)(2)	8400	0.2	1680
35.410(a)	600	1	600
35.415(a)(2)	4000	0.2	800
35.415(b)	1	1	1
35.606	40	1	40
35.610(a)	80	0.5	40
35.634(c)	2890	0.5	1445
35.643(a)	1	2	2
35.643(b)	1	2	2
35.645	30	0.5	15
Total	8,422,955		18,788
NRC Form 473	300	0.5	150

Recordkeeping Requirements

Section	No. of Recordkeepers	Annual Hours per Recordkeeper	Total Recordkeeping Hours	Record Detention Period
35.20		see 35.12 (b) and (c)*		license duration
35.21(b)(2)		see 35.12 (b) and (c)*		license duration
35.22(a)(4) and (a)(5)	2200	4	8800	license duration
35.23(b)		see 35.12(b) and (c)*		license duration
35.27(c)		see 35.27(a)*		3 years after last use
35.29(b)	50	1	50	3 years after last service
35.31(b)	1200	1	1200	license renewal or termination
35.33(c)	300	2	600	10 years
35.33(d)		see 35.33 (b) and (c)*		10 years
35.50(b)(4)		see 35.50(e)(4)		eqpt. duration
35.50(e)(1)	2400	0.03	72	3 years
35.50(e)(2)	2400	0.2	480	3 years
35.50(e)(3)	2400	2	4800	3 years
35.50(e)(4)	380	1	380	eqpt. duration
35.51(d) and (a)(3)	2400	0.4	960	3 years
35.53(c)	2400	8.3	20000	3 years
35.59(a)	2400	0.5	1200	eqpt. duration
35.59(d)	2400	2	4800	3 years
35.59(g)	2400	4	9600	5 years
35.59(i)	2400	0.2	480	3 years
35.70(h)	2400	80	192000	3 years
35.80(f)	20	80	1600	3 years

Recordkeeping Requirements (Continued)

Section	No. of Record-keepers	Annual Hours per Recordkeeper	Total Record-keeping Hours	Record Detention Period
35.92(b)	2400	6	14400	3 years
35.204(c)	1600	7	11200	3 years
35.205(d)	400	1	400	3 years
35.310(b)	600	1	600	3 years
35.315(a)(4)	600	1	600	3 years
35.315(a)(8)	600	0.2	120	until disposal auth'd
35.404(b)	600	1	600	3 years
35.406(b)	600	2	1200	3 years
35.406(c)	600	1	600	3 years
35.406(d)		included in 35.406(b) and (c)		
35.410(b)	600	0.1	60	3 years
35.415(a)(4)	600	1	600	3 years
35.610(c)	240	0.1	24	3 years
35.615(d)(4)	240	2	480	3 years
35.630(c)	240	1	240	eqpt. duration
35.632(g)	240	1	240	license duration
35.634(c)	240	12	2880	3 years
35.634(f)	240	12	2880	3 years
35.636(c)		included in 35.634(f)		3 years
35.641(c)		included in 35.634(f)		license duration
35.647(c)	50	0.2	10	license duration

Total Recordkeepers: 2,400
Total Recordkeeping Burden: 284,156 hours

TOTAL BURDEN, 10 CFR PART 35: 302,944 hours

TOTAL BURDEN, NRC FORM 473: 150 hours

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*These documents are prepared as a written report and must be retained by the licensee for reference. The time spent making the record is included in the noted reporting section.

Estimated Cost to Public to Respond

Section		Annual Cost to Respond
35.12(b)	See OMB Clearance No. 3150-0120	
35.12(c)	See OMB Clearance No. 3150-0120	
35.13		$253,500
35.14		6,500
35.20	included in 35.12(b) and (c)	
35.21(b)(2)	included in 35.12(b) and (c)	
35.22(a)(4) and (a)(5)		572,000
35.23(b)	included in 35.12(b) and (c)	
35.27(a)(1)		9,750
35.27(a)(2)		9,750
35.27(c)	included in 35.27(a)	
35.29(b)		3,250
35.31(b)		78,000
35.33(a)		325
35.33(b)		3,000
35.33(c)		39,000
35.33(d)	included in 35.33(b) and (c)	
35.50(b)(4)	included in 35.50(e)(4)	
35.50(e)(1)		4,680
35.50(e)(2)		31,200
35.50(e)(3)		312,000
35.50(e)(4)		24,700
35.51(d) & (a)(3)		62,400
35.53(c)		1,300,000
35.59(a)		78,000
35.59(d)		312,000
35.59(e)		130
35.59(g)		624,000
35.59(i)		31,200
35.60(b)		252,525

Section		Annual Cost to Respond
35.61(b)		378,560
35.70(d)		3,250
35.70(g)		250
35.70(h)		12,480,000
35.80(f)		104,000
35.92(b)		936,000
35.204(c)		728,000
35.205(d)		26,000
35.310(b)		39,000
35.315(a)(2)		109,200
35.315(a)(4)		39,000
35.315(a)(8)		7,800
35.315(b)		65
35.404(b)		39,000
35.406(b)		78,000
35.406(c)		39,000
35.406(d)	included in 35.406(b) and (c)	
35.410(a)		39,000
35.410(b)		3,900
35.415(a)(2)		52,000
35.415(a)(4)		39,000
35.415(b)		65
35.606		2,600
35.610(a)		2,600
35.610(c)		1,560
35.615(d)(4)		31,200
35.630(c)		15,600
35.632(g)		15,600
35.634(c)		281,125
35.634(f)		187,200
35.636(c)	included in 35.634(f)	
35.641(c)	included in 35.634(f)	
35.643(a)		130

Section	Annual Cost to Respond
35.643(b)	130
35.645	975
35.647(c)	650
Total	$19,653,27[illegible]
NRC Form 473	$9,750

Source of Burden and Cost Data and Method of Estimating and Cost

The estimates are based on submittals to NRC in past years and NRC experience since the implementation of revised Part 35 and the adoption of NRC Form 473. Cost to licensees and applicants is calculated at an average rate of $[illegible]5.00 per hour. This figure includes both salaries and overhead.

Estimate of Cost to the Federal Government

Application review activities are attributable to and reported under NRC Form 313, OMB Clearance No. 3150-0120.

Annual Cost of NRC staff review for activities other than application review (Professional effort is 300 hours @ $86.00 (hr)). = $25,800

Reason for Change in Burden

The burden has been reduced since the last clearance because of a small decrease in the number of affected licensees and because of recalculation of burden estimates. Each of the burden estimates was recalculated based on the experience of the NRC staff and licensees in working with the new requirements. In a number of cases, adjustments were found to be necessary to the number of licensees responding to a requirement, to the number of responses made annually by a respondent, to the burden for responding, or a combination of those factors. The result of the recalculation is a substantial decrease in estimated burden on the public.