"Designated Original" PDR Recd C St Mey

PAPERWORK REDUCTION ACT SUBMISSION

Please read the instructions before completing this form. For additional forms or assistance in completing this form, contact your agency's Paperwork Clearance Officer. Send two copies of this form, the collection instrument to be reviewed, the Supporting Statement, and any additional documentation to: **Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street NW, Washington, DC 20503**

1. Agency/Subagency originating request
   U.S. Nuclear Regulatory Commission

2. OMB control number
   [X] a. 3150 - 0171   [ ] b. None

3. Type of information collection *(check one)*
   - [ ] a. New collection
   - [X] b. Revision of a currently approved collection
   - [ ] c. Extension of a currently approved collection
   - [ ] d. Reinstatement, **without change**, of a previously approved collection for which approval has expired
   - [ ] e. Reinstatement, **with change**, of a previously approved collection for which approval has expired
   - [ ] f. Existing collection in use without an OMB control number

4. Type of review requested *(check one)*
   - [X] a. Regular submission
   - [ ] b. Emergency - Approval requested by (date):
   - [ ] c. Delegated

5. Will this information collection have a significant economic impact on a substantial number of small entities?
   - [ ] a. Yes
   - [X] b. No

6. Requested expiration date
   - [X] a. Three years from approval date
   - [ ] b. Other (Specify):

7. Title
   10 CFR 35.32 and 35.33, Quality Management Program and Misadministrations

8. Agency form number(s) *(if applicable)*
   Not applicable

9. Keywords
   Byproduct Material, Nuclear Materials, Radiation Protection, Reporting and Recordkeeping Requirements

10. Abstract
NRC requires licensees to implement a quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by an authorized user physician. Records and reports are required for certain errors in the administration of limited diagnostic and therapeutic quantities of byproduct material by medical use licensees.

11. Affected public *(Mark primary with "P" and all others that apply with "X")*
   - [ ] a. Individuals or households
   - [P] b. Business or other for-profit
   - [X] c. Not-for-profit institutions
   - [ ] d. Farms
   - [X] e. Federal Government
   - [X] f. State, Local, or Tribal Government

12. Obligation to respond *(Mark primary with "P" and all others that apply with "X")*
   - [ ] a. Voluntary
   - [ ] b. Required to obtain or retain benefits
   - [X] c. Mandatory

13. Annual reporting and recordkeeping hour burden

a. Number of respondents	6,300
b. Total annual responses	2,919
1. Percentage of these responses collected electronically	0 %
c. Total annual hours requested	34,743
d. Current OMB inventory	51,778
e. Difference	(17,035)
f. Explanation of difference	
1. Program change	0
2. Adjustment	(17,035)

14. Annual reporting and recordkeeping cost burden *(in thousands of dollars)*

a. Total annualized capital/startup costs	0
b. Total annual costs (O&M)	0
c. Total annualized cost requested	0
d. Current OMB inventory	0
e. Difference	0
f. Explanation of difference	
1. Program change	
2. Adjustment	

15. Purpose of information collection *(Mark primary with "P" and all others that apply with "X")*
   - [ ] a. Application for benefits
   - [ ] b. Program evaluation
   - [ ] c. General purpose statistics
   - [ ] d. Audit
   - [ ] e. Program planning or management
   - [ ] f. Research
   - [X] g. Regulatory or compliance

16. Frequency of recordkeeping or reporting *(Check all that apply)*
   - [X] a. Recordkeeping
   - [ ] b. Third-party disclosure
   - [X] c. Reporting
     - [X] 1. On occasion
     - [ ] 2. Weekly
     - [ ] 3. Monthly
     - [ ] 4. Quarterly
     - [ ] 5. Semi-annually
     - [ ] 6. Annually
     - [ ] 7. Biennially
     - [ ] 8. Other (describe)

17. Statistical methods
   Does this information collection employ statistical methods?
   [ ] Yes   [X] No

18. Agency contact *(person who can best answer questions regarding the content of this submission)*
Name: Sally Merchant
Phone: (301) 415-7874

BAF-4A
X 1.4.1, PT35 Repts + Records of misadmin
DF03

19. Certification for Paperwork Reduction Act Submissions

On behalf of this Federal agency, I certify that the collection of information encompassed by this request complies with 5 CFR 1320.9.

NOTE: The text of 5 CFR 1320.9, and the related provisions of 5 CFR 1320.8(b)(3), appear at the end of the instructions. *The certification is to be made with reference to those regulatory provisions as set forth in the instructions.*

The following is a summary of the topics, regarding the proposed collection of information, that the certification covers:

(a) It is necessary for the proper performance of agency functions;

(b) It avoids unnecessary duplication;

(c) It reduces burden on small entities;

(d) It uses plain, coherent, and unambiguous terminology that is understandable to respondents;

(e) Its implementation will be consistent and compatible with current reporting and recordkeeping practices;

(f) It indicates the retention periods for recordkeeping requirements;

(g) It informs respondents of the information called for under 5 CFR 1320.8(b)(3):

(i) Why the information is being collected;

(ii) Use of information;

(iii) Burden estimate;

(iv) Nature of response (voluntary, required for a benefit, or mandatory);

(v) Nature and extent of confidentiality; and

(vi) Need to display currently valid OMB control number;

(h) It was developed by an office that has planned and allocated resources for the efficient and effective management and use of the information to be collected (see note in Item 19 of the instructions).

(i) It uses effective and efficient statistical survey methodology; and

(j) It makes appropriate use of information technology.

If you are unable to certify compliance with any of these provisions, identify the item below and explain the reason in Item 18 of the Supporting Statement.

Signature of Senior Official or designee	Date
[signature]	11/12/96

SUPPORTING STATEMENT
FOR
10 CFR 35.32 and 35.33
"QUALITY MANAGEMENT PROGRAM AND MISADMINISTRATIONS"
(3150-0171)

REVISED CLEARANCE EXTENSION

INTRODUCTION AND OVERVIEW

NRC regulations in 10 CFR Part 35 establish requirements for the medical use of byproduct material. The regulations are issued pursuant to the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, as amended. This clearance extension addresses two provisions of 10 CFR Part 35: (1) a requirement that licensees establish and maintain a quality management program (QMP)(§ 35.32) and (2) requirements for notifications, records, and reports of misadministrations (§ 35.33).

On December 24, 1991, the NRC submitted an information collection requirements (ICR) approval request to the Office of Management and Budget (OMB) for the Quality Management (QM) and Misadministrations rule which would be effective in January 1992. In communications with OMB, the American College of Nuclear Physicians and Society of Nuclear Medicine (ACNP/SNM) expressed strong opposition to the rule. In June 1992, OMB disapproved the record collection requirements of the rule. The NRC Commissioners, finding that public health and safety warranted institution of the ICR, overrode the OMB determination.

In addition, the ACNP/SNM took the NRC to court, in American College of Nuclear Physicians and Society of Nuclear Medicine v. U.S. Nuclear Regulatory Commission. Only ten days after hearing arguments in the case, the court ruled in favor of the NRC, declaring that it saw "no need for a published opinion." 976 F.2d 45 (D.C. Cir. 1992)(Table). The court stated:

> On the record before us, we find no basis to overturn the QM rule; accordingly, the petition for review is hereby denied, substantially for the reasons stated by the NRC in its rulemaking. The NRC, in promulgating the QM rule, acted within the bounds of its broad statutory mandate to establish "such standards ... as the Commission may deem necessary or desirable to ... protect health or to minimize danger to life and property." 42 U.S.C. § 2201(b) (West Supp. 1992) (emphasis added). Moreover, the substantive requirements imposed by the QM Rule are not "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." 5 U.S.C. § 706(A) (1988).

In 1993, the NRC contracted with the National Academy of Sciences (NAS), Institute of Medicine (IOM) to conduct an external review of the NRC's medical regulatory program. The goal of the external review was to develop an assessment of the adequacy and appropriateness of the current framework for the medical use of byproduct material. The quality management program (QMP) (§ 35.32) and requirements for notifications, records, and reports of misadministrations (§ 35.33) were included in that study.

In a letter to OMB, dated November 28, 1995, the ACNP/SNM again requested that OMB disapprove the ICR associated with 10 CFR 35.32 and 35.33 as they relate

to diagnostic and therapeutic applications of byproduct material.

In December 1995, the IOM submitted its report to the NRC. The majority report (there was a dissenting opinion as well) was highly critical of NRC regulation in the medical area, and of the QM rule in particular. The IOM findings have been and are being considered within the agency-wide Strategic Assessment and Re-baselining initiative. The staff is awaiting the Commission's direction on the medical use regulatory program.

In February 1996, the OMB approved a one-year extension of the information collection provisions of NRC's QM rule rather than the three-year approval that is customary. The one-year extension necessitated that NRC begin preparation of the 1997 OMB submittal within four-months of the previous approval. The elapsed time was not sufficient to resolve the issues associated with the prospective changes to NRC's medical use program.

The Commission is seeking OMB approval of a three-year clearance extension to allow sufficient time to consider what legislative and/or regulatory changes are appropriate for NRC's medical use program.

DESCRIPTION OF THE INFORMATION COLLECTION

In the medical use of byproduct material, there have been instances where byproduct material was not administered as intended or administered to a wrong individual which resulted in unnecessary exposures to radiation, or inadequate, or incorrect diagnostic or therapeutic procedures. The most frequent causes of these incidents were: insufficient supervision, deficient procedures, failure to follow procedures, and inattention to detail. In an effort to reduce the frequency of such events, the NRC requires licensees to implement a QMP (§ 35.32) to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by an authorized user physician. In response to comments, the final rulemaking that established these new requirements, which the agency believes are essential to adequately protect the health and safety of the public, also minimized the reporting burden. In the rulemaking, NRC also revised the definition for "misadministration" in § 35.2, "Definitions," and distinguished between the "misadministrations" and lesser "recordable events" for which reporting to NRC is not necessary. These revisions considerably reduced the number of incidents that must be reported to the NRC or the Agreement States. When compared to the previous definition, the number of incidents that meet the revised definition of misadministration has resulted in a greater than 10 fold reduction in the reporting burden. There has been a corresponding reduction in the regulatory effort.

The cost for this rule was "front loaded," in that, all affected licensees were required to submit a QMP to be reviewed by the applicable regulatory agency. This implementation burden has been completed by current NRC licensees and 19 of the 29 States who have agreements with the NRC that allow them to regulate the use of byproduct material as Agreement States. However, ten Agreement States have not completed their adoption of the rule. Therefore, this ICR cost estimate reflects the one-time cost for the development and submission of QMPs for approximately 2000 Agreement States

licensees in those ten Agreement States. It should be noted that the Commission is currently reviewing the issue of compatibility relative to the QM rule for the Agreement States. If relief is granted to the Agreement States from certain QM rule compatibility requirements, the staff will submit a modification of the burden estimate that reflects the changes.

A. JUSTIFICATION

1. Need for and Practical Utility of the Collection of Information

In order to obtain a license issued pursuant to 10 CFR Part 35, medical applicants, who plan to use byproduct material in certain diagnostic and therapeutic ranges, must submit a QMP to provide high confidence that byproduct material will be administered as directed by an authorized user physician (§ 35.32). The rulemaking and related regulatory guide were developed to include generally accepted good practices in the medical uses of byproduct material for therapy, and include specific measures intended to prevent many of the kinds of human errors observed and reported to the NRC over a number of years.

In comments provided during rulemaking, members of the Society of Nuclear Medicine and NRC's Advisory Committee on the Medical Uses of Isotopes indicated a belief that NRC medical use licensees already had procedures in place to assure that the administration of byproduct material was as directed by an authorized user physician. However, when reviewed, 72 percent of the licensee-submitted QMPs did not contain such procedures. The unexpected number of licensees that did not submit (nor apparently have) procedures to assure that byproduct material is administered as directed by an authorized user is an indication of the need for a Quality Management Rule.

The recordkeeping and reporting requirements of the quality management rule serve a number of valuable functions. First, they provide assurance both to the licensees and to the NRC that sound safety practices are being followed, and that licensees are taking appropriate followup actions if and when mishaps occur. Second, they provide a basis for enforcement action by the NRC to correct safety deficiencies and take appropriate action against licensees and/or individuals if public health and safety is being endangered. Third, they furnish data that can be used to adjust NRC regulatory standards generically to ensure that they are sufficient to protect health and safety, but at the same time not more burdensome than necessary. Fourth, they can reveal generic problems of which the medical community can then be made aware by NRC.

For the calculations required in this justification, the staff estimates that 30 therapeutic misadministrations per year will be reported by NRC licensees over the next 3 years. The staff bases this on the number of such misadministrations reported by NRC licensees for years 1993, 1994, and 1995. Assuming that Agreement State licensees and NRC licensees

have similar medical use programs, and the Agreement States license 2.5 times as many licensees, the staff estimates that 105 (30+75) misadministrations per year will be reported nationwide. Information on the recordkeeping and reporting requirements is described by specific section below.

Section 35.32(a) requires that medical use licensees, who use byproduct material for limited diagnostic and therapy procedures, establish, implement, and maintain a QMP to provide high confidence that byproduct material will be administered as directed by an authorized user physician. The QMP must include written policies and procedures which require that prior to certain administrations, a written directive is prepared, that the individual's identity is verified by more than one method, that final treatment plans, doses, and administrations are in accordance with the written directive, and that any unintended deviation from the directive is identified, evaluated, and acted upon. At this time, all affected NRC licensees have submitted a QMP which has undergone an initial NRC review, or have provided a negative declaration that they will not utilize byproduct materials affected by the QMP requirements prior to the submission of a QMP. New licensees, subject to the requirements, must submit a written QMP with their application. Additionally, 2000 Agreement State licensees are expected to submit a QMP to the appropriate Agreement State within the next 3 years. Licensee implementation and maintenance of their QMP is reviewed during an NRC or Agreement State inspection.

Section 35.32(b)(1) requires licensees to develop procedures for and conduct a review of the QMP including, since the last review, an evaluation of a representative sample of administrations, all recordable events, and all misadministrations. Reviews must be conducted at intervals no greater than 12 months. This is necessary to evaluate the effectiveness of the QMP and identify issues that may lead to modifications of the QMP.

Section 35.32(b)(2) requires licensees to evaluate QMP reviews and make modifications, if required, to ensure their effectiveness.

Section 35.32(b)(3) requires licensees to retain records of each annual review of the QMP, including the evaluations and findings of the review, in an auditable form for 3 years. The existence of these reviews is confirmed during NRC inspection.

Section 35.32(c)(3) requires licensees to evaluate and respond to each "recordable event" by retaining a record of the relevant facts and corrective action, in an auditable form for 3 years. This enables the licensee to identify error trends. It enables the inspector to evaluate the licensee's response to such errors.

Section 35.32(d) requires licensees to retain each written directive and a record of each administration for 3 years after the date of the administration, to ensure that each administration was in accordance with the written directive. A sample of the licensee's written

directives is reviewed during an NRC inspection.

Section 35.32(e) requires the licensee to submit any voluntary modifications to the QMP to NRC within 30 days after the modification is made, to ensure that the modification does not decrease the effectiveness of the program.

Section 35.32(f)(1) requires each applicant for a new license to submit a QMP to NRC as part of a license application to ensure that the new licensee will implement a QMP that will provide high confidence that byproduct material will be administered as directed by the authorized user physician.

Section 35.32(f)(2) required licensees in existence on January 27, 1992, to submit certification that a QMP had been implemented as well as a copy of the QMP to assure NRC that a QMP had been implemented. This requirement has been satisfied.

Section 35.33(a)(1) requires licensees to notify NRC by telephone no later than the next calendar day after discovery of a misadministration. This will enable NRC to promptly take any necessary actions based on the circumstances.

Section 35.33(a)(2) requires licensees to submit a written report to NRC within 15 days of the discovery of a misadministration to provide NRC a synopsis of the event, its cause(s), and corrective actions taken, and to assure that all notifications were made.

Section 35.33(a)(3) requires licensees to notify the referring physician and the individual subject to the misadministration no later than 24 hours after discovery, or as soon as possible, if the patient or the referring physician can not be reached within 24 hours. Patients and their referring physician(s) need this information to make timely decisions regarding possible health care needs.

Section 35.33(a)(4) requires the licensee to furnish a written report of the misadministration to the patient, if the patient has been notified orally of the misadministration, within 15 days of the discovery of the misadministration. To satisfy this requirement, the licensee may provide the patient with either a copy of the report that was submitted to NRC, or a description of both the event and any consequences that may affect him/her. The description of the event must include a statement that the report submitted to NRC can be obtained from the licensee.

Section 35.33(b) requires the licensee to retain a record of the misadministration for 5 years to ensure that the record is available for the next NRC inspection so that NRC can ascertain whether misadministrations have been investigated by the licensee and that corrective action has been taken.

2. Agency Use of Information

Quality Management Program (QMP) Requirements: The reporting and record keeping requirements related to the QMP allow license reviewers to determine if licensees have developed a systematic approach to providing high confidence that byproduct material or the radiation therefrom will be administered as requested by authorized users. In addition, it enables inspectors to determine compliance with the requirement to implement the QMP.

Notifications, Reports, and Records of Misadministrations: The notification, reporting and recordkeeping requirements ensure that the NRC is notified of significant events and that the patient and referring physician are notified of the event. In addition, it allows the NRC to determine whether to take any immediate actions, such as to conduct a special inspection of a licensee's facility or to alert other medical use licensees, to prevent similar events which may have generic implications. The recordkeeping requirements allow NRC inspectors to review misadministrations and other events that have occurred, including any corrective action taken by the licensee.

3. Reduction of Burden Through Information Technology

The NRC has not received any electronic submittals of QMPs. However, licensees have submitted parts of misadministration reports electronically. There is no legal obstacle to the use of information technology, and the NRC is developing processes that will soon assist licensees in doing so.

4. Effort to Identify Duplication and Use Similar Information

There is no source for the information other than from the medical use licensees. The Information Requirements Control Automated System has been searched. There is no duplication with other collections of information.

5. Effort to Reduce Small Business Burden

In 1990, prior to the rulemaking, the NRC conducted a pilot program (OMB Clearance No. 3150-0145) to determine the impact and efficacy of the proposed "Basic Quality Assurance Program, Records and Reports of Misadministrations or Events Relating to the Medical Use of Byproduct Material." Several participants of the pilot program were licensees in private practices. Following the 60-day test, they indicated that, with certain modifications, they could incorporate the proposed rule into their procedures of medical practice and that the impact would be minimal. The NRC will re-address this issue in the planned revision of 10 CFR Part 35.

6. Consequences to Federal Program or Policy Activities if the Collection Is Not Conducted or is Conducted Less Frequently

If the collection is not conducted, there would be no assurance that circumstances resulting in misadministrations, that endanger the health and safety of the general public, would be corrected. Under the current requirements, less frequent reporting is not possible for the following reasons:

10 CFR 35.32: The requirement to develop and submit a QMP is a one-time effort which has been completed by all affected NRC licensees and approximately one-half of Agreement States licensees. Additionally, once a QMP that meets the rule is submitted, the frequency that licensees' QMPs are modified is determined by the licensee's need to modify the QMP to correct deficiencies in their own QMP program. Therefore, the stated frequencies are at the minimum level.

10 CFR 35.33: Licensees are required to report misadministrations, by telephone, within 24 hours after discovery, followed by a written report within 15 days after discovery. The requirement for one telephone call followed by a written report is the minimum frequency to inform the NRC about a misadministration so that any follow-up action can be taken.

7. Circumstances Which Justify Variation from OMB Guidelines

Contrary to the OMB Guidelines in 5 CFR 1320.6(b), Section 35.33 requires licensees to report misadministrations, by telephone, within 24 hours after discovery, followed by a written report within 15 days after discovery. Since a misadministration may have health and safety implications for patients or research subjects, the NRC believes that 24-hour notification is important to assure that appropriate follow-up action is immediately taken. The submittal of a report within 15 days assures that the licensee has adequately investigated the event, identified appropriate corrective actions to prevent recurrence, and met applicable notification, recordkeeping, and reporting requirements.

8. Consultations Outside NRC

Comments were received from the Department of Nuclear Safety, the State of Illinois, dated December 5, 1996, (attached) responding to NRC's Federal Register notice (October 7, 1996), announcing the submission of an ICR request to OMB and solicitation of public comments. Some of the comments expressed by the State of Illinois representative were in opposition to the necessity for some of the reporting requirements. These comments, and others of a similar nature, including comment 1, which questions the necessity for, and utility of the ICR, will be considered when the QM rule is reviewed within a planned revision of 10 CFR Part 35. In response to comment 2, the burden to the Agreement States for their overview activities, including inspection effort, is

covered in a separate clearance package, 3150-0183, "Policy Statements, Criteria for Discontinuance of NRC Regulatory Authority, Agreement State Radiation Control Programs, and State Evaluation Questionaires." In response to the second part of comment 2, the time an Agreement State licensee takes to modify their original QMP submittal is accounted for on page 12 of the submittal. A third part of comment 2 addressed the burden of implementing Temporary Instruction 2800/025, Inspection of Quality Management Programs. This guidance was temporary (2 years), and has expired. NRC and Agreement State inspectors were provided interim guidance (dated August 1, 1996) for inspections of facilities that require QMP. The final guidance will be provided in January 1997. In response to the third comment, misadministrations caused by patient intervention will be addressed in the revision of Part 35. The fourth comment, which recommended excluding certain categories of misadministrations, will be addressed during the Part 35 revision which is expected to begin in 1997.

The QM rule has been reviewed as part of the NRC-sponsored independent review of the NRC's medical use program by the National Academy of Sciences. Additionally, a Congressional appropriations committee recommended that NRC reconsider the ICR associated with this regulation. The NRC believes this concern will be satisfied through the ongoing review of the NRC medical use program which may include a revision of 10 CFR Part 35, including 10 CFR 35.32 and 33. This effort is expected to begin in 1997. Consultations and meetings with the medical community are planned as part of that rulemaking.

9. Payment or Gift to Respondents

Not applicable.

10. Confidentiality of Information

None, except for proprietary information.

11. Justification for Sensitive Questions

There are no sensitive questions.

12. Estimated Burden and Burden Hour Cost

There are two primary considerations in the calculation of this burden: First, the current number of medical use licensees in the United States is approximately 2000 for the NRC and 5000 for the Agreement States. Of those licensees that require submission of a QMP (approximately 90 percent or 6300 licensees), all of the applicable NRC licensees (1800) and an estimated 2500 of the Agreement State licensees have submitted a QMP to the appropriate regulatory agency. Therefore, it is

estimated that 2000 Agreement State licensees will submit a QMP within the next 3 years.

Second, based on findings from a pilot program and discussions with medical licensees in multiple public meetings during promulgation of the rule, it was assumed that 90 percent of licensees, who must implement a QMP, will have policies and procedures (e.g., prepared to meet professional audit programs or Joint Commission on Accreditation of Healthcare Organization requirements) that could be adjusted, prepared, and submitted to the NRC to comply with the requirements. However, based on the NRC's experience in reviewing the 1800 QMPs submitted by NRC licensees, 72 percent of the submittals did not meet the requirements, and modifications were required. The NRC has included this unexpected and additional burden in this estimate for the development of the 2000 QMPs to be submitted by the Agreement State licensees to the appropriate Agreement State.

These public burden estimates are based on NRC data, collected during the past 4 years and on staff projections of new applications and amendment requests expected to be received during the next 3 years. The estimates assume that the Agreement States will implement the rule exactly as has the NRC. Differences in Agreement State adoption or implementation would result in either greater or lesser burden. The average burden is calculated at the NRC labor cost rate of $120 per hour, which includes overhead. A burden breakout is included in Tables 1 through 3.

The following will be the estimated ICR burden and burden hour cost for the implemented rule:

BURDEN FOR NRC LICENSEES:

Each year, the NRC receives approximately 63 new license applications, and approximately 100 applications to amend existing licenses to add a modality, that require the establishment and submittal of a QMP. Since the modification of an existing QMP to add a modality may range from a minor change to a major effort, the average burden is estimated to be 10 hours. Therefore:

63 licensees X 40 hrs (new licensees-develop QMP) =	2,520 hrs/yr
100 licensees X 10 hrs (add modality-modify QMP) =	1,000 hrs/yr
63 licensees X 4 hrs (develop review procedures) =	252 hrs/yr
163 licensees X 72% (require modification) = 117 X 3 hrs (modify) =	351 hrs/yr

Burden and cost for new applicants and new modalities added in NRC States = 4,123 hrs/yr X $120 = $494,760

An estimated 15 percent of the 1800 licensees who have previously submitted QMPs, will modify their existing QMP each year to increase the program's efficiency. This does not include the burden for modification of new applications and applications to add a modality to an existing license that does not meet the requirements.

1800 submitted QMPs X 15% = 270 modifications per yr
270 modifications X 3 hrs per licensee = 810 hrs/yr

Burden for NRC licensees to modify QMPs = 810 hrs/yr X $120 = $97,200

Burden Associated with Notifications, Reports, and Records of Misadministration:

NRC licensees reported an average of 30 misadministrations per year for years 1993 through 1995. The definitions for misadministrations focus on therapy events in which NRC frequently requests the services of a medical consultant to review the event, and conducts reactive inspections. In calculating the burden for 10 CFR 35.33, the time commitment for licensees to interact with these consultants and NRC inspectors has been considered. Therefore, this burden has been estimated to average 16 hours per licensee, per event. Additionally, NRC estimates 15 minutes for notification of event discovery, 30 minutes for notification of referring physician and individual who received the misadministration, and 15 minutes for furnishing the report.

30 misadministrations reported/yr X 17 hrs/event = 510 hrs/yr

Licensees must retain a record of a misadministration for 5 yrs:
30 misadministrations X 10 minutes (to file record) = 5 hrs/yr

Based upon inspections of implemented QMPs to date, 15 percent of NRC licensees were found to have records of "recordable events" (§ 35.32(c)(3)) during inspection. Therefore,

1800 X 15% = 270 "recordable events"/yr X 30 minutes (to record) = 135 hrs/yr

Each of the 1800 NRC licensees must retain the records of the annual QMP review for 3 years:

1800 X 1 hr/yr = 1,800 hrs/yr

Burden associated with notifications, reports, and records of misadministration = 2,450 hrs/yr X $120 = $294,000

TOTAL BURDEN FOR NRC LICENSEES = 7383 hrs/yr X $120 = $885,960/yr

BURDEN FOR AGREEMENT STATE LICENSEES:

In order to estimate the burden to the Agreement State licensees, the following assumptions were made:

1. Ninety percent of the 2000 Agreement State licensees will have existing policies and procedures that could be adjusted, prepared, and submitted to the Agreement State to comply with the requirements of the rule. An average burden of 5 hours is estimated for preparation and submittal of a modified QMP.

2. Ten percent of the 2000 licensees will have to develop and submit a QMP. This will be a one-time burden of approximately 40 hours for each of the 200 licensees.

3. Based on the NRC's experience, 72 percent of the 2000 QMPs initially submitted to the Agreement States will require modifications to meet the requirements of the rule. This will result in a burden of 3 hours each to modify the QMP for approximately 1440 licensees.

One time burden to Agreement State Licensees for Initial Development, Submittal (States who will adopt the rule within next 3 years):

Development of QMP by 10% of 2000 licensees = 200 licensees
X 40 hrs = 8000 hrs annualized over 3 yrs = 2667 hrs/yr

Preparation and submittal of existing procedures:
90% X 2000 licensees = 1800, annualized over 3 yrs =
600 submittals X 5 hrs each for preparation and submittal = 3,000 hrs/yr

Based on the NRC's experience, 72 percent of the QMP submittals will require modification:

2000 licensees X 72% (require modification)= 1440 annualized over 3 yrs = 480 QMPs/yr that require modification.
480 submittals/yr X 3 hrs/submittal to make modification = 1,440 hrs/yr

Each of the 2000 licensees must also develop procedures for an annual review of the QMP (4 hrs).

2000 licensees annualized over 3 yrs = 667 licensees/yr
667 licensees/yr X 4 hrs to develop procedures for QMP review = 2,668 hrs/yr

Agreement State licensees' burden = 9,775 hrs/yr X $120 = $1,173,000

Burden to New Applicants - Agreement State:

Each year, the NRC receives approximately 63 new license applications, and approximately 100 applications to amend existing licenses to add a modality, that require the establishment and submittal of a QMP. Because the Agreement States have 2.5 times the number of licensees as the NRC, it is estimated that an average of 158 applications for new licenses and 250 applications to add new modalities to existing licenses will be received each year. Since the modification of an existing QMP to add a modality may range from a minor change to a major effort, the average burden is estimated to be 10 hours. Therefore:

158 licensees X 40 hrs (new licensees-develop QMP) = 6,320 hrs/yr
250 licensees X 10 hrs (add modality - modify QMP) = 2,500 hrs/yr
158 licensees X 4 hrs
(new licensees-develop review procedures) = 632 hrs/yr

408 licensees X 72% require modification =
294 licensees X 3 hrs (modify) = 882 hrs/yr

Burden for new applicants and modalities added in Agreement States = 10,334 hrs/yr X $120 = $1,240,080

Burden for making modifications to previously submitted QMP:

An estimated 15 percent of the 2500 licensees who have previously submitted QMPs, will modify their existing QMP each year to increase the program's efficiency. This does not include the burden for modification of new applications and applications to add a modality to an existing license that do not meet the requirements.

2500 submitted QMPs X 15% (mod./yr)= 375 modifications/yr
375 mod./yr X 3 hrs (to make modification) = 1,125 hrs/yr

Burden for Agreement State licensees to modify QMPs = 1,125 hrs/yr

Burden Associated with Notifications, Reports, and Records of Misadministration:

The Agreement States have approximately 2.5 times the number of licensees as the NRC. Additionally, the NRC has no information to demonstrate that the frequency of incidents at Agreement State licensees is different than that of the NRC licensees. Therefore, for purposes of estimating the burden, based on an average of 30 misadministrations per year for NRC licensees, the NRC estimates 75 misadministrations per year for Agreement State licensees.

The estimated burden to report a misadministration is 16 hours per event. Additionally, NRC estimates 15 minutes for notification of event

discovery, 30 minutes for notification of referring physician and individual who received the misadministration, and 15 minutes for furnishing the report.

75 misadministrations reported/yr X 17 hrs/event = 1,275 hrs/yr

75 misadministrations X 10 minutes (to file record) = 13 hrs/yr

To date, based on inspection of NRC licensees, 15 percent of Agreement State licensees, per year, will have records of recordable events (§ 35.32(c)(3)) during inspection:

4500 X 15% = 675
675 records/yr X 30 minutes to make the record = 338 hrs/yr

Each of the 4500 Agreement State licensees must evaluate and retain records of an annual QMP review for 3 years:

4500 X 1 hr/yr = 4,500 hrs/yr

Burden associated with notifications, reports, and records of misadministration = 6,126 hrs/yr X $120 = $735,120

TOTAL BURDEN FOR AGREEMENT STATE LICENSEES =
27,360 hrs/yr X $120 = $3,283,200

Additional details on the reporting and recordkeeping burden are found in Tables 1 through 3 (attached)

The total compliance burden estimate, for NRC and Agreement State licensees is summarized below:

	Number of Licensees who will respond:	Total Annual Burden (hrs):	Cost: ($120/hr)
Reporting:	6300	24,400 hrs/yr	$2,928,000
Recordkeeping:		10,343 hrs/yr	1,241,160
Total Burden:		34,743 hrs/yr	$4,169,160

13. Estimate of Other Additional Costs

Not applicable.

14. Estimate of Annualized Cost to the Federal Government

Quality Management Program (QMP)

All initial QMPs for NRC licensees have been submitted and reviewed. Therefore, the continuing cost will be for the review of QMPs submitted as part of new license applications, when additional therapy modalities (e.g., brachytherapy, teletherapy) are added to an existing NRC license, and within 30 days of modifying existing QMPs. The QMPs are reviewed as part of the license application for new and amended licenses, and modifications are reviewed at the time of inspection. The NRC receives approximately 63 new applications per year and approximately 100 requests to amend existing licenses to add a modality. Additionally, based on the number of QMP modifications submitted to the NRC in the past year, it is estimated that 15 percent of licensees will modify their QMPs each year.

Assuming 3 hours would be needed for the QMP review for 63 new licenses and 100 amendments to add therapy modalities per year:

3 hrs X 163 licensing actions/yr = 489 hrs/yr X $120 = $ 58,680/yr

Assuming 2 hours would be needed to review a modification made to a previously reviewed QMP and 270 (estimated 15 percent) modifications are submitted by NRC licensees per year:

2 hrs X 270 modifications/yr = 540 hrs/yr X $120 = $ 64,800/yr

The ongoing cost to the NRC for review of QMPs =
1029 hrs/yr X $120 = $123,480/yr

Notifications, Reports, and Records of Misadministrations

Based on statistical data, the staff estimates that 30 misadministrations per year will occur in NRC States over the next 3 years. Assuming that an average of 80 hours of NRC staff effort will be required to respond to each event, the cost to the NRC will be $288,000 per year.

80 hrs/misadministration X 30 misadministrations/yr = 2400 hrs/yr
2400 hrs/yr X $120/hr = $288,000/yr

The estimate includes time for the NRC Operations Center to respond to the original call, for the NRC staff to follow up with the action appropriate to the event (e.g., if needed, conduct an inspection, secure medical consultant services, etc.), and review the written report (submitted 15 days after the event was reported).

Total annualized cost to the NRC for all activities is estimated to be:
1029 hrs + 2400 hrs = 3429 hrs X $120 = $411,480/yr

These costs are fully recovered through fee assessments to NRC licensees, pursuant to 10 CFR Parts 170 and 171.

15. Reasons for Change in Burden or Cost

The following are the reasons for the most significant changes in the burden estimate:

1. The increase in the cost from $116/hr in the previous submission to $120/hr for the 1997 submission.

2. This estimate includes the one-time burden of the submission and review of the QMPs submitted by the approximately 2000 Agreement State licensees in the 10 States that have not yet adopted the rule. In the initial submission, it was assumed that the Agreement States would implement the QM rule by January 1995. However, at the time of the 1996 submittal, 13 of the 29 Agreement States had not as yet adopted the rule. Since the earlier submission, an additional three States, representing approximately 1000 licensees, have adopted the QM rule.

3. The estimated burden on the Agreement States' regulatory agencies, previously included in this ICR, is now included in OMB Clearance 3150-0183 "Office of State Programs Requests to Agreement States for Information."

4. At the time of the 1996 submittal, the best data the NRC possessed estimated the number of licensee reported events that met the misadministration criteria as 25 misadministrations per year. Since that time, an improvement in data collection and analysis has increased that number to an average of 30 misadministrations per year. The Agreement States have approximately 2.5 times as many licensees. Therefore, we estimate approximately 105 misadministrations per year nationwide.

16. Publication for Statistical Use

The NRC tabulates and publishes an annual summary of misadministrations and other events.

17. Reason for Not Displaying the Expiration Date

The requirement will be contained in a regulation. Amending the Code of Federal Regulations to display information that, in an annual publication, could become obsolete would be unduly burdensome and too difficult to keep current.

18. Exceptions to the Certification Statement

There are no exceptions.

B. Collection of Information Employing Statistical Methods

Statistical methods are not used in this collection of information.

Table 1 (Annualized)

Reporting Requirements (§ 35.32): (Assuming 6300 licensees)

Section	Item	Hours Per Event	Total Burden hrs/yr	Cost at $120/hr
35.32(a)	Licensees:			
	Agreement State (one time): Develop and maintain a written QMP (includes submittal), Approximately 67 licensees (200 licensees/3 yrs)	40 hrs	*2,667	$320,040
	Submission of QMP (Submit existing procedures, 600 (90%) licensees (1800 licensees/3 years)	5 hrs	*3,000	$360,000
	NRC & Agreement State: 221 new application QMPs	40 hrs	8,840	$1,060,800
	350 amending license to add modality (submit QMP)	10 hrs	3,500	$420,000

Table 1

35.32(e)	Submit modification of QMP within 30 days after modification is made: (72% initial failure rate for first time submittals)			
	Agreement State Licensees (one time):			
	72% of initial submittals = 480 QMPs	3 hrs	*1,440	$172,809
	NRC Licensees:			
	Modify 72% of new and added modality applications =117	3 hrs	351	$42,120
	15% existing QMPS= 270	3 hrs	810	$97,200
	Agreement State Licensees:			
	Modify 72% of new and added modality applications = 294	3 hrs	882	$105,840
	15% of existing QMPs = 375	3 hrs	1125	$135,000
35.32(f)(1)	Submit a QMP to appropriate agency	Included in § 35.32(a)		
35.32(f)(2)	Submit written certification	Requirement complete		

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* One time burden for Agreement States that have yet to adopt the rule: 7,107 hrs/yr

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Reporting Burden (§ 35.32) per yr: 22,615 hrs/yr X $ 120 = $2,713,800

Table 2 (Annualized)

Reporting Requirements (§ 35.33): (Assuming 105 misadministrations per yr)

Section	Item	Hours Per Event	Total Burden hrs/yr	Cost at $120/hr
35.33(a)(1)	Notify NRC or Agreement State by phone no later than the next calendar day after discovery of misadministration.	15 min	26 hrs	$3,150
35.33(a)(2)	Licensee written report to regulatory agency within 15 days after discovery of misadministration.	16 hrs	1,680 hrs	$201,600
35.33(a)(3)	Licensee notification to referring physician and individual who received the misadministration no later than 24 hours after discovery.	30 min	53 hrs	$6,300
35.33(a)(4)	Licensee written report to patient within 15 days of misadministration.	15 min May be same report as 35.33(a)(2) above	26 hrs	$3,150

Reporting Burden (§ 35.33) per yr: 1,785 hrs/yr X $120 = $214,200

Table 3 (Annualized)

Recordkeeping burden (§ 35.32): (Assuming 6300 licensees)

Section	Item	Hours Per Event	Total Burden hrs/yr	Cost at $120/hr
35.32(b)(1)	Licensees: Develop procedures for review:			
	Agreement State (one-time): 667 initial development	4 hrs	*2,668	$320,160
	NRC and Agreement State: 221 New licensees/yr	4 hrs	884	$106,080
35.32(b)(2)	Licensees (6300 total): Evaluate QMP reviews and make modifications, if needed:	50 min.	5,250	$630,000
35.32(b)(3)	Retain records of each audit and management evaluation of the QMP for 3 years.	10 min.	1,050	$126,000
35.32(c)(3)	Retain record of relevant facts and corrective action relative to recordable event, for 3 years. (945 records/yr)	30 min.	473	$56,760
35.32(d)	Retain each written directive and a record of each administration for 3 years.	Historically, part of patient's medical record.		

Recordkeeping burden (§ 35.32) per yr: 10,325 hrs/yr X $120 = $1,239,000

*One-time burden for licenses of Agreement States that have yet to adopt the rule: 2,668 hrs/yr

Table 4 (Annualized)

Recordkeeping burden (§ 35.33): (Assuming 105 misadministrations per yr)

Section	Item	Assumed No. of Events/yr	Hours Per Event	Total Burden hrs/yr	Cost at $120/hr
35.33(b)	Licensee shall retain a record of the misadministration for 5 years.	105	10 min	18 hours	$2160

Recordkeeping burden (§ 35.33) per yr: 18 hrs/yr X $120 = $2160

STATE OF ILLINOIS
DEPARTMENT OF NUCLEAR SAFETY
1035 OUTER PARK DRIVE
SPRINGFIELD, ILLINOIS 62704
217-785-9900
217-782-6133 (TDD)

Jim Edgar
Governor

Thomas W. Ortciger
Director

December 5, 1996

Ms. Brenda Jo Shelton
NRC Clearance Officer
U.S. Nuclear Regulatory Commission
T-6 F33
Washington, D.C. 20555-0001

Re: 61 FR 52470-52471, Notice of pending NRC action to submit an information collection request to OMB and solicitation of public comment.

Dear Ms. Shelton:

The Illinois Department of Nuclear Safety (Department) does not support the NRC's Quality Management Plan (QMP) as specified in 10 CFR 35, and therefore we oppose any plan to continue certain information collection requirements. The Department recognizes a physician's right to practice medicine, and we also recognize the need for a regulatory agency to ensure patient and worker safety. To this end, we support the need for licensees to self-identify and correct certain actions that may result in recordable events. In addition, it is necessary for a regulatory agency to be aware of "misadministrations" to ensure the licensee has taken steps to avoid similar occurrences in the future. We are not convinced that the QMP rule, as written, achieves that goal without undue burden on licensees and regulatory agencies.

In fact, there have been no significant changes to the rule since it was disapproved by the OMB on June 26, 1992, and subsequently overridden by the Commission. There appears to be no new evidence to convince the OMB that they should not disapprove of the current regulation, also.

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?

The Department is not convinced that the information collected under the QMP rule as written has any practical utility. In a letter to Chairman Jackson dated April 19, 1996, the Department urged the NRC to rescind the QM rule as a result of the NAS-IOM study. As written, this rule has caused frustration and animosity among the NRC, medical licensees and Agreement States.

2. Is the burden estimate accurate?

No. The burden estimate does not take into account the amount of time individual Agreement States would spend to review and inspect licensee's QMPs in a manner similar to NRC's review and inspection program.

For example, the NRC contracted with Lawrence Livermore (at great expense) to review the QMP documents received from licensees when the rule was first implemented. As a result of that review, more than 1200 programs, out of the 1709 reviewed, received a letter from the NRC indicating that the submitted written program had flaws that needed to be corrected. There is no indication that time spent reviewing QMPs by regulatory agencies was included in the burden estimate. It is also unclear whether time licensees spent responding to NRC's deficiency letters was included in the burden estimate.

In addition, Agreement States received Temporary Instruction 2800/025 for use by the NRC field inspectors in determining compliance with the QMP rule. This instruction is extremely detailed and would be quite time-consuming (estimated at six hours per affected licensee inspection). We do not believe this level of detail is necessary to implement a "performance-based" rule, and we see no evidence of this time commitment being reflected in the burden estimate.

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

The goal of the information collection is not clear. Regulatory agencies already have an understanding of how misadministrations occur, yet information collection does nothing to address the actual cause of misadministrations. For example, there are numerous "misadministrations" caused by patient intervention. How does an information collection program help the licensee to keep a patient from deciding to terminate treatment? Information collection cannot stop random human error, either. Has the NRC discovered some <u>new</u> reason for the occurrence of misadministrations based on the information collected to date?

4. How can the burden of the information collection be minimized, including the use of automated collection techniques or other forms of information technology?

The NRC could reduce the information collection burden by excluding certain categories of "misadministrations" such as patient intervention from the reporting requirements.

Thank you for the opportunity to comment early in the process. If you have questions about these comments, please contact either me or Kathy Allen at (217) 785-9947.

Sincerely,

Steven C. Collins

Steven C. Collins, Chief
Division of Radioactive Materials

cc: Richard Bangart, OSP
Jim Lynch, R III

[7590-01-P]

U. S. NUCLEAR REGULATORY COMMISSION

Agency Information Collection Activities: Submission for OMB Review; Comment Request.

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

ACTION: Notice of the OMB review of information collection and solicitation of public comment.

SUMMARY: The NRC has recently submitted to OMB for review the following proposal for the collection of information under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). The NRC hereby informs potential respondents that an agency may not conduct or sponsor, and that a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

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

2. The title of the information collection:
   10 CFR 35.32 and 35.33, "Quality Management Program and Misadministrations"

3. The form number if applicable: Not Applicable.

4. How often the collection is required:

For quality management program (QMP):

Reporting: One time submittal of a quality management program (QMP) for each existing and new licensee, when the QMP is modified, or when new modalities (uses) are added to an existing license.

Ten Agreement States, who should have adopted the rule by January 1995, have not done so. Therefore, this estimate includes the one-time burden for the development of QMPs by these ten Agreement State licensees.

Recordkeeping: Records of written directives, administered dose or dosage, annual review, and recordable events, for 3 years.

For Misadministrations:

Reporting: Whenever a misadministration occurs.

Recordkeeping: Records of misadministrations for 5 years.

5. Who will be required or asked to report:

NRC Part 35 licensees who use byproduct material in limited diagnostic and therapeutic ranges and similar type of licensees regulated by Agreement States.

6. An estimate of the number of responses: Approximately 2919 per year

7. The estimated number of annual respondents: 6300

8. An estimate of the total number of hours needed annually to complete the requirement or request: 34,743 hours for applicable licensees (24,400 hrs/yr for reporting and 10,343 hrs/yr for recordkeeping).

9. An indication of whether Section 3507(d), Pub. L. 104-13 applies: Not Applicable

10. Abstract: In the medical use of byproduct material, there have been instances where byproduct material was not administered as intended or was administered to a wrong individual, which resulted in unnecessary exposures or inadequate diagnostic or therapeutic procedures. The most frequent causes of these incidents were: insufficient supervision, deficient procedures, failure to follow procedures, and inattention to detail. In an effort to reduce the frequency of such events, the NRC requires licensees to implement a quality management program (§ 35.32) to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by an authorized user physician.

Collection of this information enables the NRC to ascertain whether misadministrations are properly identified, evaluated, and investigated by the licensee and that corrective action is taken. Additionally, NRC has a

responsibility to inform the medical community of generic issues identified in the NRC review of misadministrations.

A copy of the submittal 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 the submittal 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). The document will be available on the bulletin board for 30 days after the signature date of this notice. 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 should be directed to the OMB reviewer by (insert date 30 days after publication in the Federal Register):

Edward Michlovich
Office of Information and Regulatory Affairs (3150-0171)
NEOB-10202
Office of Management and Budget
Washington, DC 20503

Comments can also be submitted by telephone at (202) 395-3084.

The NRC Clearance Officer is Brenda Jo. Shelton, (301) 415-7233.

Dated at Rockville, Maryland, this 2nd day of December 1996.

For the Nuclear Regulatory Commission

Gerald F. Cranford, Designated Senior Official

for Information Resources Management

Comments can also be submitted by telephone at (202) 395-3084.

The NRC Clearance Officer is Brenda Jo. Shelton, (301) 415-7233.

Dated at Rockville, Maryland, this 20th day of December 1996.

For the Nuclear Regulatory Commission

Original signed by
Gerald F. Cranford

Gerald F. Cranford, Designated Senior Official

for Information Resources Management

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