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1. Agency/Subagency originating request U.S. Nuclear Regulatory Commission	2. OMB control number <input checked="" type="checkbox"/> a. 3150 - 0171 <input type="checkbox"/> b. None
3. Type of information collection (check one) <input type="checkbox"/> a. New collection <input type="checkbox"/> b. Revision of a currently approved collection <input checked="" type="checkbox"/> c. Extension of a currently approved collection <input type="checkbox"/> d. Reinstatement, without change , of a previously approved collection for which approval has expired <input type="checkbox"/> e. Reinstatement, with change , of a previously approved collection for which approval has expired <input type="checkbox"/> f. Existing collection in use without an OMB control number	4. Type of review requested (check one) <input checked="" type="checkbox"/> a. Regular <input type="checkbox"/> c. Delegated <input type="checkbox"/> b. Emergency - Approval requested by (date): 5. Will this information collection have a significant economic impact on a substantial number of small entities? <input type="checkbox"/> a. Yes <input type="checkbox"/> b. No 6. Requested expiration date <input checked="" type="checkbox"/> a. Three years from approval date <input checked="" type="checkbox"/> b. Other (Specify): 10/31/2002

7. Title
10 CFR 35, Quality Management Program and Misadministrations

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

9. Keywords
Byproduct material, Reporting and recordkeeping requirements

10. Abstract
The Quality Management Rule requires licensees to provide reports and keep records relating to medical byproduct misadministrations and requires the physician to provide written directives to patients treated with byproduct material.

11. Affected public (Mark primary with "P" and all others that apply with "X") <input type="checkbox"/> a. Individuals or households <input type="checkbox"/> d. Farms <input checked="" type="checkbox"/> b. Business or other for-profit <input checked="" type="checkbox"/> e. Federal Government <input checked="" type="checkbox"/> c. Not-for-profit institutions <input checked="" type="checkbox"/> f. State, Local or Tribal Government	12. Obligation to respond (Mark primary with "P" and all others that apply with "X") <input type="checkbox"/> a. Voluntary <input type="checkbox"/> b. Required to obtain or retain benefits <input checked="" type="checkbox"/> c. Mandatory
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13. Annual reporting and recordkeeping hour burden a. Number of respondents <u>6,300</u> b. Total annual responses <u>3,194</u> 1. Percentage of these responses collected electronically <u>0.0</u> % c. Total annual hours requested <u>34,743</u> d. Current OMB inventory <u>34,743</u> e. Difference <u>0</u> f. Explanation of difference 1. Program change 2. Adjustment	14. Annual reporting and recordkeeping cost burden (in thousands of dollars) a. Total annualized capital/startup costs <u>0</u> b. Total annual costs (O&M) <u>0</u> c. Total annualized cost requested <u>0</u> d. Current OMB inventory <u>0</u> e. Difference <u>0</u> f. Explanation of difference 1. Program change 2. Adjustment
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15. Purpose of information collection (Mark primary with "P" and all others that apply with "X") <input type="checkbox"/> a. Application for benefits <input type="checkbox"/> e. Program planning or management <input type="checkbox"/> b. Program evaluation <input type="checkbox"/> f. Research <input type="checkbox"/> c. General purpose statistics <input checked="" type="checkbox"/> g. Regulatory or compliance <input type="checkbox"/> d. Audit	16. Frequency of recordkeeping or reporting (check all that apply) <input checked="" type="checkbox"/> a. Recordkeeping <input checked="" type="checkbox"/> b. Third-party disclosure <input checked="" type="checkbox"/> c. Reporting <input checked="" type="checkbox"/> 1. On occasion <input type="checkbox"/> 2. Weekly <input type="checkbox"/> 3. Monthly <input type="checkbox"/> 4. Quarterly <input type="checkbox"/> 5. Semi-annually <input type="checkbox"/> 6. Annually <input type="checkbox"/> 7. Biennially <input type="checkbox"/> 8. Other (describe)
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17. Statistical methods Does this information collection employ statistical methods? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	18. Agency contact (person who can best answer questions regarding the content of this submission) Name: <u>Frank Cardile</u> Phone: <u>301-415-6185</u>
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**SUPPORTING STATEMENT
FOR
10 CFR 35.32 and 35.33
"QUALITY MANAGEMENT PROGRAM AND MISADMINISTRATIONS"
(3150-0171)**

CLEARANCE EXTENSION

DESCRIPTION OF THE INFORMATION COLLECTION

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. Two provisions of 10 CFR Part 35 include: (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).

Part 35, including §§ 35.32 and 35.33, is being revised in its entirety to incorporate specific improvements in NRC's regulations governing the medical use of byproduct material. That rulemaking, and the clearance package associated with it (3150-0010), covers all sections of Part 35, including the QMP and misadministration provisions currently cleared under OMB Clearance No. 3150-0171. The current requirements in § 35.32 to submit and maintain a QMP are being eliminated. However, the requirements in § 35.32 associated with written directives are being retained to provide high confidence that byproduct material will be administered as directed by the authorized user, and are included in §§ 35.40 and 35.2040 of the revision to Part 35. The current requirements in §§ 35.32 and 35.33 defining misadministrations and requiring notifications, reports, and records of misadministrations are being modified to refer instead to "medical events," to address patient intervention and wrong treatment site, and to make the reporting threshold dose-based where possible. These requirements are included in § 35.3045 of the revision to Part 35.

The proposed rule revision of Part 35 was published in the Federal Register for public comment on August 18, 1998. NRC staff reviewed and addressed public comments and, on May 31, 2000, submitted a draft final rule to the Commission. The final rule was affirmed by the Commission on October 23, 2000. Following submittal of the final rule and associated clearance package to the Office of Management and Budget (OMB), a notice was published in the Federal Register on March 16, 2001, announcing a 30-day public comment period on the submittal.

It is anticipated that the effective date of the final rule revising Part 35, including the revisions to §§ 35.32 and 35.33, will be March 2002, and the OMB clearance for §§ 35.32 and 35.33 will be then included under the OMB clearance for Part 35 (3150-0010). Currently, the OMB clearances for these two sections are due to expire October 31, 2001. In view of the fact that these parts will shortly thereafter be covered under OMB clearance 3150-0010, the Commission is seeking a 1-year clearance extension for the information collection requirements in these sections to allow sufficient time for OMB to complete its review of the NRC clearance package for the revision to Part 35, for NRC to publish the final rule, and for the rule to become effective. Because the final Part 35 and its OMB clearance will be in place in a short time period, the

burden hour estimates in this extension package are not being revised from those contained in the previous OMB approval for §§ 35.32 and 35.33 under OMB Clearance No. 3150-0171.

A. JUSTIFICATION

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

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 recordkeeping and reporting requirements of §§ 35.32 and 35.33 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 are 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. Information concerning the requirements imposed by specific sections is provided 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. Licensee implementation and maintenance of their QMP are 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 cannot 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

The reporting and recordkeeping 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. 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

While a number of medical licensees are considered small businesses under the NRC's current definitions, the health and safety consequences of improper use of 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 while maintaining the required level of safety.

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 two-thirds of Agreement State licensees. Additionally, once a QMP that meets the rule is submitted, the frequency that licensees' QMPs are modified is determined by licensees' 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 followup action can be taken.

7. Circumstances Which Justify Variation from OMB Guidelines

Contrary to the OMB Guidelines in 5 CFR 1320.6(b), 10 CFR 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 followup 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

Revisions to 10 CFR 35.32 and 35.33 are being made as part of the complete revision of 10 CFR Part 35 to incorporate specific improvements in NRC's regulations governing the medical use of byproduct material. A final rule revising Part 35 was affirmed by the Commission on October 23, 2000 and was submitted, along with its associated clearance package, to the Office of Management and Budget (OMB) on March 13, 2001. A notice was published in the Federal Register on March 16, 2001, announcing a 30-day public comment period on the submittal. No comments on the QM provisions were received on the final rule. It is anticipated that the effective date of the final rule revising Part 35, including the revisions to Sections 35.32 and 35.33, will be March 2002, and the OMB clearance for Sections 35.32 and 35.33 will then be included under the OMB clearance for Part 35 (3150-0010).

Opportunity for public comment was published in the Federal Register on June 27, 2001 (66 FR 34274). No comments were received.

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 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 could possibly 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 originally 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 that could be submitted voluntarily by the Agreement State licensees to the appropriate Agreement State.

These public burden estimates are based on NRC data collected during the past 5 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 current NRC labor cost rate of \$144 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 requirements:

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 \$144 = \$593,712

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 \$144 = \$116,640

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

NRC licensees reported an average of 30 misadministrations per year for years 1993 through 1997. 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 § 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 \$144 = \$352,800.

TOTAL BURDEN FOR NRC LICENSEES = 7383 hrs/yr X \$144 = \$1,063,152/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. Although the NRC has taken no action to enforce a compatibility requirement on the 10 Agreement States who have not adopted the QM rule, the NRC has included the burden cost of 10 percent of the 2000 non-QM Agreement States who may develop and submit a QMP during this approval period. 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 may adopt the rule within next 3 years):

Development of QMP by 10% of 2000 licensees =

$$200 \text{ licensees} \times 40 \text{ hrs} = 8000 \text{ hrs annualized over 3 yrs} = 2,667 \text{ hrs/yr}$$

Preparation and submittal of existing procedures:

$$90\% \times 2000 \text{ licensees} = 1800, \text{ annualized over 3 yrs} =$$

$$600 \text{ submittals} \times 5 \text{ hrs each for preparation and submittal} = 3,000 \text{ hrs/yr}$$

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

$$2000 \text{ licensees} \times 72\% \text{ (require modification)} = 1440 \text{ annualized over 3 yrs} =$$

$$480 \text{ QMPs/yr that require modification.}$$

$$480 \text{ submittals/yr} \times 3 \text{ hrs/submittal to make modification} = 1,440 \text{ hrs/yr}$$

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

$$2000 \text{ licensees annualized over 3 yrs} = 667 \text{ licensees/yr}$$

$$667 \text{ licensees/yr} \times 4 \text{ hrs to develop procedures for QMP review} = 2,668 \text{ hrs/yr}$$

Agreement State licensees' burden = 9,775 hrs/yr X \$144 = \$1,407,600

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:

$$\begin{aligned} 158 \text{ licensees} \times 40 \text{ hrs (new licensees-develop QMP)} &= 6,320 \text{ hrs/yr} \\ 250 \text{ licensees} \times 10 \text{ hrs (add modality - modify QMP)} &= 2,500 \text{ hrs/yr} \end{aligned}$$

$$\begin{aligned} 158 \text{ licensees} \times 4 \text{ hrs} \\ \text{(new licensees-develop review procedures)} &= 632 \text{ hrs/yr} \end{aligned}$$

$$\begin{aligned} 408 \text{ licensees} \times 72\% \text{ require modification} &= \\ 294 \text{ licensees} \times 3 \text{ hrs (modify)} &= 882 \text{ hrs/yr} \end{aligned}$$

Burden for new applicants and modalities added in Agreement States =

$$\underline{10,334 \text{ hrs/yr} \times \$144 = \$1,488,096}$$

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.

$$\begin{aligned} 2500 \text{ submitted QMPs} \times 15\% \text{ (mod./yr)} &= 375 \text{ modifications/yr} \\ 375 \text{ mod./yr} \times 3 \text{ hrs (to make modification)} &= 1,125 \text{ hrs/yr} \end{aligned}$$

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.

$$75 \text{ misadministrations reported/yr} \times 17 \text{ hrs/event} = 1,275 \text{ hrs/yr}$$

$$75 \text{ misadministrations} \times 10 \text{ minutes (to file record)} = 13 \text{ hrs/yr}$$

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:

$$4500 \times 15\% = 675$$

$$675 \text{ records/yr} \times 30 \text{ minutes to make the record} = 338 \text{ hrs/yr}$$

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

$$4500 \times 1 \text{ hr/yr} = 4,500 \text{ hrs/yr}$$

Burden associated with notifications, reports, and records of misadministration:

$$= 6,126 \text{ hrs/yr} \times 144 = \underline{\$882,144}$$

TOTAL BURDEN FOR AGREEMENT STATE LICENSEES =

$$\underline{27,360 \text{ hrs/yr} \times 144 = \$3,939,840^*}$$

* Inflated by the 9,775 hrs/yr burden for those Agreement States who have not as yet adopted the QM rule, who may choose to develop and implement the rule during the next ICR approval period.

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)
Reporting	6300	24,400
Recordkeeping		10,343
Total		34,743

The total cost from the reporting and recordkeeping burden, at \$144/yr, is \$5,002,992.

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:

$$3 \text{ hrs} \times 163 \text{ licensing actions/yr} = 489 \text{ hrs/yr} \times \$144 = \underline{\$70,416/\text{yr}}$$

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:

$$2 \text{ hrs} \times 270 \text{ modifications/yr} = 540 \text{ hrs/yr} \times \$144 = \underline{\$77,760/\text{yr}}$$

The ongoing cost to the NRC for review of QMPs
= 1029 hrs/yr X \$144 = \$148,176/yr

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 \$345,600 per year.

$$80 \text{ hrs/misadministration} \times 30 \text{ misadministrations/yr} = 2400 \text{ hrs/yr} \\ 2400 \text{ hrs/yr} \times \$144/\text{hr} = \underline{\$345,600/\text{yr}}$$

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 \$144 = \$493,776/yr

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

15. Reasons for Change in Burden or Cost

As stated in Section 8, because the final Part 35 and its OMB clearance will be in place in a short time period, the burden hour estimates in this extension package are not being revised from those contained in the previous OMB approval for §§ 35.32 and 35.33 under OMB Clearance No. 3150-0171. The costs have been changed to reflect the current charge rate of \$144/hr. Therefore, although the burden hour estimates have not changed, the costs have increased to reflect the increase in hourly rates.

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 \$144 /hr
35.32(a)	<u>Licensees:</u>			
	<u>Agreement State (one time):</u>			
	Develop and maintain a written QMP (includes submittal), Approx. (200 licensees/3 yrs)	40	*2,667	\$384,048
	Submission of QMP (Submit existing procedures, 600 (90%) licensees (1800 licensees/3 years)	5	*3,000	\$432,000
	<u>NRC & Agreement State:</u>			
	221 new application QMPs	40	8,840	\$1,272,960
	350 amending license to add modality (submit QMP)	10	3,500	\$504,000
35.32(e)	Submit modification of QMP within 30 days after modification is made: (72% initial failure rate for first time submittals)			
	<u>Agreement State Licensees</u> <u>(one time):</u> 72% of initial submittals = 480 QMPs	3	*1,440	\$207,360
	<u>NRC Licensees:</u> Modify 72% of new and added modality applications =117	3	351	\$50,544
	15% existing QMPs= 270	3	810	\$116,640
	<u>Agreement State Licensees:</u> Modify 72% of new and added modality applications = 294	3	882	\$127,008
	15% of existing QMPs = 375	3	1125	\$162,000
35.32(f)(1)	Submit a QMP to appropriate agency	Included in § 35.32(a)		
35.32(f)(2)	Submit written certification	Rqmt complete		

* One time burden for Agreement States that have yet to adopt the rule: 7,107 hrs/yr
Reporting Burden (§ 35.32) per yr: 22,615 hrs/yr X \$ 144= \$3,256,560

Table 2 (Annualized)

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

Section	Item	Hours Per Event	Total Burden hrs/yr	Cost at \$144/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	\$3,744
35.33(a)(2)	Licensee written report to regulatory agency within 15 days after discovery of misadministration.	16 hrs	1,680 hrs	\$241,920
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	\$7,632
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	\$3,744

Reporting Burden (§ 35.33) per yr: 1,785 hrs/yr X \$144 = \$257,040

Table 3 (Annualized)

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

Section	Item	Hours Per Burden Event	Total hrs/yr	Cost at \$144/hr
35.32(b)(1)	<u>Licensees:</u> Develop procedures for review: <u>Agreement State (one-time):</u> 667 initial development	4 hrs	*2,668	\$384,192
	<u>NRC and Agreement State:</u> 221 new licensees/yr	4 hrs	884	\$127,296
35.32(b)(2)	<u>Licensees (6300 total):</u> Evaluate QMP reviews and make modifications, if needed:	50 min.	5,250	\$756,000
35.32(b)(3)	Retain records of each audit and management evaluation of the QMP for 3 years.	10 min.	1050	\$151,200
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	\$68,112
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 \$144 = \$1,486,800

*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	Burden hrs/yr	Total Cost at \$144/hr
35.33(b)	Licensee shall retain a record of the misadministration for 5 years.	105	10 min	18 hours	\$2,592

Recordkeeping burden (§ 35.33) per yr: 18 hrs/yr X \$144 = \$2,592

U. S. NUCLEAR REGULATORY COMMISSION

Agency Information Collection Activities: Submission for the Office of Management and Budget (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.

Information pertaining to the requirement to be submitted:

1. Type of submission, new, revision, or extension: Extension
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: None.

4. How often the collection is required: For quality management program (QMP): Reporting: New applicants for medical use licenses, who plan to use byproduct material in limited diagnostic and therapy quantities under Part 35, must develop a written QMP and submit a copy of it to NRC. When a new modality involving therapeutic quantities of byproduct material is added to an existing license, current licensees must submit QMP modifications. This ICR burden estimate is inflated by the one-time cost for the development and submission of QMPs for approximately 2000 Agreement States licensees in the ten Agreement States who have not adopted the rule and are not required to. 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 is 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: 6300 (for both reporting and recordkeeping).

7. The number of annual respondents: 6300 (for both reporting and recordkeeping)

8. The number of hours needed annually to complete the requirement or request: 34,743 hours for applicable licensees (Reporting: 24,400 Hrs/yr, and Recordkeeping: 10,343 Hrs/yr, or an average of 5.5 hrs per licensee).

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 (§ 35.33) are 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.

Revisions to 10 CFR 35.32 and 35.33 are being made as part of a complete revision of 10 CFR Part 35 to incorporate specific improvements in NRC's regulations governing the medical use of byproduct material. A final rule revising Part 35 was affirmed by the Commission on October 23, 2000 and was submitted, along with its associated clearance package, to the Office of Management and Budget (OMB). A notice was published in the Federal Register on March 16, 2001, announcing a 30-day public comment period on the submittal. It is anticipated that the effective date of the final rule revising Part 35, including the revisions to Sections 35.32 and 35.33, will be March 2002, and the OMB clearance for Sections 35.32 and 35.33 will be then be included under the OMB clearance for Part 35 (3150-0010).

Currently, the OMB clearances for Sections 35.32 and 35.33 are due to expire October 31, 2001. In view of the fact that these parts will shortly thereafter be covered under OMB clearance 3150-0010, the Commission is seeking a 1-year clearance extension for the information collection requirements in these sections to allow sufficient time for OMB to complete its review of the NRC clearance package for the revision to Part 35, for NRC to publish the final rule, and for the rule to become effective. Because the final Part 35 and its OMB clearance will be in

place in a short time period, the burden hour estimates in this extension package are not being revised from those contained in the previous OMB approval for Sections 35.32 and 35.33 under 3150-0171.

A copy of the final supporting statement may be viewed free of charge at the NRC Public Document Room, One White Flint North, 11555 Rockville Pike, Room O-1 F23, Rockville, MD 20852. OMB clearance requests are available at the NRC worldwide web site: <http://www.nrc.gov/NRC/PUBLIC/OMB/index.html>. The document will be available on the NRC home page site for 60 days after the signature date of this notice.

Comments and questions should be directed to the OMB reviewer listed below by (insert date 30 days after publication in the Federal Register). Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date.

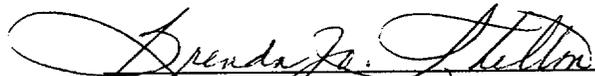
Bryon Allen
Office of Information and Regulatory Affairs (3150-0171)
NEOB-10202
Office of Management and Budget
Washington, DC 20503

Comments can also be submitted by telephone at (202) 395-3087.

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

Dated at Rockville, Maryland, this 17th day of September 2001.

For the Nuclear Regulatory Commission.


Brenda Jo. Shelton, NRC Clearance Officer
Office of the Chief Information Officer

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/S/ /RA/

Brenda Jo. Shelton, NRC Clearance Officer
Office of the Chief Information Officer

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