[7590-01-P]

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.

/S/ /RA/

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

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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.

(Original signed by)
Brenda Jo. Shelton, NRC Clearance Officer
Office of the Chief Information Officer

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