[7590-01-P]

U. S. NUCLEAR REGULATORY COMMISSION

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

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).

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

2. The title of the information collection:
   -Final rule, 10 CFR Part 35, Medical Use of Byproduct Material
   -NRC Form 313, Application for Material License, and Supplemental Forms
      NRC Form 313A, Training and Experience, and
      NRC Form 313B, Preceptor Statement

3. The form number if applicable: NRC Form 313, 313A and 313B

4. How often the collection is required: Reports of medical events, doses to an embryo/fetus or nursing child, or leaking sources are reportable on occurrence. A certifying entity desiring to be recognized by the NRC must request recognition.

5. Who will be required or asked to report: Physicians and medical institutions holding an NRC license authorizing the administration of byproduct material or radiation therefrom to humans for medical use.

6. An estimate of the number of responses: 214,402 (61,182 NRC licensees, 153,220 Agreement State licensees). In addition, 23 organizations are expected to prepare requests for recognition.

   NRC Form 313: 7 (2 NRC licensees, 5 Agreement State licensees) applications for new modalities.

7. The estimated number of annual respondents: 5793 (1,655 NRC licensees and 4,138 Agreement State licensees).

8. An estimate of the total number of hours needed annually to complete the requirement or request: Part 35: 889,754 hours (254,059 hours for NRC licensees and 635,695 hours for Agreement State licensees) (an average of 154 hours per licensee). In addition, there is a one-time burden of 368 hours on certifying boards involved in their preparing requests for recognition. NRC Form 313: 673 hours (193 hours for NRC licensees and 480 hours for Agreement State licensees).

9. An indication of whether Section 3507(d), Pub. L. 104-13 applies: Applicable

10. Abstract: 10 CFR Part 35, "Medical Use of Byproduct Material", is being restructured into a more risk-informed, more performance-based regulation. The final rule contains mandatory requirements that apply to NRC licensees authorized to administer byproduct material or radiation therefrom to humans for medical use.

    The information in the required reports and records is used by the NRC to ensure that public health and safety is protected, and that the possession and use of byproduct material is in compliance with the license and regulatory requirements.

A copy of the 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 packages 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 by (insert date 30 days after publication in the Federal Register):

Amy Farrell
Office of Information and Regulatory Affairs (3150-0010, and -0120)
NEOB-10202
Office of Management and Budget
Washington DC 20503

Comments can also be submitted by telephone at (202) 395-7318.

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

Dated at Rockville, Maryland, this 9th day of March 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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ACCESSION NUMBER:

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