[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:

   -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. An organization desiring to become a certifying entity must tender an application upon intent.

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: 93,966 (26,850 NRC licensees, 67,116 Agreement State licensees). In addition, 4 new organizations are expected to apply to become certifying entities and 35 will be required to submit modified procedures.

7. The estimated number of annual respondents: 1,902 NRC licensees and 4,755 Agreement State licensees.

8. An estimate of the total number of hours needed annually to complete the requirement or request: Part 35: 877,807 hours (251,192 hours for NRC licensees, 626,381 hours for Agreement State licensees, and 234 hours for certifying organizations) (an average of 132 hours per licensee). In addition, there is a one-time burden of 2,956 hours for certifying organizations to submit new or modified procedures. NRC Form 313: 68 additional hours (48 hours for NRC licensees and 20 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 risk-informed performance-based regulation. The proposed rule contains mandatory requirements that apply to NRC licensees authorized to administer byproduct material or radiation therefrom to humans for medical use. In addition, requirements are being added for organizations desiring to be recognized by NRC as certifying organizations.

    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.

Submit, by (insert date 30 days after publication in the Federal Register), comments that address the following questions:

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

2. Is the burden estimate accurate?

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

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 11 day of August 1998.

For the Nuclear Regulatory Commission.

Beth St. Mary, Acting NRC Clearance Officer
Office of the Chief Information Officer