

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 current valid OMB control number.

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
3. The form number if applicable: Not applicable

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 submit a one-time request for 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: The estimated number of annual responses: 242,030 (51,309 responses from NRC licensees + 1,759 recordkeepers and 184,686 responses from Agreement State licensees + 6,332 recordkeepers). Also 23 specialty certification boards are expected to request recognition under the proposed revision of Part 35 (amendment of 10 CFR Part 35, "Medical Use of Byproduct Material - Recognition of Specialty Boards").
7. The estimated number of annual respondents: 8,091 (1,759 NRC licensees and 6,332 Agreement State licensees).
8. An estimate of the total number of hours needed annually to complete the requirement or request: 1,113,217 hours (242,030 hours for NRC licensees and 871,059 hours for Agreement State licensees [an average

of 138 hours per licensee] and an additional one-time burden of 128 hours for certifying boards).

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

10. Abstract: 10 CFR Part 35, "Medical Use of Byproduct Material," contains NRC's requirements and provisions for the medical use of byproduct material and for issuance of specific licenses authorizing the medical use of this material. These requirements and provisions provide for the radiation safety of workers, the general public, patients, and human research subjects. 10 CFR Part 35 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 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 F21, Rockville, MD 20852. OMB clearance requests are available at the NRC worldwide web site: <http://www.nrc.gov/public-involve/doc-comment/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.

OMB Desk Officer
Office of Information and Regulatory Affairs (3150-0010)
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 26th day of July 2004.

For the Nuclear Regulatory Commission.

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

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.

OMB Desk Officer
 Office of Information and Regulatory Affairs (3150-0010)
 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 26th day of July 2004.

For the Nuclear Regulatory Commission.

/RA/

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

Distribution:

RGB R/F

IMNS R/F

ADAMS Accession Number:

Document Name: (O:\BROWN\PT35FinalOMB Report.wpd)

See previous concurrence *

OFFICE:	RGB:IMNS		RGB:IMNS		OCIO	
NAME:	CBrown*		CAbrams*		BShelton	
DATE:	07/ 21 /2004		07/ 21 /2004		07/ 26 /2004	

OFFICIAL RECORD COPY