

U. S. NUCLEAR REGULATORY COMMISSION

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: U. S. Nuclear Regulatory Commission (NRC)

ACTION: Notice of pending NRC action to submit an information collection request to OMB and solicitation of public comment.

SUMMARY: The NRC is preparing a submittal to OMB for review of continued approval of information collections under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

Information pertaining to the requirement to be submitted:

1. The title of the information collection:  
10 CFR Part 35, Medical Use of Byproduct Material
2. Current OMB approval number: 3150-0010
3. 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.

4. Who is 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.
5. 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").
6. The estimated number of annual respondents: 8,091 (1,759 NRC licensees and 6,332 Agreement State licensees).
7. An estimate of the 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).
8. 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.

Submit, by (insert date 60 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?
4. How can the burden of the information collection be minimized, including the use of automated collection techniques or other forms of information technology?

A copy of the draft 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 about the information collection requirements may be directed to the NRC Clearance Officer, Brenda Jo. Shelton (T-5 F-52), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, by telephone at 301-415-7233, or by Internet electronic mail to [INFOCOLLECTS@NRC.GOV](mailto:INFOCOLLECTS@NRC.GOV).

Dated at Rockville, Maryland, this 10th day of May 2004.

For the Nuclear Regulatory Commission.

IRA

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

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Dated at Rockville, Maryland, this 10<sup>th</sup> day of May 2004.

For the Nuclear Regulatory Commission.

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

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