

NUCLEAR REGULATORY COMMISSION

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

AGENCY: Nuclear Regulatory Commission (NRC).

ACTION: Notice of the OMB review of information collection.

SUMMARY: The Nuclear Regulatory Commission has recently submitted to OMB for review the following proposal for collection of information under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

1. Type of submission, new, revised, or extension: Revision.
2. The title of the information collection: Final amendments to 10 CFR 35.75, "Criteria for the Release of Individuals Administered Radioactive Material."
3. The form number if applicable: Not applicable.

050100

9611050335 961007  
PDR ORG EUSOMB  
PDR

4. How often is the collection required: On occasion; when the release of a patient is based on other than standard assumptions or requires interruption or discontinuation of breast-feeding to meet the 5-millisievert (0.5-rem) dose limit.
5. Who will be required or asked to report: Medical licensees administering radiopharmaceuticals and permanent implants and releasing patients under the provisions of 10 CFR 35.75.
6. An estimate of the number of responses: Approximately 90,350 responses per year (includes 89,000 reports, i.e., written instructions, and 1,350 recordkeepers).
7. The estimated number of annual respondents: Approximately 1,350 NRC and Agreement State licensees.
8. An estimate of the number of hours needed annually to complete the requirement or request: 17,126 hours (includes NRC and Agreement State licensees).
9. The average annual burden per respondent: 13 hours.
10. An indication of whether Section 3504(h), Pub. L. 96-511 applies: Applicable.

11. Abstract: The Nuclear Regulatory Commission (NRC) is amending the criteria for release of individuals administered radioactive material under 10 CFR Part 35. The amendment requires the licensee to provide the patient with written instructions on how to maintain doses to other individuals as low as is reasonably achievable if the dose to an individual exposed to the patient is likely to exceed 0.1 rem. In those cases where the released individual may be a breast-feeding woman, the instructions must also include guidance on the interruption or discontinuation of breast-feeding and information on the consequences of failure to follow the guidance. The amendment also requires the licensee to maintain a record of the basis for the release if the release is authorized using other than standard assumptions or that instructions were provided to a breast-feeding woman if the dose to the child from continued breast feeding could result in a total effective dose equivalent exceeding 0.5 rem. These requirements are necessary to ensure adequate protection of the public health and safety and that doses to other individuals are maintained as low as reasonably achievable.

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?
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 submittal may be viewed free of charge at the NRC Public Document Room, 2120 L Street NW, (lower level)), Washington, DC. Members of the public who are in the Washington, DC, area can access this document via modem on the Public Document Bulletin Board (NRC's Advanced Copy Document Library), NRC subsystem at FedWorld, 703-321-3339. Members of the public who are located outside of the Washington, DC, area can dial FedWorld, 1-800-303-9672, or use the FedWorld Internet address: [fedworld.gov](http://fedworld.gov) (Telnet). The document will be available on the bulletin board for 30 days after the signature date this notice. If assistance is needed in accessing the document, please contact the FedWorld help desk at 703-487-4608. Additional assistance in locating the document is available from the NRC Public Document Room, nationally at 1-800-397-4209, or within the Washington, DC, area at 202-634-3273.

Comments and questions should be directed to the OMB reviewer by (insert date 30 days after publication in the Federal Register):

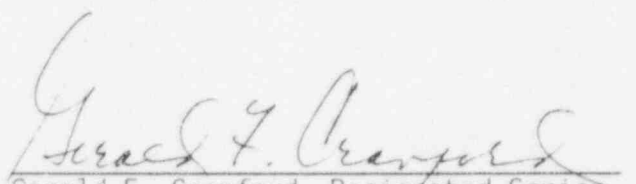
Edward Michlovich  
Office of Information and Regulatory Affairs (3150-0010)  
NEOB-10202  
Office of Management and Budget  
Washington, DC 20503

Comments can also be submitted by phone at (202) 395-3084.

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

Dated at Rockville, Maryland, this 7<sup>th</sup> day of October, 1996.

For the Nuclear Regulatory Commission.

  
Gerald F. Cranford, Designated Senior  
Official for Information Resources  
Management.