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FINAL REPLY:

John D. Graham
Office of Management and Budget (OMB)

TO:

Chairman Meserve

FOR SIGNATURE OF : ** PRI ** CRC NO: 01-0451

Chairman

DESC:

Information Collection Request for Amendments to 10 CFR Part 35, Medical Use of Byproduct Material

ROUTING:

Travers
Paperiello
Kane
Norry
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Burns/Cyr

DATE: 09/14/01

ASSIGNED TO: CONTACT:

NMSS Virgilio

SPECIAL INSTRUCTIONS OR REMARKS:

Template: SECY-017

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OFFICE OF THE SECRETARY
CORRESPONDENCE CONTROL TICKET

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ACTION OFFICE:	EDO		
AUTHOR:	John Graham		
AFFILIATION:	OMB		
ADDRESSEE:	CHRM Richard Meserve		
SUBJECT:	Concerns information collection request for amendments to 10 CFR Part 35, Medical Use of Byproduct Material		
ACTION:	Signature of Chairman		
DISTRIBUTION:	RF		
LETTER DATE:	09/10/2001		
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NOTES:	COMMISSION CORRESPONDENCE		
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DATE DUE:	09/27/2001	**DATE SIGNED:**	

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

ADMINISTRATOR
OFFICE OF
INFORMATION AND
REGULATORY AFFAIRS

SEP 10 2001

The Honorable Richard Meserve
Chairman
Nuclear Regulatory Commission
One White Flint North Building
11555 Rockville Pike
Rockville, MD 20852

Dear Chairman Meserve:

The Office of Management and Budget (OMB) has concluded our review of the information collection request for the Nuclear Regulatory Commission's (NRC) amendments to 10 CFR Part 35, Medical Use of Byproduct Material. After careful review of the NRC's amendments, we have concluded that they will yield important reductions in burden relative to the existing Part 35 reporting and record-keeping requirements. We are therefore approving the information collection request for the amendments to Part 35. The terms of clearance for the Part 35 ICR (enclosed) request that the NRC evaluate this program in order to achieve further reductions in the burden of these requirements by considering alternatives such as third-party accreditation and increased reliance on State regulations and professional standards.

I am also concerned that the NRC has not carried out a regulatory analysis of the benefits and costs of its Part 35 program. Although the NRC is exempt from the requirements of Executive Order 12866, a regulatory analysis is an important tool for evaluating any regulatory program and would aid the NRC in better understanding how to reduce burden from the Part 35 program. I encourage the NRC to undertake such a regulatory analysis in the three years prior to submitting a request to extend the authorization for the information collection request for Part 35.

Sincerely,

John D. Graham
Administrator

Enclosure

cc: The Honorable Christopher S. Bond
The Honorable James M. Inhofe

Draft Terms of Clearance for 10 CFR 35:

This information collection is approved under 5 CFR 1320. When submitting a request to revise or extend this collection, NRC should ensure the following:

- That each of the record-keeping and reporting requirements contained in 10 CFR 35 have practical utility, as required by 5 CFR 1320.5 (d)(1)(iii). In determining whether these requirements have practical utility, NRC should consider any new information regarding:

  - the risks posed by the medical use of reactor byproduct materials,
  - the burden imposed by the information collection requirements,
  - and the costs and efficacy of alternative strategies for assuring safe use of these materials—including reliance on existing professional standards and medical and pharmaceutical laws.

- That requirements for record keeping and reporting are the least burdensome necessary, as is required by 5 CFR 1320.5 (d)(1)(i). In ensuring that its approach is the least burdensome necessary, NRC should consider:

  - whether alternatives, including use of a third-party accrediting organization, would achieve the same purpose in a less burdensome way,
  - whether records and reports related to the radiation safety program and its management would be sufficient to ensure safety without requiring retention of program records and written procedures,
  - and whether the retention period for records can be shortened without damaging NRC's ability to fulfill its purpose in these regulations.

- That reporting threshold for a "medical event" ensures that all such reports have practical utility. NRC should examine any new information regarding the risks posed by variation from prescribed doses and examine whether a different threshold would better satisfy the requirements that information collected have practical utility (5 CFR 1320.5 (d)(1)(iii)) and is the least burdensome necessary (5 CFR 1320.5 (d)(1)(i)).

In making the above determinations, NRC should consult with licensees or relevant stakeholders, as well as with agreement states responsible for regulation the medical use of reactor byproduct materials.