From: <OIRA_DOCKET@omb.eop.gov>
To: <BJS1@nrc.gov>
Date: 9/19/01 3:09PM
Subject: 3150-0010 OMB NOTICE OF ACTION

NOTICE OF OFFICE OF MANAGEMENT AND BUDGET ACTION

Brenda Jo Shelton 09/18/2001
(T6 F33)
NRC Clearance Officer
U.S. Nuclear Regulatory Commission
Washington, DC 20555

In accordance with the Paperwork Reduction Act, OMB has
taken the following action on your request for approval of
a revision of an information collection received on 03/14/2001.

TITLE: 10 CFR Part 35, Medical Use of Byproduct Material

AGENCY FORM NUMBER(S): None

ACTION : APPROVED
OMB NO.: 3150-0010
EXPIRATION DATE: 09/30/2004

BURDEN	RESPONSES	BURDEN HOURS	BURDEN COSTS
Previous	6,676,254	1,294,681	0
New	214,402	889,754	16
Difference	-6,461,852	-404,927	16
Program Change		-404,927	0
Adjustment		0	16

TERMS OF CLEARANCE:

SEE PAGE 2 FOR TERMS OF CLEARANCE

TERMS OF CLEARANCE:

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

I) 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, the NRC should consider any new information regarding:

a) the risks posed by the medical use of reactor byproduct materials,

b) the burden imposed by the information collection requirements,

c) and the costs and efficacy of alternative strategies for assuring safe use of these materials--including reliance on existing professional standards and state and federal medical and pharmaceutical laws.

II) 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, the NRC should consider:

a) whether alternatives, including the use of a third-party accrediting organization, would achieve the same purpose in a less burdensome way,

b) 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,

c) and whether the retention period for records can be shortened without damaging the NRC's ability to fulfill its purpose in these regulations.

III) That the reporting threshold for a "medical event" ensures that all such reports have practical utility. The NRC should examine any new information regarding the risks posed by variation from the 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, the NRC should consult with licensees or relevant stakeholders, as well as with agreement states responsible for regulating the medical use of reactor byproduct materials.

NOTE: The agency is required to display the OMB control number and inform respondents of its legal significance (see 5 CFR 1320.5(b)).

OMB Authorizing Official Title

Donald R. Arbuckle Deputy Administrator, Office of Information and Regulatory Affairs