



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555

AD61-2

PDR

003

JUN 16 1992

MEMORANDUM FOR: Thomas E. Murley, Director
Office of Nuclear Reactor Regulation

FROM: Gerald F. Crawford, Director
Office of Information Resources Management

SUBJECT: PARTIAL DISAPPROVAL OF OMB CLEARANCE FOR FINAL
RULE, 10 CFR 26, FITNESS FOR DUTY

On January 6, 1992, NRC submitted a request for OMB review of the information collections contained in the final rule, Fitness for Duty, 10 CFR 26.24(d)(2)(iv) and 26.71(d). On February 25, 1992, OMB received a letter from the Nuclear Management and Resources Council (NUMARC) objecting to the added information collection at §26.71(d). This collection requires that, as part of the currently required biannual report of fitness-for-duty program performance data, licensees also submit data on the number of temporary suspensions or other administrative actions taken against individuals based on onsite positives for marijuana (THC) and cocaine, including appeals and their resolutions. NUMARC objected that this reporting requirement was not in the proposed rule and, therefore, had not received public comment. NUMARC believes that NRC has provided no basis for requiring submittal of this data, as the raw data are already available to NRC.

In a May 7, 1992, meeting among representatives from NRC, OMB, and NUMARC, NRC indicated that the additional information is being requested to establish a database for monitoring possible future needs to amend the 10 CFR Part 26 regulation.

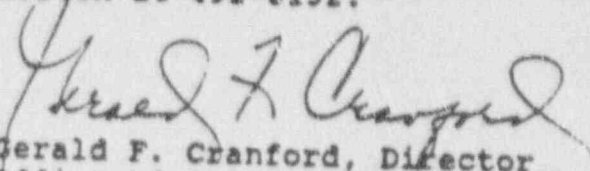
As indicated in the enclosed "Notice of Office of Management and Budget Action" dated May 26, 1992, OMB approved the information collection contained in §26.24(d)(2)(iv), but disapproved the information collection contained in §26.71(d), stating that NRC has demonstrated no compelling need for the additional data. OMB also indicated that the raw data are already available to NRC, and cited 5 CFR 1320.4(b)(3) as a reminder that NRC cannot seek to minimize its costs by shifting disproportionate costs or burdens to the public.

The final rule became effective September 25, 1991, subject to OMB approval of the two additional information collections. Since OMB disapproved the additional collection contained in §26.71(d), NRC must either amend the final rule to delete this collection or obtain a Commission override, as addressed in NRC Manual Chapter 230, "Collections of Information and Reports Management," to impose the information collection disapproved by OMB. In either

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case, NRR must also publish a notice in the Federal Register of OMB's approval of the information collections contained in §26.24(d)(2)(iv).

If you have any questions or should you need assistance, please contact Brenda Jo. Shelton at 492-8132.


Gerald F. Cranford, Director
Office of Information Resources Management

Enclosure:
As stated

cc: R. Ingram, NRR
E. McPeck, NRR



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August 14, 1992

James B. MacRae, Jr.
Acting Administrator and
Deputy Administrator
Office of Information and
Regulatory Affairs
Office of Management and Budget
Washington, D.C. 20503

Dear Mr. MacRae:

This is in response to your letter of June 26, 1992 in which OMB disapproved the information collection request (ICR) associated with the final amendment promulgated by the Nuclear Regulatory Commission (Commission) to 10 CFR Parts 2 and 35, entitled, "Quality Management Program and Misadministration." OMB concluded that this information collection request is not necessary for the proper performance of the functions of the agency and that the information will not have practical utility for the agency. This letter also addresses your partial disapproval of the ICR associated with amendments to the fitness for duty rule in 10 CFR Part 26, as reflected in your letters of May 26, 1992 and July 20, 1992.

The Commission fully supports the objectives of the Paperwork Reduction Act and strives to ensure that the private sector is requested to maintain or provide only such information as is needed to carry out regulatory responsibilities. In this vein, upon reconsideration, the Commission does not disagree with your conclusions regarding information collection requirements in our fitness for duty rule. The Commission will issue conforming changes to account for and accommodate your comments and partial disapproval of the ICR in those regulations in the near future.

On the other hand, for reasons specified below, pursuant to 44 U.S.C. 3507(c), the Nuclear Regulatory Commission has decided to override the OMB determination and requests that your office promptly assign a control number to the information collection request associated with the Quality Management and Misadministration Rule for a period of 3 years.

In its implementing regulations OMB specifies (5 CFR 1320.11, 1320.4(b) and (c)) that in approving an information collection request it evaluates whether (1) the agency has chosen the least burdensome means to obtain the information, (2) the information sought is available to the agency through

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some other means, and (3) the information sought has practical utility. Practical utility is defined (5 CFR 1320.7(o)) only as usefulness to the agency, taking into account the information's accuracy, adequacy, and reliability, and the agency's ability to process the information in a timely fashion.

Your disapproval of the ICR does not indicate that the information collection requirements are an unnecessarily burdensome way to obtain information about misadministrations and medical quality management programs, or that the information is available through some other means. Your disapproval relies on the third evaluation criterion described above and makes a finding of no practical utility. But, contrary to 5 CFR 1320.7(o), you do not discount the accuracy, reliability or adequacy of the information sought, or challenge the Commission's ability to process the information in a timely fashion. Your disapproval indicates that you have concluded that there is no need for the Commission's final rule and regulatory program to reduce injuries from misadministration and that, therefore, any paperwork burden that the rule would impose is unreasonable.

The Commission -- which is the agency charged with substantive responsibility for making such judgments -- continues to believe that its requirement for written quality management programs and misadministration reports, if complied with, has a reasonable likelihood of decreasing misadministrations (e.g. wrong dose or wrong patient) with a small incremental cost to licensees. Without the reporting and recordkeeping requirements, it would not be possible to implement and enforce these regulations effectively.

The Commission will continue to monitor implementation and inspection under the rule to assure that it provides the Commission with necessary information without imposing undue burden on the private sector. If the Commission finds the rule, in whole or in part, to be overly burdensome or ineffective, it will consider modifying or deleting portions of the rule. Further, the NRC will hold a public workshop with the medical community and other interested parties, to assure that there is mutual understanding as to the intent of the rule, especially its information collection requirements, and to discuss effective implementation. In particular, we will discuss the extent to which we can use the industry's self-auditing guidelines. Following the workshop, the Commission will develop additional guidance on compliance with the rule, written in clear language appropriate to the medical community.

James B. MacRae, Jr.

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Certification of the Override

The Commission certifies that, by unanimous vote¹, it has overridden the Office of Management and Budget's disapproval of the information collection request associated with the final amendment to 10 CFR Parts 2 and 35 entitled "Quality Management Program and Misadministration."

Sincerely,

Original signed by
James M. Taylor

James M. Taylor
Executive Director
for Operations

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*alter
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¹ At the August 12, 1992 Commission meeting the formal vote was 3-0 with Commissioners Rogers and Curtiss not present. Commissioners Rogers and Curtiss both indicated that they agreed with the majority and would also have voted formally to override if they could have been present at the meeting.