D. Danahue

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

AC 65-2
PDR 054

January 24, 1992

Mr. James B. MacRae, Jr.
Acting Administrator and
Deputy Administrator
Office of Information and
Regulatory Affairs
Office of Management and Budget
1725 - 17th Street, NW
Washington, DC 20503

Dear Mr. MacRae:

Despite considerable efforts by both of our staffs to settle the differences of opinion concerning the proposed information collection requirements associated with the final rule amending Part 35, a satisfactory resolution has not been reached. Because the January 27, 1992 implementation date is imminent, the NRC must decide on the enforceability of the information collection requirements.

Based on your conversation with members of my staff on January 23, we expect to receive a letter from OMB elaborating OMB's remaining concerns. We note that NRC submitted a revised package dated September 11, 1991 for the revised information collection requirements in the final rule. The latter reduced the burden from 65,000 hours to 6,900 hours annually. In view of the fact that we have not been advised of an OMB disapproval within 90 days of our submittal, NRC's legal counsel has concluded that we can proceed with full implementation of the amendment. Indeed, given the reduced information collection requirements in the final rule, it seems to us that OMB review of the final rule was not needed, and that the final rule can become effective on the basis of OMB's March 30, 1990 appraisal of the proposed rule. But we nevertheless can proceed with continued interaction with OMB to resolve your concerns on the collections of information associated with amended Part 35.

This experience emphasizes the importance of good timely communication between our agencies and I thank you for your personal efforts in this matter.

Sincerely,

Hugh L. Thompson, Jr.

Hugh L. Thompson, Jr.
Deputy Executive Director for
Nuclear Materials Safety, Safeguards,
and Operations Support

9202050416 XA

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

AC65-2
PDR
055

JAN 24 1992

Mr. James Taylor
Executive Director for Operations
Nuclear Regulatory Commission
Washington DC 20555

Dear Mr. Taylor:

On December 24, 1991, the Nuclear Regulatory Commission (NRC) resubmitted to the Office of Management and Budget (OMB) an information collection request (ICR) entitled "The Medical Use of Byproduct Material" for review under the Paperwork Reduction Act (PRA). This ICR would establish as a part of its quality management (QM) programs several additional recordkeeping and reporting requirements for practitioners of nuclear medicine and several types of therapy which use byproduct material. I am concerned with the NRC's failure to demonstrate clearly the practical utility of these requirements and to provide estimates of their burden as required by the PRA.

NRC reports that the purpose of this ICR is to require practitioners of nuclear medicine to maintain records and submit certain data to the NRC as part of its QM programs. These programs are designed to assure that radiopharmaceuticals are administered as prescribed by the authorized user physician, and that procedures are carried out as prescribed by authorized physicians. The NRC has not, however, clearly demonstrated that there is currently a significant problem requiring such a quality management program. Given the already high cost of medical care, it is important that the Federal government avoid further burdens for the health care sector, unless these additional requirements have practical utility and are likely to yield significant benefits. The NRC has not made this demonstration.

While OMB initially approved the QM requirements at proposal, OMB staff have reexamined these requirements in response to public comments that were received when the final package was submitted to OMB for review. OMB has received written comments from the Society of Nuclear Medicine/American College of Nuclear Physicians, and copies of letters concerning the final rule, and the pilot study from the Small Business Administration and the University of California at Los Angeles. Following these initial contacts, OMB staff discussed these requirements extensively with other members of the regulated community. These include representatives of three agreement states (New York, California, and Louisiana), several physicians who practice nuclear medicine, representatives of three other professional organizations (American College of Radiology, Joint Commission on the

A20205042001

Accreditation of Health Care Organizations, and the American Medical Association), members of the NRC's Advisory Committee on the Medical Use of Isotopes, and the staff of the Food and Drug Administration. OMB has also received numerous written comments from physicians and health care facilities in recent weeks. While the concerns outlined below are based on our own evaluation, we believe they also reflect the concerns of many of these individuals and organizations.

Practical Utility

The current rate of misadministration of radiopharmaceuticals is already quite low.[1] There appears to be widespread agreement on this point among almost everyone familiar with the issue. This is likely a result of several factors. Most practitioners already implement quality management programs on a voluntary basis; many as part of an accreditation or certification process sponsored by a professional association. There are important reasons for practitioners to do so. First, practitioners need to take every care that their procedures are done correctly to avoid malpractice suits. In addition, since records of their mistakes are available to the general public, such care is important to maintain their professional reputation. Finally, practitioners in the field are acutely aware of the public's general concerns about radiation, and take special care to ensure that mistakes do not occur to maintain the credibility of their specialty.

The care with which these procedures are conducted is reflected in the low rate of error for these procedures. Misadministrations or abnormal occurrences occur about one in every 3,300 procedures. The NRC's records indicate that there were 200 patients who received misadministrations between 1980 and 1990 in 89 recordable events. (When adjusted to account for misadministrations in agreement states, one can assume that there were perhaps 600 patients affected during this time period nationwide.) Assuming 600 errors between 1980 and 1990, this would indicate on overall error rate of approximately 0.03% for nuclear medicine, teletherapy and brachytherapy. Extrapolating from error rates in 1989 and 1990, one could roughly estimate that errors occur in 0.04% of all teletherapy procedures, in 0.02% of all brachytherapy procedures and in 0.03% of all nuclear medicine procedures.

---

[1]The NRC estimates that there were approximately 600 misadministrations between 1980 and 1990, during approximately 1,980,000 procedures. Most misadministrations have no significant health effects; there have been only a relatively small number of incidents in which misadministrations or abnormal occurrences have clearly contributed to death or serious, permanent, or debilitating injury.

These are especially low misadministration rates when compared with rates of error in the administration of other drugs. A recent journal article reported that overall, medication errors occur in 13% to 18% of all hospital administered doses.[2] Among the errors found were the administration of the wrong dose, the wrong drug, or unordered drugs, administration to the wrong patient, at the wrong time, or by the wrong route. A published study of errors in the intensive care unit of one hospital indicated a medication error rate of 2.2%.[3] Finally, a third study of medication errors in two children's hospitals found medication error rates of 0.49% and 0.45%.[4] The error rate in nuclear medicine and therapies, then, are ten to one thousand times lower than the error rate for other drugs.

Given the already low rate of misadministrations and abnormal occurrences, the NRC has failed to demonstrate how these reporting requirements are likely to further decrease these rates, and thus have any practical utility. The NRC states that most medical facilities already have quality management programs in place which are similar to, the equivalent of, or even more stringent than the program mandated by the NRC. The occurrence of misadministrations at these facilities in the past demonstrates that despite good procedures, human fallibility will always result in some errors. Furthermore, there is significant concern within the medical community that any steps which must be taken which are not directly related to the delivery of safe and accurately administered procedures might be distracting and lead to other mistakes.

Burden of the ICR

The NRC claims that these QM requirements will impose only 6,490 hours of burden on the regulated community. A review of the record suggests, however, that physicians trying to comply with this rule will probably bear a significant recordkeeping and reporting burden.[5] Physicians will need to design and implement

---

[2]"What We Know About Medication Errors: A Literature Review," Journal of Nursing Quality Assurance, November 1988, page 1).

[3]"Medication Administration Errors in an Adult Intensive Care Unit," Heart & Lung, July 1987, page 450.

[4]"Medication Error Prevention by Clinical Pharmacists in Two Children's Hospitals", Pediatrics, May 1987, page 718.

[5]Part of the problem in calculating our own estimate of the burden is the disagreement between the NRC and the regulated community as to what is required by these regulations. Since

a quality assurance program and recordkeeping system to satisfy the NRC's requirements, even though most physicians already have QM programs designed and monitored by professional associations.

In addition, it is likely that the development of a complete quality management program would take longer than the 40 hours indicated in the ICR's supporting statement. This is based on discussions with several physicians who practice in these fields, and their estimates of how long it took them to develop their programs, and OMB's own review of the regulatory guide for the rule. Furthermore, this estimate does not appear to include the time necessary for those who already have quality management programs to review carefully their programs to determine whether or not they meet the NRC's criteria.

The NRC supporting statement does not include the burden for the development of diagnostic clinical procedure manuals described in 10 CFR 35.2. Although there is no clear requirement to develop such manuals, the NRC later defined "prescribed dosage" as "an activity as documented: 1) In a written directive; or 2) Either in the diagnostic clinical procedures manual or in any appropriate record in accordance with the directions of the authorized user for diagnostic procedures." NRC's reference to the manual has been interpreted by many physicians as meaning that the NRC requires such manuals.

The NRC supporting statement also claims that there is no burden associated with maintenance of records concerning administered doses or dosages because these records are already kept as required by 10 CFR 35.53. But, the current requirements are not the same as the new requirements. The current regulations require that facilities keep records of doses that have been administered. However, they do not appear to require the maintenance of records, in an auditable form, of the prescription that led to the dose. To maintain these records in a fashion that would be easily auditable, physicians will probably have to keep a duplicate set of files.[6]

The NRC also states that there is no burden associated with changes to a quality management program, since these changes are

---

there is no agreement between the regulated community and the NRC on what is required, it is not possible for OMB to independently develop our own estimate of the burden contained in this ICR.

[6]Physicians generally keep these records in each patient's individual files; however, upon being inspected, he/she would have to remove these documents from each patient file for the inspector and then replace them once the inspection was complete. Therefore, the best way to meet this requirement is to keep duplicate records.

voluntary. However, the implementing regulations for the PRA clearly state that voluntary reporting requirements are covered under the scope of the PRA (see 5 CFR 1320.7(c)), and must therefore be included in the burden calculations. Furthermore, although these steps may be viewed as voluntary, to the extent that physicians feel they need to modify their programs consistent with good practice, they will make these changes.

OMB believes that most facilities will implement other recordkeeping procedures as part of their programs. The NRC program, as outlined in the rule and the regulatory guide, is ambiguous in some instances and very specific in others.[7] The NRC's failure to specify what records must be maintained as part of a QM program does not mean that practitioners will not have to keep records. In fact, given the uncertainty within the regulated community as to what constitutes compliance with these requirements, it is likely that people will keep extensive records to ensure that they can produce any records that NRC inspectors request to see.

Finally, based on discussions which OMB has had with several physicians, the periodic reviews described in Section 6 of the Regulatory Guidance documents are likely to impose a significant burden on practitioners without having any real practical utility. Since the overwhelming majority of licensees have no misadministration in any given year, the requirement to engage in a lengthy review of their procedures to ensure that they are doing everything possible to reduce misadministration to zero, appears to have little if any value. Although it might make sense for those facilities that experienced misadministrations to review their procedures, this requirement is imposed on a significantly larger population with no apparent benefit.

Conclusion

I am concerned that the new reporting and recordkeeping requirements have little, if any, practical utility. I do not believe, based on the supporting documents provided by the NRC,

---

[7]For instance, the ambiguity as to whether or not clinical procedure manuals are required will probably result in physicians taking the time to develop them whether or not the NRC intended to require them. On the other hand, the guidelines require that before any procedure the licensee should verify the patient's identity by asking the patient their name and then confirmed by cross-referencing information in the patient record including at least one of the following: birth date, social security number, address, signature, or identification card. This is an extremely specific requirement which would better be left to the licensee's discretion.

that these requirements will reduce the number of misadministrations or abnormal events. I am also concerned that the NRC and the regulated community have widely different estimates for the burden of meeting these requirements. Nonetheless, these requirements will clearly impose a burden on the regulated community, without any clear benefits. I encourage the NRC to once again review the concerns we have outlined above with members of the regulated community so that they may come to some understanding of exactly what burdens are imposed by this program on the regulated community, and what purpose they will serve. Since there is a significant discrepancy between what the NRC believes is the burden imposed by this program, and the burden which the regulated community feels they will be required to shoulder, we feel that such a meeting would be useful. Once both sides can agree on the requirements of this program both the NRC and OMB would be in a much better position to evaluate whether or not the burden imposed by these requirements would be justified by its practical utility.

Sincerely,

James B. MacRae, Jr.
Acting Administrator
and Deputy Administrator
Office of Information
and Regulatory Affairs

cc: Hugh L. Thompson, Jr.