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NUCLEAR REGULATORY COMMISSION

10 CFR Part 35

'92 SEP -3 P4:05

RIN: 3150 - AC65

Quality Management Program and Misadministrations:
NRC Override of OMB Disapproval of NRC Information Collection Request

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule: Announcement of NRC override of OMB disapproval of information collection request and amendment to reflect new OMB control number.

SUMMARY: The Commission has voted to override the Office of Management and Budget (OMB) disapproval of the information collection requirements imposed in the final rule entitled "Quality Management Program and Misadministrations" (July 25, 1991; 56 FR 34104). As part of this final rule, the Commission is amending its regulations to reflect OMB's assignment of a new control number to these information collection requirements. The Commission reevaluated the need for this final rule and the information collection requirements it contains. The Commission continues to believe that its requirements for written quality management programs and misadministration reports, if complied with, have a reasonable likelihood of decreasing misadministrations (e.g., wrong dose or wrong patient) with a small incremental cost to licensees.

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on 9/10/92

Without the reporting and recordkeeping requirements, it would not be possible to implement and enforce these regulations effectively.

EFFECTIVE DATE: (Insert the date of publication.)

FOR FURTHER INFORMATION CONTACT: Anthony N. Tse, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 492-3797.

SUPPLEMENTARY INFORMATION:

On July 25, 1991 (56 FR 34104), the Commission published in the Federal Register a final rule amending 10 CFR Parts 2 and 35, entitled "Quality Management Program and Misadministrations." The final rule became effective on January 27, 1992. The final rule requires that applicable Part 35 licensees implement Quality Management (QM) programs, continue to report misadministrations but at higher reporting thresholds, and keep certain records.

The Commission published two proposed rules related to this subject. The first proposed rule was published on October 2, 1987 (52 FR 36942). This proposed rule was prescriptive in that it contained specific basic quality assurance practices. In response to public comments and recommendations from the Advisory Committee on the Medical Uses of Isotopes (ACMUI), the Commission reexamined its approach and published the second proposed rule, containing performance-based requirements, on January 16, 1990 (55 FR 1439). Following publication of the January 1990 proposed rule a pilot program was conducted to

provide a real-world test of the proposed rule in licensee hospitals and clinics and to gain insights beyond those generally obtained from the public comment process. Sixty-four volunteers (23 NRC licensees and 41 Agreement State licensees) participated in the pilot program. The staff also conducted public workshops to discuss the results of the pilot program and to obtain recommendations on how to modify the proposed rule with professional organizations and Agreement States, and sought guidance from ACMUI.

During more than 20 public meetings, the impact of the recordkeeping and reporting requirements on medical use licensees received substantial attention from the NRC and the regulated community. As a result, the Commission believes that recordkeeping and reporting requirements contained in the final rule were reduced by more than half from those presented in the January 1990 proposed rule. These reductions included the removal of the recordkeeping and misadministration reporting requirements for nearly all diagnostic procedures. Considering the modifications to the proposed rule and the performance-oriented approach, the Commission concluded that the cost-effectiveness of the final rule had been optimized without significantly reducing the level of protection.

In December 1991, the NRC was notified by OMB that notwithstanding its earlier approval of the proposed rule, which received the appropriate OMB control number, it had concerns with the information collection requirements of the final rule. In order to resolve OMB's concerns, the NRC both corresponded and met with OMB. However, NRC and OMB staff interactions failed to resolve OMB concerns. In light of OMB approval of the information collection requirements contained in the proposed rule and because the final rule did not substantially change those requirements that were retained in the

final rule from the proposed rule, the information collection requirements contained in the final rule became effective on January 27, 1992.

In February 1992, the American College of Nuclear Physicians and the Society of Nuclear Medicine petitioned the U.S. Court of Appeals for the District of Columbia Circuit for review of the final rule. On May 22, 1992, the Court found no basis to overturn the Quality Management and Misadministration Rule. Accordingly, the Court denied the petition for review. The Court found that the NRC had acted within its broad statutory mandate to establish "such standards ... as the Commission may deem necessary or desirable to ...protect health or to minimize danger to life." It also concluded that the substantive requirements of the QM rule were not arbitrary, capricious, or an abuse of discretion.

Subsequently, in a letter dated June 26, 1992, OMB stated that it disapproved the information collection request (ICR) associated with the July 1991 final rule. OMB concluded that "this information collection request is not necessary for the proper performance of the functions of the agency and that the information collection will not have practical utility for the agency." However, the Paperwork Reduction Act (PRA) provides that an independent regulatory agency such as NRC may override the OMB disapproval by a majority vote of its Commissioners (44 U.S.C. 3507).

The Commission fully supports the objectives of the PRA 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. For reasons specified below, pursuant to 44 U.S.C. 3507(c), the Commission has overridden the OMB determination. In a letter dated August 14, 1992, the Commission certified that it had overridden OMB's disapproval and requested

that OMB promptly assign a new control number to the ICR 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 ICR 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 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.

OMB 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. OMB disapproval relied on the third evaluation criterion described above and made a finding of no practical utility. But, contrary to 5 CFR 1320.7(o), OMB does 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. OMB disapproval indicates that OMB has 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 requirements for written quality management programs and misadministration reports, if complied with, have 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.

On August 21, 1992, OMB assigned a new control number. Therefore, the effective period for these information collection requirements is from January 27, 1992 through August 31, 1995.

The Commission will continue to monitor implementation and inspection under the rule to ensure 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 ensure that there is mutual understanding as to the intent of the rule, especially its information collection requirements, and to discuss effective implementation. In particular, NRC will discuss the extent to which the industry's self-auditing guidelines can be used. Following the workshop, the Commission will develop additional guidance on compliance with the rule, written in clear language appropriate to the medical community.

Environmental Impact: Categorical Exclusion

The NRC has determined that this is the type of action described in categorical exclusion 10 CFR 51.22(c)(3)(ii). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this final rule.

Paperwork Reduction Act

In a letter dated June 26, 1992, OMB stated that it disapproved the NRC's information collection request associated with the rule entitled "Quality Management Program and Misadministrations."

As required by the Paperwork Reduction Act, the Commission has certified to OMB, in a letter dated August 14, 1992, that by unanimous vote the Commission had overridden the OMB's disapproval of the information collection request associated with this rule.

On August 21, 1992, OMB assigned the following new control number: 3150-0171, effective until August 31, 1995.

This new control number is only applicable to the sections in 10 CFR Part 35 amended by this rule. Information collection authority for all other sections of 10 CFR Part 35 remains under the existing general control number: 3150-0010.

List of Subjects in 10 CFR Part 35

Byproduct material, Criminal penalty, Drugs, Health facilities, Health professions, Incorporation by reference, Medical devices, Nuclear materials, Occupational safety and health, Radiation protection, Reporting and recordkeeping requirements.

Text of Final Regulations

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR Part 35.

Part 35 - Medical Use of Byproduct Material

1. The authority citation for Part 35 continues to read in part as follows:

AUTHORITY: Secs. 161, 68 Stat. 948, as amended (42 U.S.C. 2201); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841) * * *.

2. In § 35.8, paragraph (b) is revised and paragraph (d) is added to read as follows:

§ 35.8 Information collection requirements: OMB approval.

* * * * *

(b) The approved information collection requirements contained in this part appear in §§ 35.12, 35.13, 35.14, 35.21, 35.22, 35.23, 35.27, 35.29,

35.31, 35.50, 35.51, 35.53, [illegible].59, 35.60, 35.61, 35.70, 35.80, 35.92, 35.204, 35.205, 35.310, 35.315, 35.404, 35.406, 35.410, 35.415, 35.606, 35.610, 35.615, 35.630, 35.632, 35.634, 35.636, 35.641, 35.643, 35.645, and 35.647.

* * * * *

(d) OMB has assigned control number 3150-0171 for the information collection requirements cont[illegible] in §§ 35.32 and 35.33.

Dated at Rockville, Maryland, this 3rd day of September 1992.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,
Secretary of the Commission.