NOTICE OF OFFICE OF MANAGEMENT AND BUDGET ACTION

AC65-2 062
PDR

TO: BRENDA JO. SHELTON (7714-MNBB)
NRC CLEARANCE OFFICER
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555
Nuclear Regulatory Commission

ACTION DATE
08/21/92

ON 08/20/92, YOU REQUESTED APPROVAL OF THE FOLLOWING INFORMATION COLLECTION:
TITLE: MEDICAL USE OF BYPRODUCT MATERIAL -- 10 CFR PART 35
AGENCY FORM NOS.:

IN ACCORDANCE WITH THE PAPERWORK REDUCTION ACT, WE HAVE TAKEN THE FOLLOWING ACTION ON THIS INFORMATION COLLECTION:

APPROVED FOR USE THROUGH 08/31/95. OMB NO. 3150-0171.
THE OFFICE OF MANAGEMENT AND BUDGET CONTROL NUMBER MUST BE DISPLAYED IN ACCORDANCE WITH 5 CFR 1320. UNLESS OTHERWISE PROVIDED IN "REMARKS," EXPIRATION DATES MUST ALSO BE DISPLAYED AS REQUIRED BY 5 CFR 1320.

EFFECT ON BURDEN:	RESPONSES	REPORTING HOURS
PREVIOUS STATUS	0	0
NEW STATUS	3,520	6,490
DIFFERENCE	3,520	6,490
EXPLANATION OF DIFFERENCE:		
ADJUSTMENTS		
CORRECTION-ERROR	0	0
CORRECTION-REESTIMATE	0	0
CHANGE IN USE	0	0
PROGRAM CHANGES		
INCREASE	3,520	6,490
DECREASE	0	0

REMARKS:
OVERRIDE BY AN INDEPENDENT REGULATORY AGENCY.

OMB NO. 3150-0171

ABSTRACT:
RADIATION SAFETY, NUCLEAR MEDICINE, RADIATION THERAPY, RADIOACTIVE MATERIALS, QUALITY MANAGEMENT PROGRAM
REQUIRES LICENSEES TO ESTABLISH AND MAINTAIN A WRITTEN QUALITY MANAGEMENT PROGRAM AND SUBMIT TO THE NRC A COPY OF THE PROGRAM AND CERTIFICATION THAT IT HAS BEEN IMPLEMENTED.

ALLOWANCE LETTER: NO FUNCTION:
ON PLAN: NO EXCEED BUDGET: NO 3504(H): NPRM
NO. OF FORMS: 1 USE: PUBLIC REQUEST: NEW
RESPONDENTS: 3,520 RESPONSES: 3,520 HOURS: 6,490
AFFECTED PUBLIC: NON-PROFIT INST & SMALL BUS/ORG
SMALL BUSINESS: YES ACTIVITY TYPE:
PURPOSE: REG/COMP
FREQUENCY: ANNL
COLLECTION METHOD: MAIL S/A
RETENTION: COLLECTION AGENT: RQSTNG DPT/AGCY CONFIDENTIALITY: NO
COMPULSORY STATUS: MANDATORY
FEDERAL COST: PUBLIC COST:
REVIEWER: Ron Minsk

ACTION APPROVED BY:	AUTHORIZING OFFICIAL /S/JAMES B. MACRAE FOR	TITLE: DEPUTY ADMINISTRATOR OFFICE OF INFORMATION AND REGULATORY AFFAIRS	DATE 08/21/92

IMPORTANT: BECAUSE THIS INFORMATION COLLECTION HAS BEEN APPROVED, PLEASE SEND TO THE O.M.B. AS SOON AS AVAILABLE: ONE COPY OF THE FINAL PRINTED (OR OTHERWISE REPRODUCED) REPORT FORM, OR REPORTING OR RECORDKEEPING REQUIREMENT, TRANSMITTAL LETTER, INSTRUCTIONS, AND ANY DOCUMENT BEING SENT TO EACH RESPONDENT.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
Office of Public Affairs
Washington, D.C. 20555

No. 92-122
Tel. 301/504-2240

FOR IMMEDIATE RELEASE
(Monday, August 17, 1992)

NRC VOTES TO OVERRIDE OMB DISAPPROVAL OF INFORMATION COLLECTION REQUIREMENTS FOR MEDICAL USES OF RADIOACTIVE MATERIAL

The Nuclear Regulatory Commission has voted to override the Office of Management and Budget's disapproval of an information collection request associated with the NRC's regulations on the medical uses of radioactive material.

On July 25, 1991, the NRC amended its regulations to require licensees who use radioactive materials for therapeutic procedures and certain procedures involving radioactive iodine to implement a quality management program to ensure that the radioactive material or radiation from the material will be used by technologists and other medical personnel as directed by authorized physicians. The amendment affected about 2000 NRC and 4000 Agreement State licensees. It became effective on January 27, 1992, for NRC licensees and remains in effect.

The quality management rule includes requirements that:

- Prior to administration of a radioactive material, a written directive must be prepared (to eliminate confusion resulting from oral directives);
- The patient's identity must be verified by more than one method as the individual named in the written directive;
- Final plans for treatment with certain techniques using radioactive material must be in accordance with the written directive;
- Each administration of radioactive material or radiation from the material must be in agreement with the written directive; and
- Any unintended deviation from the written directive must be identified and evaluated, and appropriate action taken.

At the same time the Commission changed its reporting and recordkeeping requirements related to the quality management program and to misadministrations that are reportable to the NRC and made conforming amendments to its enforcement policy.

On June 26, 1992, OMB notified the NRC that the Information Collection Request submitted to OMB in connection with this amendment had been disapproved.

In overriding OMB's disapproval, the NRC said that it continues to believe that its quality management and misadministration rule has a reasonable likehood of decreasing misadministrations (for example, wrong dose or wrong patient) with a small incremental cost to licensees, and that the rule would be of little value without the recordkeeping and reporting requirements.

The Paperwork Reduction Act authorizes an independent regulatory agency, such as the NRC, to override an OMB disapproval by a majority vote of its Commissioners. Under this law, the override is valid for three years.

In its letter of disapproval, the OBM expressed concern that, based on its discussions with members of the regulated community and the NRC staff, there appears to be significant confusion on exactly what information collection requirements are imposed by the quality management and misadministration rule. The NRC staff intends to clarify any such potential misunderstanding through a public workshop--with details to be announced shortly.

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Regulatory Commission, according to the following schedule:

i. NRC–U requiring full field investigation	$3,000
ii. NRC–U requiring full field investigation (expedited processing)	3,400
iii. NRC–U based on certification of comparable full field background investigation	[1] 0
iv. NRC–U or R renewal	[1] 52
v. NRC–R	[1] 52
vi. NRC–R based on certification of comparable investigation	[2] 0

[1] If the NRC determines, based on its review of available data, that a full field investigation is necessary, a fee of $3,000 will be assessed prior to the conduct of the investigation.

[2] If the NRC determines, based on its review of available data, that a National Agency Check and Credit investigation is necessary, a fee of $52.00 will be assessed prior to the conduct of the investigation; however, if a full field investigation is deemed necessary by the NRC, based on its review of available data, a fee of $3,000 will be assessed prior to the conduct of the investigation.

PART 25—ACCESS AUTHORIZATION FOR LICENSEE PERSONNEL

3. The authority citation for part 25 continues to read as follows:

Authority: Secs. 145, 161, 68 Stat. 942, 948, as amended (42 U.S.C. 2165, 2201); sec. 201, 88 Stat. 1242 as amended (42 U.S.C. 5841); E.O. 10865, as amended, 3 CFR 1959–1963 COMP., p. 398 (50 U.S.C. 401, note); E.O. 12356, 47 FR 14874, April 6, 1982.

Appendix A also issued under 96 Stat. 1051 (31 U.S.C. 9701).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§ 25.13, 25.17(e), 25.33 (b) and (c) are issued under sec. 1611, 68 Stat. 948, as amended, (42 U.S.C. 2201(i)); and §§ 25.13 and 25.33(b) are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

4. In § 25.21 paragraph (b) is revised to read as follows:

§ 25.21 Determination of initial and continued eligibility for access authorization.

* * * * *

(b) The NRC Division of Security must be promptly notified of developments that bear on continued eligibility for access authorization throughout the period for which the authorization is active (e.g., persons who marry subsequent to the completion of a personnel security packet must report this change by submitting a completed NRC Form 354, "Data Report on Spouse").

5. Section 25.27 is revised to read as follows:

§ 25.27 Reopening of cases in which requests for access authorizations are cancelled.

(a) In conjunction with a new request for access authorization (NRC Form 237) for individuals whose cases were previously cancelled, new fingerprint cards (FD–257) in duplicate and a new Security Acknowledgment (NRC Form 176) must be furnished to the NRC Division of Security along with the request.

(b) Additionally, if 90 days or more have elapsed since the date of the last Questionnaire for Sensitive Positions (SF–86), the individual must complete a personnel security packet (see § 25.17(c)). The NRC Division of Security, based on investigative or other needs, may require a complete personnel security packet in other cases as well. A fee, equal to the amount paid for an initial request, will be charged only if a new or updating investigation is required.

6. Appendix A is revised to read as follows:

APPENDIX A.—FEES FOR NRC ACCESS AUTHORIZATION

Category	Fee
Initial "L" Access Authorization	[1] $52
Reinstatement of "L" Access Authorization	[1] 52
Extension or Transfer of "L" Access Authorization	[1] 52
Initial "Q" Access Authorization	3,000
Initial "Q" Access Authorization (expedited processing)	3,400
Reinstatement of "Q" Access Authorization	[2] 3,000
Reinstatement of "Q" Access Authorization (expedited processing)	[2] 3,400
Extension or Transfer of "Q"	[2] 3,000
Extension or Transfer of "Q" (expedited processing)	[2] 3,400

[1] If the NRC determines, based on its review of available data, that a full field of investigation is necessary, a fee of $3,000 will be assessed prior to the conduct of the investigation.

[2] Full fee will only be charged if investigation is required.

Dated at Rockville, MD this 24th day of August 1992.

For the Nuclear Regulatory Commission.

James M. Taylor,

Executive Director for Operations.

[FR Doc. 92–21752 Filed 9–9–92; 8:45 am]

BILLING CODE 7590–01–M

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10 CFR Part 35

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.

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

EFFECTIVE DATE: September 10, 1992.

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 18, 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 4) 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's 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 Misadministrations 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 collections 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, 1320.6(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 1320.3(g)) 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(c), 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 22, 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 as 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, 35.59, 35.80, 35.81, 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 contained in §§ 35.32 and 35.33.

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

For the Nuclear Regulatory Commission.
Samuel J. Chilk,
Secretary of the Commission.

[FR Doc. 92–21754 Filed 9–9–92; 8:45 am]
BILLING CODE 7590–01–M

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10 CFR Part 50

RIN 3150–AE12

Minor Modifications to Nuclear Power Reactor Event Reporting Requirements

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) has amended its regulations to make minor modifications to the current nuclear power reactor event reporting requirements. The final rule applies to all nuclear power reactor licensees and deletes reporting requirements for some events that have been determined to be of little or no safety significance. The final rule reduces the industry's reporting burden and the NRC's response burden in event review and assessment.

EFFECTIVE DATE: October 13, 1992.

FOR FURTHER INFORMATION CONTACT: Raji Tripathi, Office for Analysis and Evaluation of Operational Data, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone (301) 492–4435.

SUPPLEMENTARY INFORMATION:

Background

The Commission is issuing a final rule that amends the nuclear power reactor event reporting requirements contained in 10 CFR 50.72, "Immediate Notification Requirements for Operating Nuclear Power Reactors," and 10 CFR 50.73, "Licensee Event Report System." The final rule is issued as part of the Commission's ongoing activities to improve its regulations. Specifically, this final rule amends 10 CFR 50.72 (b)(2)(ii) and 10 CFR 50.73 (a)(2)(iv). On June 26, 1992 (57 FR 28642), the Commission issued a proposed rule requesting public comments on these amendments.

Over the past several years, the NRC has increased its attention to event reporting issues to ensure uniformity, consistency, and completeness in reporting. In September 1991, the NRC's Office for Analysis and Evaluation of Operational Data (AEOD) issued for comment a draft NUREG–1022, Revision 1,[1] "Event Reporting Systems 10 CFR 50.72 and 10 CFR 50.73—Clarification of NRC Systems and Guidelines For Reporting." Following resolution of public comments, the NUREG will be issued in the final form. The NUREG will contain improved guidance for event reporting.

NRC's reviews of operating experience and the patterns of licensees' reporting of operating events since 1984 have indicated that reports on some of these events are not necessary for the NRC to perform its safety mission and that continued reporting of these events would not contribute useful information to the operating reactor events database. Additionally, these unnecessary reports would have continued to consume both the licensees' and the NRC's resources that could be better applied elsewhere. The NRC has determined that certain types of events, primarily those involving invalid engineered safety feature (ESF) actuations, are of little or no safety significance.

Valid ESF actuations are those actuations that result from "valid signals" or from intentional manual initiation, unless it is part of a preplanned test. Valid signals are those signals that are initiated in response to actual plant conditions or parameters satisfying the requirements for ESF initiation.

Invalid actuations are by definition those that do not meet the criteria for being valid. Thus, invalid actuations include actuations that are not the result of valid signals and are not intentional manual actuations. Invalid actuations include instances where instrument drift, spurious signals, human error, or other invalid signals caused actuation of the ESF (e.g., jarring a cabinet, an error in use of jumpers or lifted leads, an error in actuation of switches or controls, equipment failure, or radio frequency interference).

NRC's evaluation of both the reported events since January 1984, when the existing rules first became effective, and the comments received during the Event Reporting Workshops conducted in Fall of 1990 identified needed improvements in the rules. The NRC determined that invalid actuation, isolation, or realignment of a limited set of ESFs including the systems, subsystems, or components (i.e., an invalid actuation, isolation, or realignment of only the reactor water clean-up (RWCU) system,

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[1] Free single copy may be requested by writing to the Distribution and Mail Services Section, U.S. Nuclear Regulatory Commission, Washington, DC 20555. A copy is also available for inspection or copying for a fee at the NRC Public Document Room, 2120 L Street, NW., (Lower Level), Washington, DC 20555.