# RULEMAKING ISSUE
## NOTATION VOTE

June 21, 2002 SECY-02-0111

FOR: The Commissioners

FROM: William D. Travers, Director
Executive Director for Operations

SUBJECT: PROPOSED RULE TO AMEND 10 CFR PART 35 TO REQUIRE LICENSEES TO NOTIFY NRC OF AN INDIVIDUAL RECEIVING A DOSE EXCEEDING 50 MILLISIEVERTS (5 REM) FROM A PATIENT RELEASED UNDER 10 CFR 35.75

PURPOSE:

To provide for Commission consideration a draft proposed rule, as requested in the Commission's October 23, 2000, Staff Requirements Memorandum, that would amend 10 CFR Part 35, "Medical Use of Byproduct Material," to require licensees to notify the U.S. Nuclear Regulatory Commission (NRC), no later than the next calendar day after the licensee becomes aware that an individual received or is estimated to have received a dose exceeding 50 millisieverts (mSv) [5 rem] from a patient released under 10 CFR 35.75, "Release of individuals containing unsealed byproduct material or implants containing byproduct material." In addition, the proposed rule would require the licensee to submit a written report within 15 days after discovery of the event and to provide a copy of the report to the identified exposed individual.

BACKGROUND:

During preparation of the final rule that would revise 10 CFR Part 35, which was affirmed by the Commission on October 23, 2000, the staff noted that licensees were not required to notify NRC when they learn that an individual received a dose in excess of the dose specified in 10 CFR 35.75 for patient release and that licensees were not required to notify the exposed individual of the exposure. The staff also noted that the Statement of Considerations for the

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final rule published on January 29, 1997 (62 FR 4120) that revised 10 CFR 35.75 did not discuss whether reporting was required if the licensee: (1) failed to comply with 10 CFR 35.75 and an individual received a dose in excess of 5 mSv (0.5 rem); or (2) complied with 10 CFR 35.75, but learned that an individual exposed to the released individual received a dose in excess of 5 mSv (0.5 rem). As a result of this information, the Commission directed that the issue of notification be addressed in a separate rulemaking.

DISCUSSION:

In Staff Requirements Memorandum (SRM) SECY-00-0118, "Final Rules - 10 CFR Part 35, 'Medical Use of Byproduct Material' and 10 CFR Part 20, 'Standards for Protection Against Radiation,'" dated October 23, 2000 (Attachment 1), the Commission disapproved the staff's recommendation to develop a rulemaking plan, with options, for revising 10 CFR Parts 20 and 35 to add a requirement for a licensee to report events in which an individual receives an exposure in excess of 5 mSv (0.5 rem) from an individual released under 10 CFR 35.75. Instead, the Commission directed the staff to develop, for Commission consideration, a proposed amendment to Part 35 that would require the licensee to notify NRC, no later than the next calendar day, after the licensee becomes aware that an individual received or is estimated to have received a dose exceeding 50 mSv (5 rem) from a patient released under 10 CFR 35.75. In addition, the rule was to include a requirement for the licensee to submit to the Commission a written report within 15 days after discovery of the event and to provide identified exposed individual(s) with a copy of the report. The reporting and notification threshold was to be consistent with the reporting and notification requirements in § 35.3047. The rulemaking was to address a patient release that was not in compliance with § 35.75, as well as a release that was in compliance, i.e., it would address instances in which the licensee either:

(1) believes the basis of the release may have been incorrect or the release instructions may have been inadequate, OR

(2) learns, through voluntary means, that the patient did not follow the physician's instructions;

AND

An individual received or is estimated to have received a dose in excess of 50 mSv (5 rem).

The Commission also instructed the staff to include language in the Statement of Consideration for the proposed rule to clearly indicate that the Commission was not modifying its previous position that:

a. the NRC does not intend to enforce a patient's compliance with the licensee's instructions; and

b. it is not the licensee's responsibility to ensure compliance by patients once they leave the licensee's facility.

During development of this proposed rule, the staff interfaced with NRC's federal Advisory Committee on the Medical Uses of Isotopes (ACMUI) and with the Agreement States as required by NRC's rulemaking policy.

ACMUI Views

The ACMUI discussed the proposed amendment to 10 CFR Part 35 at its November 2000, meeting. The ACMUI recommended that the reporting be limited to errors made in the release procedure or delivery of instructions to the patient that result in exposures to individuals other than the patient in excess of 50 mSv (5 rem). The ACMUI again discussed the rulemaking at its meeting on April 18, 2001.

Although the ACMUI acknowledged the value of reporting that a member of the public received a dose greater than 50 mSv (5 rem), the ACMUI reaffirmed its previous recommendation. In addition, members provided staff with the following specific concerns, which are listed in the Federal Register notice for the proposed rule for the purpose of soliciting public comment.

- Licensees may be reluctant to release patients under § 35.75 because of repercussions associated with the reporting requirement, such as, negative press and loss of public confidence. This will result in more expensive care for these patients.
- Licensees should be granted anonymity when reporting the event and not be held responsible for patients who disregard instructions.
- Licensees may have to report based on information that may be difficult to verify. For example, an individual could call the licensee with a concern or a question about the patient's behavior.
- Patients and licensees could be subject to intrusive investigations with possible loss of patient confidentiality.
- Dose reconstructions would be based on numerous variables with significant ranges of uncertainties.
- Low frequency of known events and problems with rule enforcement and implementation do not justify NRC resource expenditures.
- NRC and licensee effort should focus on compliance with § 35.75.

Agreement State Issues

This amendment would be a matter of compatibility between NRC and Agreement States. The compatibility classification is "C," which means an NRC program element, the essential objective of which Agreement States should adopt to avoid conflicts, duplication, or gaps in the regulation of Agreement State material on a nationwide basis, and that, if not adopted, would result in an undesirable consequence.

The draft proposed rule was forwarded to Agreement States on May 21, 2001, for comment. Comments were received from five Agreement States (Attachment 2). None of the comments supported the proposed notification requirement. Some of the comments were outside the scope of this rulemaking and are not included in the summary of comments provided below.

- The notification requirement would be both burdensome and unnecessary.
- The proposed rule would be unenforceable and would not appear to be effective in reducing risk to members of the public.
- The 500 mrem limit of 10 CFR Part 20 should be the reporting requirement.

- A reporting value of 5,000 mrem may give the NRC a false sense that the revised rule is working, when, in fact, there may be many cases of individual members of the public being exposed beyond the 500 mrem limit.
- Creating rules that are exceptions to the exposure limits of Part 20 questions the validity of the Part 20 limits.
- Licensees should not be required to report such exposures but should be required to keep a record of such exposures for review during an inspection.

RESOURCES

NRC will incur a small resource burden during development and implementation of this rule and revision of associated licensing and inspection guidance. Approximately 1.2 FTE would be needed for this rulemaking. The subsequent revision of licensing and inspection guidance would also result in some small resource burden, depending on the revisions needed. However, the revisions to inspection guidance would be addressed during the normal three-year review/revision cycle for inspection-related documents.

COORDINATION:

The Office of the General Counsel has no legal objection to the proposed rulemaking. The Office of the Chief Financial Officer has reviewed this paper for resource implications and has no objections. The proposed rule would amend information collection requirements that must be received by the Office of Management and Budget no later than the date the proposed rule is forwarded to the Federal Register for publication.

RECOMMENDATIONS:

If the Commission decides to go forward with this proposed rule, the staff recommends the following:

1. Approve for publication, in the Federal Register, the proposed amendments to Part 35 after the revised Part 35 is published in the Federal Register.

2. Note:

   a. That the proposed amendments will be published in the Federal Register, allowing 75 days for public comment.

   b. That the Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification and the reasons for it, as required by the Regulatory Flexibility Act, 5 U.S.C. 605(b).

   c. That a draft Regulatory Analysis has been prepared for this rulemaking.

   d. That appropriate Congressional committees will be informed of this action.

   e. That a press release will be issued by the Office of Public Affairs when the proposed rulemaking is filed with the Office of the Federal Register.

f. An Office of Management and Budget (OMB) review is required and a clearance package will be forwarded to OMB no later than the date the proposed rule is submitted to the Office of the Federal Register for publication.

g. That resources to complete and implement this rulemaking, as well as associated licensing and inspection guidance, are included in the current FY 2002 and FY 2003 budgets.

***/RA/***

William D. Travers
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Attachments: 1. SRM SECY 00-0118
2. Agreement State Comments
3. Draft Federal Register Notice

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