RULEMAKING ISSUE
NOTATION VOTE

May 18, 2010 SECY-10-0062

FOR: The Commissioners

FROM: R. W. Borchardt
Executive Director for Operations

SUBJECT: REPROPOSED RULE: MEDICAL USE OF BYPRODUCT MATERIAL – AMENDMENTS/MEDICAL EVENT DEFINITIONS (RIN 3150- AI26)

PURPOSE:

To request Commission approval to publish a reproposed rule in the *Federal Register* that would amend 10 CFR Part 35. The rule would revise 10 CFR 35.40 and 35.3045 governing medical use of byproduct material related to reporting and notifications of medical events (MEs). Section 35.24 would also be revised to require that licensees provide training to staff on the requirements of § 35.3045. Additionally, § 35.41 would be revised to require licensees to assess the dose to the treatment site no later than 60 days from the date that the patient left the post-treatment recovery area. This paper does not address any new commitments.

BACKGROUND:

In a Staff Requirements Memorandum (SRM) dated July 25, 2008 (ML082100074), "Staff Requirements – SECY-08-0080 – Proposed Rule: Medical Use of Byproduct Material – Amendments/Medical Event Definitions" the Commission approved publication of a proposed rule to amend 10 CFR Part 35 related to reporting and notification of medical events and to clarify requirements for permanent implant brachytherapy (SECY-08-0080, June 6, 2008, Proposed Rule: Medical Use of Byproduct Material – Amendments/Medical Event Definitions").

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The proposed rule was published in the *Federal Register* on August 6, 2008 (73 FR 45635), with a 75-day comment period. The comment period was extended by 18 days (73 FR 58063) as requested by the U. S. Nuclear Regulatory Commission's (NRC) Advisory Committee on the Medical Use of Isotopes (ACMUI). A total of 57 comment letters were received. Many of the comments were form letters with identical language. Most of the comments were from medical universities, hospitals, private physicians, and professional organizations representing the medical community. The comments were primarily not supportive of parts of the rulemaking.

During late summer and early fall of 2008, a substantial number of MEs were reported to the NRC. The staff reviewed and analyzed the circumstances of, and data from, these events. Based on its evaluation of this information, including an independent analysis by an NRC medical consultant, the staff believes that a number of MEs that were reported in 2008 would not be categorized as MEs under the proposed rule published on August 6, 2008; this is inconsistent with the original regulatory intent. The original intent of the proposed rule was to clarify the requirements for permanent implant brachytherapy so that licensees would be able to identify MEs more easily and in a more timely manner. An unintended effect of the proposed rule would have been that some significant events would not be identified, categorized, and reported as MEs. Additionally, the evaluation of the circumstances and data from the substantial number of MEs reported in 2008 prompted the staff to reevaluate the regulations related to training requirements and time frames for licensees to assess the dose to the treatment site for permanent implant brachytherapy. Therefore, the proposed rule language and rationale have been modified to reflect this new information and the staff recommends the revised proposed rule be published for public comment.

DISCUSSION:

The reproposed rule would amend the current regulations by: (1) adding activity-based criteria for defining some MEs for permanent implant brachytherapy; (2) adding a requirement to report, as an ME, any administration requiring a written directive (WD) if a WD is required and not prepared, and documentation in medical records or licensees' standard written procedures that existed prior to the administration is insufficient to determine if an ME has occurred; (3) clarifying requirements for WDs for permanent implant brachytherapy; (4) adding a requirement that licensees provide and document training to their staff on the requirements of § 35.3045; (5) adding a requirement that licensees must assess the dose to the treatment site no later than 60 days from the date that the patient leaves the post-treatment recovery area; and (6) making certain administrative and clarification changes. The reproposed rule would facilitate the ability of medical licensees to recognize some MEs in permanent implant brachytherapy earlier and, therefore, be able to take corrective actions sooner than under current regulations. These changes to the regulations are based in part on recommendations from the ACMUI as well as the staff's evaluation of the circumstances of, and data from, the substantial number of MEs reported in 2008.

In the course of resolving public comments on the proposed rule, the rulemaking working group required the assistance of an ad hoc steering committee composed of division level managers to resolve public comments received on one specific ME criterion. This criterion compares what the Authorized User (AU) planned to implant to what was actually implanted and continued to use the current regulatory magnitude of variance of plus or minus 20 percent for determining if an ME occurred.

An issue of particular concern to the commenters regarding the proposed rule was the potential impact on “real-time” brachytherapy prostate implantation, which is a treatment method being used with greater frequency. In “real-time” brachytherapy procedures, the number of radioactive seeds is adjusted as needed during the procedure to achieve the required dose to the treatment site rather than implanting a predetermined number of seeds. Some commenters expressed a concern that being held to the plus or minus 20 percent variance of what was planned was too restrictive and could severely limit their ability to use this type of procedure. The Steering Committee reviewed all the known concerns and determined that the ME criterion should not be changed because there were no data to support another variance. The staff will continue to monitor and evaluate reported ME’s for trends and make appropriate recommendations to the Commission as necessary. Additional discussion concerning this issue is in the Summary of Public Comments on the Proposed Rule in the *Federal Register* Notice (Enclosure 1).

Also, as stated above, the language and rationale of the proposed rule published on August 6, 2008, have been modified in this reproposed rule. Briefly, changes that have been made to the proposed rule in this reproposed rule include: (1) the retention of dose-based criteria which had been removed in the proposed rule for identifying MEs; (2) the addition of a requirement that licensees provide and document training regarding requirements for reporting an ME to individuals who participate in procedures using byproduct material requiring a WD; and (3) the addition of a requirement, that for permanent implant brachytherapy, a licensee must assess the dose to the treatment site and sites other than the treatment site identified in the pre-implantation WD (in accordance with published protocols accepted by nationally recognized professional organizations) within 60 days from when the patient leaves the post-treatment recovery area. The comments received on the proposed rule published on August 6, 2008, and the changes made to the proposed rule as a result of the evaluation of the circumstances of and data from the substantial number of MEs reported in 2008, are discussed in detail in the *Federal Register* Notice (Enclosure 1). Additionally, per SRM-COMSECY-09-0026, “Request For Rebaselining of Medical Event Definition Rulemaking to Reflect Recent Veterans Administration Experience” changes made to the proposed rule language published on August 6, 2008, are highlighted in Rule Language Changes (Enclosure 2).

The reproposed rule supports NRC’s 2008-2013 Strategic Plan in the areas of safety and organizational excellence. In the area of safety, the reproposed rule supports strategic safety goal 1 (develop, maintain, and implement licensing and regulatory programs for materials users to ensure the adequate protection of health and safety) by facilitating the ability of medical licensees to recognize MEs in permanent implant brachytherapy earlier and therefore, be able to take corrective actions sooner. Taking prompt corrective actions based on ME findings increases the protection of the health and safety of patients.

In the area of organizational excellence, the reproposed rule supports the openness objective. Specifically, the NRC solicited input from the public on the preliminary draft language and on the proposed rule supported openness strategy 3, (providing for fair, timely, and meaningful stakeholder involvement in NRC decision making), and strategy 5 (initiating early communication with stakeholder on issues of substantial interest). The public had been provided with 75 days and an extension of 18 days for a total of 93 days during which to comment on the proposed rule published on August 6, 2008. The reproposed rule will be available for public comment for 60 days.

CONSULTATION WITH ACMUI:

ACMUI, a staff level advisory committee to the Division of Materials Safety and State Agreements (MSSA), was consulted by the rulemaking working group and MSSA on many occasions during the development of the proposed rule published on August 6, 2008, and this reproposed rule. Staff sought and received ACMUI's recommendations for changing the regulations and forwarded them to the Commission in SECY-05-0234 (December 27, 2005). In addition to interacting with the rulemaking working group, ACMUI submitted written comments during the public comment period for the proposed rule published on August 6, 2008. Although all of ACMUI's recommendations were not incorporated in this proposed rulemaking, notably, not removing dose-based criteria for determining MEs, their advice and expertise was very valuable in developing this proposed rule.

AGREEMENT STATE ISSUES:

A copy of the draft final rule *Federal Register* notice was provided to the Agreement States so they could have an early opportunity for review.

Two Agreement States (Florida and Washington) and the Organization of Agreement States (OAS) provided comments on the draft *Federal Register* notice. All of the commenters were generally supportive of the proposed changes. The comments are addressed in the reproposed rule FRN and did not raise significant substantive issues.

The NRC staff has analyzed the reproposed rule in accordance with the procedures established within Part III of the Handbook to Management Directive 5.9, "Categorization Process for NRC Program Elements." The staff has determined that:

> Sections 35.24(h), 35.40(b), and 35.41(d) are classified as Compatibility Category "H&S." The Compatibility Category Health & Safety (H&S) identifies program elements that are not required for purposes of compatibility, but have particular health and safety significance. An Agreement State should adopt the essential objectives of such program elements in order to maintain an adequate program.
>
> Sections 35.24(i), 35.40(c), and 35.2024(a) are classified as Compatibility Category "D." The NRC program elements in this category are those that do not meet any of the criteria of Category A, B, or C, and, thus, do not need to be adopted by the Agreement States for purposes of compatibility.
>
> Section 35.3045 is classified as Compatibility Category "C." The NRC program elements in this category are those that do not meet the criteria of Category A or B, but the essential objectives of which an Agreement State should adopt to avoid conflict, duplication, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of Agreement State material on a nationwide basis. An Agreement State should adopt the essential objectives of the NRC program elements.

The Standing Committee on Compatibility reviewed the reproposed rule and agreed that these amendments to the NRC regulations are a matter of compatibility between the NRC and the Agreement States. The Committee agreed with the staff's compatibility designations.

RECOMMENDATIONS:

That the Commission:

1. Approve for publication in the *Federal Register* the reproposed amendments to Part 35 (Enclosure 1).

Note:

a. That the reproposed amendments will be published in the *Federal Register*, allowing 60 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 and is incorporated into the *Federal Register* Notice.

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 reproposed rulemaking is filed with the Office of the Federal Register.

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

RESOURCES:

To complete and implement the rulemaking, 1.0 full-time equivalent position will be required. These resources are within existing budget allocations.

COORDINATION:

The Office of the General Counsel has no legal objection to the reproposed rulemaking. The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objections.

/RA/

R. W. Borchardt
Executive Director
for Operations

Enclosures:
1. *Federal Register* Notice
2. Rule Language Changes

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1. *Federal Register* Notice
2. Rule Language Changes **ML100890086** WITS201000012/EDATS: SECY-2010-0034

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