FOR: The Commissioners

FROM: Luis A. Reyes
Executive Director for Operations

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

PURPOSE:

To request Commission approval to publish a proposed rule, in the *Federal Register*, that would amend 10 CFR Part 35. The proposed amendments would revise 10 CFR 35.40 and 35.3045 that govern medical use of byproduct material related to reporting and notifications of medical events (MEs) to clarify requirements for permanent implant brachytherapy.

BACKGROUND:

Several medical use events involving therapeutic use of byproduct material in 2003, as well as advice from the Advisory Committee on the Medical Use of Isotopes (ACMUI), prompted the Commission to issue a Staff Requirements Memorandum (SRM)-M04032B (ML040760566) in March 2004, directing the staff to provide the Commission with recommendations concerning the current definition of medical events. The SRM recommended that the staff involve ACMUI in the development of these recommendations.

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In March 2004, the NRC staff began its interactions with the ACMUI on issues relating to the adequacy of ME criteria for permanent implant brachytherapy. ACMUI established a Medical Event Subcommittee (MESC) in October 2004, to develop ACMUI recommendations on these issues. In June 2005, ACMUI received and approved, with modification, the recommendations prepared by the MESC. NRC staff endorsed and supported ACMUI recommendations.

The NRC staff requested Commission approval to develop ACMUI recommendations into a proposed rule in SECY-05-0234 (ML053180408). In February 2006, the Commission issued SRM-SECY-05-0234 (ML060460594) directing the staff to forgo the development of a rule making plan; to proceed directly with developing a proposed rule to modify the written directives in 10 CFR 35.40 and medical event reporting requirements in 10 CFR 35.3045 for permanent implant brachytherapy; and to solicit public input on the drafting of the proposed rule.

A working group was formed and drafted the proposed rule language. Public input on the preliminary draft rule language was solicited via regulations.gov (Docket # NRC-2008-0071) on February 8, 2008 and noticed in the *Federal Register* (73 FR 8830) on February 15, 2008. Additionally, the preliminary draft rule language and information on how to provide input was sent out on the NRC's Medical List Server on February 8, 2008. Public input on the suggested language resulted in revising the proposed language related to information required on the preimplantation written directive (WD) and in other clarifications of the proposed regulation.

DISCUSSION:

Amending the current regulations would change the criteria for defining a medical event (ME) for permanent implant brachytherapy from dose based to activity based; add a requirement to report, as an ME, any administration requiring a WD if a WD was not prepared; clarify requirements for WDs for permanent implant brachytherapy; and make certain administrative and clarification changes. The proposed rule would facilitate the ability of medical licensees to recognize MEs in permanent implant brachytherapy earlier and therefore be able to take corrective actions sooner than under current regulations. These proposed changes to the regulations are based in part on recommendations from ACMUI as well as NRC's Medical Radiation Safety Team.

The proposed rule supports NRC's 2008-2013 Strategic Plan in the areas of safety and operational excellence. In the area of safety, the proposed rule supports the NRC Safety Goal (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 being able to take corrective actions sooner. Taking prompt corrective actions based on ME findings increases the health and safety of patients.

In the area of operational excellence, the proposed rule supports the openness objective. Specifically, soliciting input from the public on the preliminary draft language 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).

AGREEMENT STATE ISSUES: **(WAITING FOR RESPONSES)**

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

Agreement States (name States) provided comments on the draft Federal Register notice.
Discuss comments and resolution
Discuss any compatibility issues.

NRC staff has analyzed the proposed 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:

> § 35.3045 of the proposed rule 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.
>
> § 35.40(c) of the proposed rule is 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.
>
> § 35.40(b), is 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.

RECOMMENDATIONS:

That the Commission:

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

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 and is included within the proposed rule.

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. 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.

RESOURCES:

To complete and implement the rulemaking, 0.8 full-time equivalent positions will be required. These resources are included in the current budget.

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 Commission Paper for resource implications and has no objections. The rule suggests changes in information collection requirements that must be submitted to OMB no later than the date the proposed rule is forwarded to the *Federal Register* for publication.

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Enclosure:
Federal Register Notice

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