[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 35

RIN 3150-AI26

[NRC-2008-XXXX]

Medical Use of Byproduct Material – Amendments/Medical Event Definitions

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations that govern medical use of byproduct material related to reporting and notifications of medical events (MEs) to clarify requirements for permanent implant brachytherapy. The proposed amendments would change the criteria for defining an ME for permanent implant brachytherapy from dose-based to activity-based; add a requirement to report, as an ME, any administration requiring a written directive (WD) if a WD was not prepared; clarify requirements for WDs for permanent implant brachytherapy; and make certain administrative and clarification changes.

These amendments regarding permanent implant brachytherapy are being proposed in response to several incidents involving therapeutic use of byproduct material. The proposed changes are based in part on recommendations from NRC's Advisory Committee on the Medical Use of Isotopes (ACMUI) and the NRC's Medical Radiation Safety Team. This proposed rule would affect all medical licensees that perform procedures using byproduct material that require completion of a WD.

DATES: The comment period expires (**insert 75 days from date of publication)**. Comments received after this date will be considered if it is practical to do so, but the NRC is able to assure consideration only for comments received on or before this date.

ADDRESSES: Please include the following number RIN 3150-AI26 in the subject line of your comments. Comments on rulemakings submitted in writing or in electronic form will be made available to the public in their entirety on the NRC's web site in the Agencywide Documents Access and Management System (ADAMS) and at http:www.regulations.gov. Personal information, such as your name, address, telephone number, e-mail address, etc., will not be removed from your submission. You may submit comments by any one of the following methods.

Electronically: Via the Federal eRulemaking Portal (Docket ID NRC-2008-**XXXX**) and follow instructions for submitting comments. Address questions about this docket to Carol Gallagher 301-415-5905; e-mail Carol.Gallagher@nrc.gov.

Mail comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff.

E-mail comments to: Rulemaking.Comments@nrc.gov. If you do not receive a reply e-mail confirming that we have received your comments, contact us directly at 301-415-1966.

Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 am and 4:15 pm Federal workdays. (Telephone 301-415-1966).

Fax comments to: Secretary, U.S. Nuclear Regulatory Commission at 301-415-1101.

You may submit comments on the information collections by the methods indicated in the Paperwork Reduction Act Statement.

Publicly available documents related to this rulemaking may be viewed electronically on the public computers located at the NRC's Public Document Room (PDR), Room O-1 F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland. The PDR reproduction contractor will copy documents for a fee.

Publicly available documents created or received at the NRC after November 1, 1999, are available electronically at the NRC's Electronic Reading Room at http://www.nrc.gov/reading-rm/adams.html. From this site, the public can gain entry into ADAMS, which provides text and image files of NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the PDR Reference staff at 1-800-397-4209, 301-415-4737 or by e-mail to pdr.resource@nrc.gov.

FOR FURTHER INFORMATION CONTACT: Edward M. Lohr, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone 301-415-0253, e-mail, Edward.Lohr@nrc.gov.

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I. Background

MEs are events that meet the criteria in 10 CFR 35.3045(a) or (b). These events are incidents in which the end result of a medical use of radioactive material is significantly different from what was planned. The ME could be a result of an error in calculating or delivering a radiation dose, administering the wrong radionuclide or the wrong amount of the correct radionuclide, or other factors that are described in 10 CFR 35.3045.

Medical licensees are required to report MEs to the NRC and to notify the referring physician and the individual who is the subject of the ME so that: 1) NRC is aware of the events that led to the unplanned outcome, to determine what actions, if any, need to be taken to prevent recurrence; 2) other medical use licensees can be made aware of generic problems that result in MEs; and 3) patients and their physicians can make timely decisions regarding remedial and prospective health care.

For all medical uses, the variance criterion threshold for licensee submission of an ME report is an administered total dose (or dosage) that differs from the prescribed dose (or dosage), as defined in the WD, by more than 20 percent. The basis for this ME criterion reporting threshold is that variances of this magnitude may reflect quality assurance (QA)

problems with the licensees' programs and also have the potential to result in harm to the patient. This 20 percent criterion, and others relating to reporting of MEs, appears in 10 CFR 35.3045. 10 CFR 35.40 establishes the requirements for a WD.

Several medical use events in 2003 involving therapeutic use of byproduct material, as well as advice from ACMUI, prompted the NRC to reconsider the appropriateness and adequacy of the regulations for MEs and WDs with regard to use of byproduct material that require completion of a WD. These medical use events included the implantation of brachytherapy sources in the wrong treatment site by several licensees. Other medical use events were not reportable as MEs because a WD was not prepared for use of byproduct material when a WD was required, and under current regulations such events are not reportable as MEs. In addition, there is no basis for determining whether an ME has occurred.

Another issue identified from these medical use events was that criteria for MEs for permanent implant brachytherapy are dose-based. Under current regulations, determining whether an ME has occurred for permanent implant brachytherapy is not done until the dose to the treatment site is determined, and often this is not done for some time after the procedure. ACMUI recommended that the criteria for defining most MEs for permanent implant brachytherapy be based on activity, which allows for a determination if an ME has occurred at the end of the procedure. Activity-based criteria allows for earlier recognition by the licensee that an ME has occurred and allows corrective actions to be taken sooner, resulting in an increase in the health and safety of the patient. Additionally, because the AU can control where the brachytherapy sources are implanted, activity-based ME criteria would result in fewer occurrences of MEs for permanent implant brachytherapies.

ACMUI, in considering the issue of defining MEs involving permanent implant brachytherapy, concluded that the 20 percent variance from the prescription criterion in the existing rule continued to be appropriate for permanent implant brachytherapy if both the

prescription and the variance could be expressed in units of activity, rather than in units of dose, because there is no suitable clinically used dose metric available for judging the occurrence of MEs. The NRC staff agrees that, for permanent implant brachytherapy, total source strength (activity-based) is an acceptable alternative to total dose (dose-based) for the purpose of determining the occurrence of most MEs.

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.

The ACMUI recommendations included:

1. For all permanent implants, most MEs should be defined in terms of the total source strength implanted in the treatment site, not in terms of absorbed dose.

2. Any implant in which the total source strength implanted in the treatment site deviates from the WD by more than 20 percent (in either direction) should be classified as an ME.

3. Implants in which more than 20 percent of the total source strength documented in the preimplantation WD is implanted in tissue or organs adjacent to the treatment site [within 3 centimeters (cm) (1.2 in.) of the treatment site boundary] should be classified as MEs.

4. Implants should be classified as MEs if:

a. sealed radioactive sources (seeds) are implanted in distant [beyond 3 cm (1.2 in.) from the treatment site boundary] tissue or organs;

b. the excess dose to the distant tissue or organ exceeds 0.5 Sv (50 rem); and

c. the excess dose to the tissue or organ is at least 50 percent greater than the dose that would have been delivered if the seeds had been implanted in the correct tissue volume.

5. An implant is an ME if the dose calculations used to determine the total source strength documented in the WD, to achieve the authorized user's intention for absorbed dose to the treatment site, are in error by more than 20 percent in either direction.

6. The AU is to complete any revisions (to the WD for permanent implants) to account for any medically necessary plan adaptations before the patient is released from licensee control after the implantation procedure and immediate post-operative period.

7. Seeds that were correctly implanted but subsequently migrated are excluded as grounds for any ME.

ACMUI meetings on these issues were noticed in the *Federal Register* and open to the public. Members of the public participated in discussions of these matters during the meetings.

Based on the ACMUI and NRC staff recommendations, the Commission directed the NRC staff in a Staff Requirements Memorandum (SRM-SECY-05-0234, February 15, 2006) to:

(1) Retain the 20 percent delivered dose variation in 10 CFR 35.3045(a) as an appropriate threshold for ME reporting for all medical use modalities except permanent implant brachytherapy; and

(2) Develop a proposed rule to modify both the WD requirements in 10 CFR 35.40 and the ME reporting requirements in 10 CFR 35.3045 for permanent implant brachytherapy medical use to convert from dose-based to activity-based.

II. Discussion

A. What Action is the NRC Taking?

The NRC is proposing to modify 10 CFR 35.40 and 35.3045 to establish separate ME criteria and WD requirements for permanent implant brachytherapy. This proposed amendment would add as an ME a criterion for the failure to prepare a WD when required.

Additionally, the proposed rule would make minor administrative and clarification changes.

Section 35.3045 would be restructured to create separate paragraphs specific to ME criteria for permanent implant brachytherapy (such as seeds and microspheres). Regulations for all other uses of byproduct material requiring a WD (such as temporary implant brachytherapy and radiopharmaceuticals) would be left combined. Additionally, minor changes would also be made to the language in the regulations to accommodate this proposed revision.

B. Who Would This Action Affect?

This proposed rule would affect all NRC and Agreement State medical licensees who perform procedures using byproduct material that require completion of a WD.

C. What Steps Did NRC Take to Involve the Public in this Proposed Rulemaking?

The NRC took several initiatives to enhance stakeholder involvement and to improve efficiency during the rulemaking process. Public input was solicited on the preliminary draft rule language via http://www.regulations.gov (Docket ID # NRC-2008-0071) on February 8, 2008, and noticed in the *Federal Register* 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. All public input on the preliminary draft rule language received was considered in formulating this proposed rule.

After consideration of public input on the preliminary language, the NRC revised the proposed language related to information required on a preimplantation WD and made other clarifications to the proposed regulations. The NRC also received comments that concerned the technical basis for this rulemaking. These comments will be considered with all other public comments received during the comment period on this proposed rule.

In addition, this proposed rule is based partly on recommendations from ACMUI. The issues were addressed in ACMUI's briefing to the Commissioners on March 2, 2004, and discussed in its March 2004 meeting. As a result of ACMUI's briefing, the Commission directed the NRC staff in SRM-M040302B, dated March 16, 2004, to provide recommendations concerning the current ME definition.

A MESC was established by ACMUI at its October 2004 meeting to develop recommendations on these issues. ACMUI subsequently considered these issues: (1) as the principal subject of its mid-cycle teleconference in January 2005 and during a March 2005 teleconference; (2) during the ACMUI spring meeting in April 2005; and (3) as the principal subject of a teleconference in June 2005. MESC's recommendations were accepted by ACMUI and forwarded to the NRC on July 19, 2005.

ACMUI meetings on these issues were noticed in the *Federal Register* and open to the public. Members of the public participated in discussions of these matters during the meetings.

D. Why Change the ME Criteria for Permanent Implant Brachytherapy?

Currently, the ME criteria for permanent implant brachytherapy are dose-based. The proposed rule would define ME criteria in terms of the total source strength (activity-based) rather than dose or dosage (dose-based). This change focuses on what the AU can control; namely, into which organ or treatment site the sources are implanted, instead of the absorbed dose distribution, over which AU control is limited. Additionally, for the most commonly practiced forms of image-guided source implantation, definitive dose distributions may not be available until several weeks after completion of the procedure. On the other hand, the number of sources implanted in the treatment site (and hence total source strength) can be assessed before releasing the patient from licensee control (e.g., via intraoperative imaging for prostate implants.)

Criteria for defining an ME for permanent implant brachytherapy would address situations that are specific to permanent implant brachytherapy. Currently, the criteria for defining an ME for permanent implant brachytherapy are incorporated into requirements for temporary implant brachytherapy and therapeutic use of unsealed byproduct materials.

E. Would All MEs for Permanent Implant Brachytherapy be Assessed in Terms of Activity?

The proposed rule would allow for a limited situation in which a dose-based criterion is retained in assessing if an ME occurred in permanent implant brachytherapy. Specifically, prior to implantation, an AU prescribes his or her treatment intention in units of absorbed dose to the treatment site, and the intended dose along with the corresponding calculated total source strength is documented in the preimplantation WD. However, an error may be made in the calculations used to determine the total source strength that will deliver the desired dose. As a result, although the prescribed total source strength is delivered, the intended dose to the treatment site is not achieved. If an ME were assessed solely in terms of whether the correct source strength specified in the preimplantation WD was implanted, treatment planning errors, many of which could adversely affect the patient's clinical outcome, would not be subject to regulatory oversight. Therefore, as recommended by ACMUI, the proposed rule would provide in § 35.3045(a)(3) that an administration is an ME if an error in the calculations used to determine the total source strength documented in the preimplantation WD results in a delivered dose differing by more than 20 percent from the intended dose to the treatment site.

F. Why Add an ME Criterion for Failure to Prepare a WD When Required?

Under current regulations, a WD must be dated and signed by an AU before the administration of I-131 sodium iodine greater than 1.1 megabecquerels (30 microcuries), any

therapeutic dosage of unsealed byproduct material, or any therapeutic dose of radiation from byproduct material. Prescribed dosage and dose are defined differently in § 35.2.

The NRC has determined that all therapeutic and certain diagnostic procedures involving radioactive material, sealed or unsealed, must have WDs to ensure that the health and safety of the patient is protected. Unintended events have occurred at licensed facilities in which therapeutic doses requiring a WD have been administered to patients without a WD. These incidents were not reportable or subject to the requirements of the current regulations for determining if an ME has occurred because a WD was not prepared. Under the current regulations, if a WD is not prepared for therapeutic procedures that prescribe dose or dosage, then licensees do not have a basis for determining if an ME has occurred, nor is there a requirement to report such an event as an ME to the NRC. Adding a criterion that an incident must be reported as an ME if there has been a failure to prepare a WD when required would ensure that the health and safety of medical patients are protected.

G. Can the AU Modify the Preimplantation WD During the Administration of Brachytherapy?

No. Making changes to the preimplantation WD would constitute revising the WD. As is also provided by the current regulations, revisions to the WD must be made before implantation begins. The reason the preimplantation WD cannot be changed is that the preimplantation WD serves as the basis for determining if an ME has occurred.

However, the current regulations specify that after implantation but before completion of the procedure, certain information required by the regulations must be added to the WD. The current regulations do not clearly define "completion of the procedure" for permanent implant brachytherapy. As a result, there has been confusion as to when the required information must be added to the WD. The proposed rule would clarify that this information must be added after administration, but before the patient leaves the post-treatment recovery area.

The requirement in the current regulation to document the treatment site and nuclide on the WD after administration for permanent implant brachytherapy would be removed because this information is already required by the preimplantation WD and modifying these two items after the procedure has begun would constitute a revision of the WD. A requirement for the AU to sign the WD after administration but before the patient leaves the post-treatment recovery area would be added to ensure that the information added to the WD has been reviewed and approved by the AU. This change would clarify the intent of the current regulation that the AU must approve all required information on the WD.

H. Where Does the 20 Percent Deviation From the Preimplantation WD Originate?

ACMUI, in its recommendations to the NRC, stated that "any implant in which the total source strength implanted in the treatment site deviates from the written directive by more than 20 percent (in either direction) should be classified as an ME." The rational for this recommendation was that the AU should be afforded the option of positioning up to 20 percent of the total source strength for seed implantation into tissue or organs adjacent to the treatment site. For example, in treating the prostate with permanent implant brachytherapy, a small number of radioactive seeds need to be placed 2-10 millimeters outside the prostate in order to provide adequate dosimetric coverage. In addition, the 20 percent latitude also accounts for variations in treatment-site definition, difficulties in visualizing the target organ by intraoperative imaging, and other phenomena that contribute to uncertainty in estimating the fraction of seeds implanted in the treatment site.

The 20 percent dose threshold is comparable to the variation encountered in normal medical practice, due mainly to the limited control the AU has over the positioning of seeds and hence the dose delivered by permanent implants. Raising the relative absorbed dose threshold (e.g., to 50 percent), would reduce the number of clinically acceptable implants deemed to be

MEs, but would not take into consideration implants that constitute technical errors with quality assurance (QA) significance that could relate to health issues.

I. Would One Sealed Source Implanted Beyond the 3 cm Boundary Constitute an ME?

Yes, with the exception of sealed sources that migrate after implantation, a single brachytherapy source implanted beyond 3 cm from the outside boundary of the treatment site would constitute an ME. In its recommendations to the NRC (SECY-05-0234, December 27, 2005, Enclosure 2), ACMUI distinguished between two scenarios for defining MEs for implants outside the treatment site.

The first scenario relates to sealed sources permanently implanted in tissue or organs adjacent to the treatment site. In this case, ACMUI recommended that up to 20 percent of the total source strength documented in the preimplantation WD be allowed in the adjacent area before being considered an ME. ACMUI concluded that "a 20 percent threshold strikes a reasonable balance between permitting seed implantation outside of the target to boost peripheral doses [a medically legitimate objective] and detecting gross mispositioning of seeds into an adjacent organ rather than the intended treatment site." ACMUI recommended that 3 cm from the outside boundary of the treatment site be used to define the adjacent area.

The second scenario relates to sealed sources permanently implanted in tissue or organs beyond the adjacent area (3 cm) of the treatment site. In this case, ACMUI concluded that tissues and organs that are more than 3 cm from the outside treatment site boundary would be considered distant sites and that any sealed source implanted beyond the 3 cm boundary would constitute an ME. Both of ACMUI's recommendations have been incorporated into this proposed rule.

J. What Are the New Information Requirements for a Brachytherapy WD?

Information that is required in a WD is crucial to ensuring that a patient receives the appropriate treatment. Therefore, based on recommendations from ACMUI, the specific WD requirements for permanent implant brachytherapy would be changed from dose-based to activity-based.

The permanent implant brachytherapy WD requirements would include specifying at what point a permanent implant brachytherapy procedure is considered to be complete. ACMUI, in its recommendations to the NRC, noted that "completion of the procedure" is not currently defined in Part 35.

Requiring the AU to sign the WD after administration but before the patient leaves the post-treatment area would ensure that the information added to the WD has been reviewed and approved by the AU. This change would clarify the intent of the current regulation that the AU approve all required information on the WD.

K. Has NRC Prepared a Cost-Benefit Analysis of the Proposed Actions?

The NRC staff has prepared a draft Regulatory Analysis for this rulemaking. This analysis shows a reduction in cost by approximately $5,211 annually from this proposed rule. More detailed information on this subject is in Section XI of this document.

L. Has NRC Evaluated the Paperwork Burden to Licensees?

This proposed rule would contain new or amended information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq). The NRC staff has estimated the impact this proposed rule would have on reporting and recordkeeping requirements of NRC and Agreement State licensees. The NRC seeks public comment on

these estimates of reduced burden to licensees from the proposed rule. More information on this subject is in Section IX, Paperwork Reduction Act Statement, of this document.

M. What Should I Consider as I Prepare My Comments to NRC?

Commenters may wish to consider the following in providing their comments:

(1) Identify the rulemaking (RIN 3150-AI26);

(2) Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes;

(3) Describe any assumptions and provide any technical information and/or data that you used;

(4) If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced;

(5) Provide specific examples to illustrate your concerns, and suggest alternatives;

(6) Explain your views as clearly as possible;

(7) Make sure to submit your comments by the comment period deadline identified; and

(8) See Section VI of the Supplemental Information for the request for comments on the use of plain language, Section IX for the request for comments on the information collection, and Section XI for the request for comments on the draft regulatory analysis.

III. Discussion of Proposed Amendments by Section

1. Section 35.40 Written directives.

This section would be amended to create specific requirements for a WD for permanent implant brachytherapy. The section would be restructured to accommodate the specific requirements for a WD for permanent implant brachytherapy. Additionally, there would be an

administrative change to the paragraph numbering.

2. Section 35.3045 Report and notification of a medical event.

This section would be amended to separately establish the criteria for MEs involving permanent implant brachytherapy. The proposed amendment would change the requirements for defining most MEs for permanent implant brachytherapy from dose-based to activity-based. A requirement would be added to report, as an ME, any administration requiring a WD if a WD was not prepared. In addition, the NRC is proposing to make certain administrative and clarification changes including an update to reflect the new NRC Operations Center phone number.

IV. Criminal Penalties

For the purpose of Section 223 of the Atomic Energy Act (AEA), the Commission is proposing to amend 10 CFR Part 35 under one or more of Sections 161b, 161i, or 161o of the AEA. Willful violations of the rule would be subject to criminal enforcement.

V. Agreement State Compatibility

Under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" approved by the Commission on June 30, 1997 (62 FR 46517), specific requirements within this rule should be adopted by Agreement States for purposes of compatibility or because of health and safety significance. Implementing procedures for the Policy Statement establish specific categories which have been applied to categorize the requirements in Part 32 and 35. A Compatibility Category "A" designation means the requirement is a basic radiation protection standard or deals with related definitions, signs,

labels, or terms necessary for a common understanding of radiation protection principles. Compatibility Category “A” designated Agreement State requirements should be essentially identical to those of the NRC. A Compatibility Category “B” designation means the requirement has significant transboundary implications. Compatibility Category ‘‘B’’ designated Agreement State requirements should be essentially identical to those of the NRC. A Compatibility Category “C” designation means the essential objectives of the requirement should be adopted by the State to avoid conflicts, duplications, or gaps. The manner in which the essential objectives are addressed in the Agreement State requirement need not be the same as NRC provided the essential objectives are met. A Compatibility Category “D” designation means the requirement does not have to be adopted by an Agreement State for purposes of compatibility. 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. States should adopt the essential objectives of such program elements in order to maintain an adequate program.

Summary of NRC Rules With Compatibility or Health and Safety Designations Under the Proposed Rule Covering 10 CFR Part 35

Section and paragraph	Section title
	CATEGORY C
§ 35.3045.....	Report and notification of a medical event.
	CATEGORY D
§ 35.40(c).....	Written directives.
	CATEGORY H&S
§ 35.40(b).....	Written directives.

VI. Plain Language

The Presidential Memorandum "Plain Language in Government Writing" published June 10, 1998 (63 FR 31883), directed that the Government's documents be in clear and accessible language. The NRC requests comments on this proposed rule specifically with respect to the clarity and effectiveness of the language used. Comments should be sent to the address listed under the "ADDRESSES" heading.

VII. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995 (Pub. L. 104-113) requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this proposed rule, the NRC would amend 10 CFR 35.40 and 35.3045 to revise the criteria for defining MEs and clarify requirements for WDs for permanent implant brachytherapy. This action does not constitute the establishment of a standard that establishes generally applicable requirements.

VIII. Environmental Impact: Categorical Exclusion

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

IX. Paperwork Reduction Act Statement

This proposed rule contains new or amended information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq). This proposed rule has been submitted to the Office of Management and Budget for review and approval of the information collection requirements.

Type of submission, new or revision: Revision

The title of the information collection: Part 35 Medical Use of Byproduct Material – Amendments/Medical Event Definitions

The form number if applicable: N/A

How often the collection is required: As events occur. Historically, the number of MEs reported from the NRC and Agreement State medical licensees have averaged 35 annually.

Who will be required or asked to report: NRC and Agreement State medical licensees who perform therapeutic procedures using byproduct material.

An estimate of the number of annual responses: -2 (reduction of one from NRC medical licensees and one from Agreement State licensees).

The estimated number of annual respondents: -2 (reduction of one from NRC medical licensees and one from Agreement State licensees).

An estimate of the total number of hours needed annually to complete the requirement or request: Reduction of -20.2 hours (10.1 hours per response).

Abstract: The NRC is proposing to amend 10 CFR 35.40 and 35.3045 to revise the criteria for defining MEs and clarify requirements for WDs for permanent implant brachytherapy. The proposed amendments would change the criteria for defining an 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 brachytherapy; and would make certain administrative and clarification changes.

These proposed amendments regarding permanent implant brachytherapy are based in part on ACMUI recommendations and on the NRC's Medical Radiation Safety Team recommendations in response to several incidents involving therapeutic use of byproduct material. This proposed rule would affect all medical licensees that perform therapeutic procedures using byproduct material.

The NRC is seeking public comment on the potential impact of the information collections contained in this proposed rule and on the following issues:

1. Is the proposed information collection necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility?
2. Is the estimate of burden accurate?
3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?
4. How can the burden of the information collection be minimized, including the use of automated collection techniques?

A copy of the OMB clearance package may be viewed free of charge at the NRC Public Document Room, One White Flint North, 11555 Rockville Pike, Room O-1 F21, Rockville, Maryland 20852. The OMB clearance package and rule are available at the NRC worldwide Web site: http://www.nrc.gov/public-involve/doc-comment/omb/index.html for 60 days after the signature date of this notice.

Send comments on any aspect of these proposed information collections, including suggestions for reducing the burden and on the above issues, by (**INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER**) to the Records and FOIA/Privacy

Services Branch (T-5 F52), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet electronic mail to INFOCOLLECTS.RESOURCE@NRC.GOV and to the Desk Officer, Nathan J. Frey, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0010), Office of Management and Budget, Washington, DC 20503. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date. You may also e-mail comments to Nathan_J._Frey@omb.eop.gov or comment by telephone at (202) 395-7345.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

X. Regulatory Analysis

The Commission has prepared a draft regulatory analysis on this proposed regulation and has included it in this document. The analysis examines the costs and benefits of the alternatives considered by the Commission.

1. INTRODUCTION

The NRC proposes to amend its regulations to revise the criteria for defining MEs and clarify requirements for WDs for permanent implant brachytherapy. The rule would amend 10 CFR 35.40 and 35.3045. The proposed amendments would change the criteria for defining an ME for permanent implant brachytherapy from dose-based to activity-based; would add a

requirement to report, as an ME, any administration requiring a WD if a WD was not prepared; would clarify requirements for WDs for brachytherapy, and would make certain administrative and clarification changes.

This proposed rule regarding permanent implant brachytherapy is based in part on the recommendations from ACMUI and the NRC's Medical Radiation Safety Team in response to several incidents involving brachytherapy. The issues raised by these incidents were discussed in several ACMUI public meetings. Public input was solicited during the development of the proposed rule language.

Several medical use events involving therapeutic use of byproduct material in 2003, as well as advice from ACMUI, prompted the NRC to reconsider the appropriateness and adequacy of the regulations for MEs and WDs with regard to therapeutic use of byproduct material.

1.1 Description of the Proposed Action

The proposed rule would amend § 35.3045 to change the criteria for defining an ME for permanent implant brachytherapy in terms of total source strength implanted rather than in terms of absorbed dose. The proposed rule does retain a limited dose-based ME criterion as recommended by ACMUI. This criterion applies if the calculations used to determine the total source strength documented in the WD are in error by more than 20 percent. As in the current regulations, source migration would be specifically excluded as grounds for treatment-site-accuracy MEs. One additional ME criterion would be added that would require a medical licensee to report, as an ME, any administration requiring a WD if a WD was not prepared.

Section 35.40 would be amended to clarify requirements for WDs required for permanent implant brachytherapy for before and after administration. A detailed analysis of this amendment is included in Section 4 of this Regulatory Analysis.

The proposed rule also would also make certain administrative and clarification changes. These changes include updating the phone number for the NRC Operations Center, revising the numbering of various paragraphs in §§ 35.40 and 35.3045, and other minor clarifications.

1.2 Need for the Proposed Action

The change from a dose-based to an activity-based criterion for establishing criteria for MEs for permanent brachytherapy implants is proposed because the current dose-based criteria do not adequately address MEs for permanent brachytherapy implants.

Several medical use events involving therapeutic use of byproduct material in 2003, as well as advice from ACMUI, prompted the NRC to reconsider the appropriateness and adequacy of the regulations for MEs and WDs with regard to use of byproduct material that require completion of a WD. These medical use events included the implantation of brachytherapy sources in the wrong treatment site by several licensees. Other medical use events were not reportable as MEs because a WD was not prepared for use of byproduct material when a WD was required, and under current regulations such events are not reportable as MEs. In addition, there is no basis for determining whether an ME has occurred.

Another issue identified from these medical use events was that criteria for MEs for permanent implant brachytherapy are dose-based. Under current regulations, determining whether an ME had occurred for permanent implant brachytherapy was not done until the dose to the treatment site was determined and often was not done for some time after the procedure. ACMUI recommended that the criteria for defining most MEs for permanent implant brachytherapy be based on activity which allows for a determination if an ME has occurred at the end of the procedure. Activity-based criteria allow for earlier recognition by the licensee that an ME has occurred and allow corrective actions to be taken sooner, which results in an

increase in the health and safety of the patient. Additionally, because the AU can control where the brachytherapy sources are implanted, activity-based ME criteria would result in less occurrences of MEs for permanent implant brachytherapies.

Information required on a WD is crucial to ensure that a patient receives the appropriate administration. Changing from a dose-based to activity-based criteria for defining most MEs for permanent implant brachytherapy would also entail changing the information required in a WD.

2. TECHNICAL BASIS FOR THE PROPOSED RULE

For all medical uses, the variance criterion threshold for licensee submission of an ME report is an administered total dose (or dosage) that differs from the prescribed dose (or dosage), as defined in the WD, by more than 20 percent. The basis for this ME criterion reporting threshold is that variances of this magnitude may reflect quality assurance (QA) problems with a licensee's program and also have the potential to harm the patient. This 20 percent criterion, and others relating to reporting of MEs, appears in 10 CFR 35.3045. 10 CFR 35.40 defines the requirements for a WD.

Several medical use events involving therapeutic use of byproduct material that require completion of a WD in 2003, as well as advice from the ACMUI, prompted the NRC to reconsider the appropriateness and adequacy of the regulations for MEs and WDs. ACMUI, in considering the issue of defining MEs involving permanent implant brachytherapy, concluded that the 20 percent variance from the prescription criterion in the existing rule continued to be appropriate for permanent implant brachytherapy if both the prescription and the variance could be expressed in units of activity, rather than in units of dose, because there is no suitable clinically used dose metric available for judging the occurrence of MEs. The NRC staff agreed that, for permanent implant brachytherapy, total source strength (activity-based) is an acceptable alternative to total dose (dose-based) for the purpose of determining the occurrence

of most MEs.

In March 2004, the NRC staff began its interactions with the ACMUI on the issues related to the adequacy of ME definitions. ACMUI established a 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. ACMUI meetings on these issues were noticed in the *Federal Register* and open to the public. Members of the public participated in discussions of these matters during the meetings.

Based on the ACMUI and NRC staff recommendations, the Commission directed the NRC staff in a Staff Requirements Memorandum (SRM-SECY-05-0234, February 15, 2006) to (1) retain the 20 percent delivered dose variation in 10 CFR 35.3045(a), as an appropriate threshold for ME reporting for all medical use modalities except permanent implant brachytherapy; and (2) develop a proposed rule to modify both the WD requirements in 10 CFR 35.40 and the ME reporting requirements in 10 CFR 35.3045 for permanent implant brachytherapy medical use to convert from dose-based to activity-based.

3. IDENTIFICATION OF ALTERNATIVE APPROACHES

The NRC considered two alternatives for the proposed rule:

<u>Alternative 1: No-Action</u>

Under this alternative, the Commission would make no changes to current regulations. This could result in the continued delay in recognizing MEs related to implant brachytherapy by medical licensees. Corrective actions based on MEs might not be taken in a timely manner which could affect the health and safety of patients.

<u>Alternative 2: Revise the criteria for defining MEs and clarify requirements for WDs for permanent implant brachytherapy.</u>

This alternative would amend the regulations as described in Section 1.1 and 1.2 of this

Regulatory Analysis and is the preferred alternative for reasons stated in Section 1.2.

4. ANALYSIS OF VALUES AND IMPACTS

This section examines the values (benefits) and impacts (costs) expected to result from NRC's proposed rule.

Report and Notification of a Medical Event (§ 35.3045)

The NRC staff, based on a review of historic reporting of MEs, anticipates a decrease in reported MEs from the use of the new ME criteria for permanent implant brachytherapy by approximately four per year. This would result in a reduction of cost by approximately $10,423.

Based on NRC staff estimates, the number of MEs would increase by approximately two per year from the new reporting requirements when a WD is not prepared when required. This would result in an increase of cost by approximately $5,211.

The net result is that the proposed amendment to § 35.3045 would decrease cost to medical licensees by $5,211.

Written Directives (§ 35.40)

Information Required to be Documented on a Written Directive for Permanent Implant Brachytherapy	
Current Regulations	Proposed Rule Change
(Before Implantation)	(Before Implantation*)
Date & signature of the Authorized User	Date & signature of the Authorized User
Treatment site	Treatment site
Radionuclide	Radionuclide
Dose	Intended dose
	Calculated total source strength
(After Implantation)	(After Implantation*)
Total source strength	Total source strength
Number of sources implanted	Date & signature of the Authorized User
Treatment site	
Radionuclide	
* The proposed rule language uses "administration" in lieu of "implantation."	

As noted in the table above, the information required on a WD for permanent implant brachytherapy under the proposed rule does not differ greatly from the current regulatory requirements. The proposed rule would add the requirement of documenting the calculated total source strength in the WD before implantation. Source strength must be known before a dose can be calculated; therefore this requirement is not a new burden on the medical licensee. Also, requiring the source strength to be documented in the WD would be an insignificant change. The term “dose” in the current language means “intended dose” and is a clarification in the proposed rule language and would not constitute a new requirement.

Under both the current regulations and the proposed rule the WD must be completed after implantation. The requirement under the proposed rule to have the AU sign and date the WD when the post implantation information is documented would be an insignificant change for the medical licensee.

The result of the proposed amendment to § 35.40 is that there would be a negligible increase of burden or cost to the medical licensees.

The characteristics, in both the public and private sectors that would be affected by the proposed rule, are listed below. These are called "attributes," and are based on the list of potential attributes provided by NRC in Chapter 5 of its Regulatory Analysis Technical Evaluation Handbook. Only the following attributes would be impacted by this proposed rule:

Industry Implementation. The NRC anticipates that there would be a reduction in the number of MEs reported under the new criteria for permanent implant brachytherapy and an increase in the number of MEs reported from the new reporting requirement when a WD is not prepared when required, resulting in a decrease in the total number of MEs reported. The change in information required to be documented in the WD for permanent implant brachytherapy would not place any significant additional burden on the medical licensees. Therefore, the industry

would have a decrease in expenses from implementation of this proposed rule.

NRC Implementation. NRC would incur one-time costs to support development of the rule following publication in the *Federal Register* through publication of the final rule. NRC may also need to revise guidance documentation during the implementation time period.

Other Government. Agreement State governments may incur a one-time cost for adopting this proposed rule, if it becomes a final rule, into their State regulations governing the use of radioactive material. Under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" approved by the Commission on June 30, 1997 (62 FR 46517), specific requirements within this rule should be adopted by Agreement States for purposes of compatibility or because of health and safety significance. Implementing procedures for the Policy Statement establish specific categories which have been applied to categorize the requirements in Parts 35. The proposed rule would amend the following sections and paragraphs that are covered under the Policy Statement:

1. § 35.3045, which has a Compatibility Category C designation under the Policy Statement. A Compatibility Category "C" designation means the essential objectives of the requirement should be adopted by the State to avoid conflicts, duplications, or gaps. The manner in which the essential objectives are addressed in the Agreement State requirement need not be the same as NRC provided the essential objectives are met.

2. § 35.40(c), which has a Compatibility Category D designation under the Policy Statement. A Compatibility Category "D" designation means the requirement does not have to be adopted by an Agreement State for purposes of compatibility.

3. § 35.40(b), which has a Compatibility Category Health & Safety (H&S) designation under the Policy Statement. The Compatibility Category H&S identifies program elements that

are not required for purposes of compatibility, but have particular health and safety significance. States should adopt the essential objectives of such program elements in order to maintain an adequate program.

Each Agreement State had its own unique procedure it must follow to amend its State regulations governing the use of radioactive material. The NRC recognizes that there is a cost for Agreement States to amend their State regulations to adopt this proposed rule if it becomes a final rule. On average each State would expend 0.1 FTE to amend their State regulation, which, based on $76,000 per FTE, would equal $7,600 per State. With 34 Agreement States, the total cost would be $258,400.

The Agreement States are required to report MEs that occur under their license jurisdiction to the NRC. As noted in Section 4 of this Regulatory Analysis, the proposed amendment to § 35.3045 would decrease the cost to the medical licensees and the proposed amendment to § 35.40 would have a negligible increase of burden or cost to the medical licensees. Also, there would be no additional burden to the Agreement States for licensing or inspections.

Other Considerations. Public confidence in NRC may be affected positively by the rule. The public may have more confidence in NRC's program for protection of patient health and safety as a result of clarifying the specific criteria for MEs resulting from permanent implant brachytherapy.

5. DECISION RATIONALE AND IMPLEMENTATION

The assessment of costs and benefits discussed previously leads the NRC to the conclusion that the proposed rule, if implemented, would not have a significant economical impact on medical licensees who are performing therapeutic procedures using byproduct

material. The proposed rule would make it easier for AUs to determine if MEs have occurred, thereby facilitating timely reporting and other appropriate actions and therefore, increase patient health and safety. Requiring licensees to report, as an ME, when a WD is not prepared when required would increase patient health and safety as well as ensure the proper documentation of the procedure.

The revised requirements for a WD for permanent implant brachytherapy would make determining if an ME has occurred during the procedure easier, therefore improving the reliability of ME recognition and reporting. Requiring the AU to sign and date the WD at the end of the procedure would ensure that any changes made during the procedure were authorized by the AU.

The Commission requests public comment on the draft regulatory analysis. Comments on the draft regulatory analysis may be submitted to the NRC as indicated under the ADDRESSES heading.

After publication of this proposed rule in the *Federal Register* and consideration and resolution of public comments, a final rule will be published.

XI. Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the Commission certifies that this rule would not, if promulgated, have a significant economic impact on a substantial number of small entities.

XII. Backfit Analysis

The NRC has determined that the backfit rule (§§ 50.109, 70.76, 72.62, or 76.76) does not apply to this proposed rule because this amendment would not involve any provisions that would impose backfits as defined in 10 CFR Chapter I. Therefore, a backfit analysis is not required.

List of Subjects

10 CFR Part 35

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

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. 553; the NRC is proposing to adopt 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 as follows:

AUTHORITY: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); sec. 651(e), Pub. L. 109–58, 119 Stat. 806–810 (42 U.S.C. 2014, 2021, 2021b, 2111).

2. In § 35.40, paragraphs (b)(5) and (c) are revised, paragraph (b)(6) is redesignated as paragraph (b)(7), and a new paragraph (b)(6) is added to read as follows:

§ 35.40 Written directives.

* * * * *

(b) * * *

(5) For high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose;

(6) For permanent implant brachytherapy:

(i) Before administration (preimplantation): the treatment site, the radionuclide, the intended dose to the treatment site and other sites as necessary, and the corresponding calculated total source strength required; and

(ii) After administration but before the patient leaves the post-treatment recovery area: the total source strength implanted, the date, and signature of AU; or

* * * * *

(c)(1) A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed byproduct material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

(2) If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented as soon as possible in

the patient's record. A revised written directive must be signed by the authorized user within 48 hours of the oral revision.

* * * * *

3. In § 35.3045, paragraph (a) and the footnote to paragraph (c) are revised to read as follows:

§ 35.3045 Report and notification of a medical event.

(a) A licensee shall report as a medical event any administration requiring a written directive if a written directive was not prepared or any event, except for an event that results from patient intervention, in which --

(1) The administration of byproduct material or radiation from byproduct material, except permanent implant brachytherapy, results in--

(i) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and

(A) The total dose delivered differs from the prescribed dose by 20 percent or more;

(B) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

(C) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

(ii) A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following--

(A) An administration of a wrong radioactive drug containing byproduct material or the wrong radionuclide for a brachytherapy procedure;

(B) An administration of a radioactive drug containing byproduct material by the wrong route of administration or by use of the wrong applicator in a brachytherapy procedure;

(C) An administration of a dose or dosage to the wrong individual or human research subject;

(D) An administration of a dose or dosage delivered by the wrong mode of treatment; or

(E) A leaking sealed source.

(iii) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) and by 50 percent or more the dose expected to that site if the administration had been carried out as specified in the written directive.

(2) The administration of byproduct material or radiation from byproduct material for permanent implant brachytherapy (excluding sources that were implanted in the correct site but migrated outside the treatment site) results in—

(i) The total source strength administered differing by 20 percent or more from the total source strength documented in the preimplantation written directive.

(ii) The total source strength administered outside the treatment site and within 3 cm (1.2 in) of the boundary of the treatment site exceeding 20 percent of the total source strength documented in the preimplantation written directive.

(iii) Brachytherapy source(s) implanted beyond 3 cm (1.2 in) from the outside boundary of the treatment site, except for brachytherapy source(s) at other sites noted in the preimplantation written directive.

(iv) A dose to the skin or an organ or tissue other than the treatment site exceeding by 0.5 Sv (50 rem) and by 50 percent or more the dose expected to that site if the administration had been carried out as specified in the preimplantation written directive.

(v) A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following--

(A) An administration of the wrong radionuclide;

(B) An administration by the wrong route of administration;

(C) An administration to the wrong individual or human research subject;

(D) An administration delivered by the wrong mode of treatment; or

(E) A leaking sealed source.

(3) An error in calculating the total source strength for permanent implant brachytherapy documented in the preimplantation written directive that resulted in an administered total source strength that delivered a dose differing by more than 20 percent from the intended dose to the treatment site.

* * * * *

(c) * * *

[3] The commercial telephone number of the NRC Operations Center is (301) 816-5100.

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Dated at Rockville, Maryland, this day of , 2008.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,
Secretary of the Commission.