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.
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> 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.
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> 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

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 35

RIN 3150-AI26

[NRC-2008-0071]

Medical Use of Byproduct Material – Amendments/Medical Event Definitions

AGENCY: Nuclear Regulatory Commission.

ACTION: Reproposed rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is reproposing a proposed rule originally published on August 6, 2008 (73 FR 45635). In this reproposed rule, the NRC proposes to amend its regulations governing the medical use of byproduct material related to reporting and notifications of medical events (ME). The amendments would add criteria based on activity (total source strength) for defining some MEs for permanent implant brachytherapy; add a requirement to report as an ME situations in which a written directive (WD) is required and not prepared and documentation in either an individual's medical records and the licensee's standard written procedures (or both) that existed prior to the administration is insufficient to determine if an ME has occurred; clarify requirements for WDs for permanent implant brachytherapy; add a requirement that licensees provide and document training to their personnel on the requirements that specify reporting and notification of a medical event; and add 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 make certain administrative and clarification changes.

The NRC is taking this action as a result of the NRC's evaluation of information concerning a substantial number of MEs that were reported during the summer and early fall of 2008. Based on its evaluation of the circumstances and data from these events, the NRC believes that the proposed rule published on August 6, 2008, appears to be inconsistent with the original regulatory intent. The original regulatory 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. Additionally, the intent was not to adversely impact the detection of errors such that significant errors would not be identified and reported as MEs. However, the NRC now believes that an unacceptable number of permanent implant brachytherapy errors that were appropriately reported and categorized as MEs in 2008 would not be MEs under the proposed rule published on August 6, 2008. Additionally, the evaluation of the circumstances and data from these more recent events prompted the NRC to reevaluate its 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 adjusted to incorporate this new information.

Briefly summarized, the changes that have been made to the August 6, 2008, proposed rule involve the retention of dose-based criteria (in addition to activity-based criteria) for identifying MEs, the addition of the requirement that licensees provide and document training to individuals who participate in procedures using byproduct material requiring a WD on the requirements for reporting and notification of a ME, and the addition of the requirement that for permanent implant brachytherapy, a licensee assess the dose to the treatment site and sites other than the treatment site identified in the pre-implantation WD (as specified by then-existing current published protocols accepted by nationally recognized professional organizations) within

60 days from when the patient leaves the post-treatment recovery area. The proposed rule is being reproposed in its entirety for public comment.

DATES: Submit comments on the rule by (**insert 60 days from date of publication**). Submit comments specific to the information collections aspects of this rule by (**insert date 30 days from date of publication**). Comments received after these dates 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 Docket ID NRC-2008-0071 in the subject line of your comments. For instructions on submitting comments and accessing documents related to this action, see Section I, "Submitting Comments and Accessing Information" in the SUPPLEMENTARY INFORMATION section of this document. You may submit comments by any one of the following methods.

Federal Rulemaking Web Site: Go to http://www.regulations.gov and search for documents filed under Docket ID NRC-2008-0071. Address questions about NRC dockets to Carol Gallagher, telephone 301-492-3668, e-mail Carol.Gallager@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 301-415-1677.

Hand-deliver comments to: 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. Federal workdays (Telephone 301-415-1677).

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.

SUPPLEMENTARY INFORMATION:

I. Submitting Comments and Accessing Information

Comments submitted in writing or in electronic form will be posted on the NRC Web site and on the Federal rulemaking Web site http://www.regulations.gov. Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including any information in your submission that you do not want to be publicly disclosed. The NRC requests that any party soliciting or aggregating comments received from other persons for submission to the NRC inform those persons that the NRC will not edit their comments to remove any identifying or contact information, and therefore, they should not include any information in their comments that they do not want publicly disclosed.

You can access publicly available documents related to this document, including the following documents, using the following methods:

NRC's Public Document Room (PDR): The public may examine and have copied for a fee, publicly available documents at the NRC's PDR, Room O-1F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland.

NRC's Agencywide Documents Access and Management System (ADAMS): Publicly available documents created or received at the NRC are available electronically at the NRC's Electronic Reading Room at http://www.nrc.gov/reading-rm/adams.html. From this page, 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 NRC's PDR reference staff at 1-800-397-4209, or 301-415-4737, or by e-mail to PDR.Resource@nrc.gov.

Federal Rulemaking Web Site: Public comments and supporting materials related to this proposed rule can be found at http://www.regulations.gov by searching on Docket ID NRC-2008-0071.

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.

II. 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 intended. The ME could result from 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, in certain cases, the individual who was the subject of the ME so that:

(1) The 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.

Several medical use events in 2003 involving therapeutic use of byproduct material, as well as advice from the Advisory Committee on the Medical Use of Isotopes (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 situations were not reportable as MEs because of lack of clarity as to when and how certain information was to be entered into the WD. Additionally, the evaluation of the circumstances and data related to a substantial number of MEs reported in 2008 prompted the NRC to reevaluate its regulations related to training requirements and time frames for licensees to assess the dose to the treatment site for permanent implant brachytherapy.

Another issue identified from these medical use events was that criteria for most 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 most criteria for defining 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. These activity-based criteria allow for earlier recognition by the licensee that an ME has occurred, and, therefore, licensees can complete more timely reviews of the circumstances leading to the ME, identify root causes, and make necessary and prompt corrections to assure that the byproduct material is being used effectively and with minimum risk to the patient and the public.

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.

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 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 these public meetings, ACMUI, in a letter to the NRC dated July 19, 2005, recommended several changes to the regulations. Many of ACMUI's recommendations are included in this reproposed rule.

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.

The NRC published a proposed rule for public comment on August 6, 2008 (73 FR 45635), with a 75 day comment period. The comment period was extended by 18 days (73 FR 58063; October 6, 2008) at the request of ACMUI. Fifty-seven comments, many which

were form letters, were submitted to the NRC regarding the proposed rule. These comments and the NRC's responses are discussed in Section IV, "Summary of Public Comments on the Proposed Rule" in the SUPPLEMENTARY INFORMATION section of this document.

During late summer and early fall of 2008, a substantial number of MEs were reported to the NRC. The NRC reviewed and analyzed the circumstances and data from these events. Based on its evaluation of this information, including an independent analysis conducted by the NRC's medical consultant, the NRC concluded that an unacceptable number of permanent implant brachytherapy errors that were appropriately reported and categorized as MEs in 2008 would not be MEs under the proposed rule published on August 6, 2008 (73 FR 45635). This is inconsistent with the original regulatory intent of the proposed rule which 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. Further, the intent was not to adversely impact the detection of errors such that significant errors would not be identified and reported as MEs. The NRC believes that an unacceptable number of significant permanent implant brachytherapy errors that were reported in 2008 would not be MEs under the August 6, 2008, proposed rule. Additionally, the evaluation of the circumstances and data prompted the NRC to reevaluate its 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 adjusted to incorporate this new information.

The changes in this reproposed rule from the August 6, 2008, proposed rule include the retention of dose-based criteria (in addition to proposing some activity-based criteria) for identifying MEs, the addition of a requirement that licensees provide and document training to individuals who participate in procedures using byproduct material requiring a WD on the

requirements for reporting and notification of a ME; and the addition of a requirement that for permanent implant brachytherapy, a licensee assess the dose to the treatment site and sites other than the treatment site identified in the pre-implantation WD (as specified by then-existing current published protocols accepted by nationally recognized professional organizations) within 60 days from when the patient leaves the post-treatment recovery area.

The NRC is reproposing the August 6, 2008, proposed rule in its entirety for public comment.

III. Discussion

A. What Action is the NRC Taking?

The NRC is proposing to amend 10 CFR 35.24, 35.40, 35.41, 35.2024 and 35.3045. Section 35.24 would be amended to add a requirement that licensees provide and document training on the requirements in § 35.3045 to individuals who participate in procedures using byproduct material requiring a WD prior to the first use, annually, and after each revision of § 35.3045. This amendment is being proposed in response to the NRC's concern that numerous individuals who had been involved in medical procedures involving MEs, indicated that they did not have a clear understanding of the ME requirements. These individuals were also unsure of their responsibilities when they believed that an ME had occurred. The NRC believes training individuals involved in procedures using byproduct material requiring a WD on the ME requirements, and on recognition of a situation in which a ME may have occurred, is essential to ensure patient health and safety.

Section 35.40 would be changed to establish separate WD requirements for permanent implant brachytherapy. Information required for permanent implant brachytherapy would be

required to be recorded on the pre-implantation WD and the post-implantation WD. Additionally, a requirement to complete the post-implantation WD before the patient leaves the post-treatment recovery area would be added.

The information required by the new paragraph (b)(6) would clarify that the WD is divided into two parts; i.e., the pre-implantation WD and the post-implantation WD. The proposed rule would provide that the information required by the pre-implantation WD must be documented prior to the start of the administration and cannot be revised once the administration begins and that the information required by the post-implantation WD must be documented before the patient leaves the post-treatment recovery area. The term “post-treatment recovery area,” as used in paragraph (b)(6) is intended to mean the area or place where a patient recovers immediately following the brachytherapy procedure before being released to a hospital room or, in the case of an out-patient treatment, released from the licensee’s facility.

Section 35.41 would be amended to require the licensee to assess the dose to the treatment site within 60 days of when the patient leaves the post-treatment recovery area. The assessment would have to be done as specified in then-existing current published protocols accepted by nationally recognized professional organizations. The assessment would be used to determine if an ME must be reported as required by one of the criteria in § 35.3045.

Section 35.2024 would be amended to add record keeping requirements to support the proposed change to § 35.24. Record keeping requirements would require including a list of topics covered, the date of training, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the training. These records would have to be retained for 5 years.

Section 35.3045 would be restructured to create separate paragraphs specific to ME criteria for permanent implant brachytherapy (such as the use of seeds). Regulations for all

other uses of byproduct material requiring a WD (such as temporary implant brachytherapy and radiopharmaceuticals) are left combined. This amendment would add a requirement to report as an ME instances when a WD is required, but not prepared, and documentation in an individual's medical records that existed prior to the administration is insufficient to determine if an ME has occurred. For uses of byproduct material requiring a WD other than permanent implant brachytherapy, the licensee's standard written procedures that existed prior to the administration may also be used in determining if an ME has occurred when a WD is not prepared.

Additionally, minor changes have been made to the language in the regulations to accommodate these proposed revisions.

B. Who Would This Action Affect?

This 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 Rulemaking?

The NRC took several initiatives to enhance stakeholder involvement and to improve efficiency during the rulemaking process. 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 Medical Event Subcommittee (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. The NRC posted preliminary draft rule language on the Federal rulemaking website *regulations.gov* (Docket ID # NRC-2008-0071) on February 8, 2008, and published a notice of availability of the preliminary draft rule language in the *Federal Register* on February 15, 2008 (73 FR 8830). Additionally, the preliminary draft rule language and information on how to provide input was sent to subscribers of the NRC's Medical List Serve on February 8, 2008.

The NRC published a proposed rule for public comment on August 6, 2008 (73 FR 45635), with a 75 day comment period. The comment period was extended by 18 days (73 FR 58063; October 6, 2008) at the request of ACMUI. These comments and the NRC's responses are discussed in Section IV., "Summary of Public Comments on the Proposed Rule" in the SUPPLEMENTARY INFORMATION section of this document.

D. Why Add Additional ME Criteria for Permanent Implant Brachytherapy?

The proposed rule would establish specific criteria for defining MEs for permanent implant brachytherapy separate from temporary implant brachytherapy and therapeutic use of unsealed byproduct materials.

Current regulations define ME criteria in terms of dose or dosage (dose-based). Dose-based criteria are being retained in the reproposed rule to ensure that the patient receives the

dose that the physician intended. Under standard medical practice, dose to the treatment site is the only true measure of whether the procedure delivered the prescribed treatment and, in accordance with established scientific principles, dose is the only measure of potential biological damage to sites other than the treatment site. The dose variance limits in the current regulations for the treatment site and other sites are also retained in the proposed rule.

However, this proposed change would also add activity-based criteria to focus on errors that can be recognized at the end of the procedure rather than when the dose to the treatment site is assessed at a later time. The addition of these activity-based criteria, which is based in part on ACMUI recommendations, would allow for earlier recognition by the licensee in certain situations that an ME has occurred, and, therefore, licensees would be able to complete more timely reviews of the circumstances leading to the ME, identify root causes, and make necessary and prompt corrections to assure that the byproduct material is being used effectively and with minimum risk to the patient. The proposed activity-based criteria are not intended to replace or supersede the dose-based criteria that are in the current regulations. Each criterion, whether activity or dose based, must be evaluated independently to determine if an ME has occurred.

E. Why Add a Requirement to Report as an ME a Failure to Prepare a WD When Required?

NRC regulations require that all therapeutic and certain diagnostic procedures involving radioactive material, sealed or unsealed, have WDs to ensure that the health and safety of the patient is protected. When a WD is not prepared when required, determining if an ME has occurred and whether there was potential harm to the patient may not be possible. Unintended

events have occurred at licensed facilities in which therapeutic doses requiring a WD have been administered to patients without preparing a WD.

However, MEs are not intended to identify minor administrative errors. In many cases, the information required by a WD is documented in either an individual's medical records or the licensees' standard written procedures (or both) that existed prior to the administration and this information can be used to determine if an ME has occurred.

Therefore, the proposed rule provides that the licensee may use an individual's medical records that existed prior to the administration to determine if an ME has occurred when a WD was not prepared. Additionally, for uses of byproduct material requiring a WD other than permanent implant brachytherapy, the licensee's standard written procedures that existed prior to the administration may also be used in determining if an ME has occurred when a WD is not prepared. This requirement ensures that the health and safety of medical patients are protected. However, not preparing a WD when required is still a violation of NRC regulations.

F. What Are the New Information Requirements for a Permanent Implant Brachytherapy WD?

The requirement to document the intended dose to the treatment site and other sites as applicable would be added to the pre-implantation WD. Many brachytherapy procedures that are properly conducted result in a dose to sites other than the treatment site. Documenting the dose to these other sites enables the Authorized User (AU) to identify and clarify that doses to these sites are necessary in order to deliver the prescribed dose to the treatment site.

Current regulations specify that after implantation but before completion of the procedure, certain information required by the regulations must be added to the WD. However, the current regulations do not clearly define "completion of the procedure" for permanent

implant brachytherapy and as a result there has been confusion as to when the required information must be added to the post-implantation WD. This proposed rule would remove the term “completion of the procedure” and clarify that post-implantation information must be documented in the WD after administration but before the patient leaves the post-treatment recovery area.

The permanent implant brachytherapy post-implantation WD requirements would include documenting the total source strength implanted, the date, and the signature of an AU for § 35.400 uses for manual brachytherapy.

The requirement in the current regulation to document the treatment site and nuclide in the post-implantation WD after administration for permanent implant brachytherapy is removed because this information is already required by the pre-implantation WD and modifying the pre-implantation WD after the procedure has begun is not permitted.

For § 35.400 manual brachytherapy, a requirement for an 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 post-implantation WD has been properly reviewed and approved. This change would clarify the intent of the current regulation that an AU must approve all required information on the WD.

G. Can the AU Revise the Pre-implantation WD After Beginning the Administration of Brachytherapy?

No. Once the administration of brachytherapy has begun no changes may be made to the pre-implantation WD. As is also provided by the current regulations, revisions to the WD must be made before implantation begins. The reason the pre-implantation WD cannot be

changed is that the pre-implantation WD serves as one of the bases for determining if an ME has occurred.

However, § 35.40(c) allows for an existing WD to be revised by an AU prior to beginning the administration in order to account for any changes in the treatment site (such as organ volume and shape) that may have occurred between the time of planning the treatment and the implantation procedure. This revision to the existing WD, per § 35.40(c)(1), can be done orally, just before administration of the brachytherapy begins, as long as the AU signs the revised WD within 48 hours.

H. What is Meant by Post-Treatment Recovery Area in the Post-Implantation WD?

The post-treatment recovery area, as used in the post-implantation WD, is the area or place where a patient recovers from the brachytherapy procedure before being released back to a hospital room or, in the case of an out-patient treatment, released to leave the facility.

I. Why Was Reference to a 3 cm Boundary Removed From the Reproposed Rule?

Many public comments were received related to defining any ME criterion based on implanting sources within 3 cm (1.2 in) of the treatment site. Specifically, the commenters stated that defining the treatment site boundaries and placing a 20 percent deviation limit on sources that could be implanted within the 3 cm boundary of the treatment site would interfere with clinical judgment of the AU. As discussed in Section IV in response to public comments, the NRC reviewed recent advances in technology and other factors and agreed that having an ME criterion based on a 3 cm boundary could create unintended ambiguity and could potentially interfere with the clinical judgment of the AU. Therefore, the proposed rule language was

changed to remove references to any boundaries beyond the treatment site.

J. Do the Changes to §§ 35.40 and 35.3045 Apply to Use of Microspheres?

No. Microsphere use in permanent implant brachytherapy is currently regulated under § 35.1000, which is not part of this rulemaking.

K. Does the Same AU Who Signs the Pre-Implantation WD have to Sign the Post-Implantation WD?

No. The proposed rule language would be changed to reflect that any AU authorized for uses for manual brachytherapy regulated under § 35.400 may sign the post-implantation WD.

L. Has NRC Prepared a Cost-Benefit Analysis?

NRC staff has prepared a regulatory analysis for this rulemaking. This analysis shows an increase in cost by approximately $11,352 annually from this proposed rule. More detailed information on this subject is in Section XII., “Regulatory Analysis” in the SUPPLEMENTARY INFORMATION section of this document.

M. Has NRC Evaluated the Paperwork Burden to Licensees?

This reproposed 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). The NRC staff has estimated the impact this reproposed rule would have on reporting and recordkeeping requirements of NRC and Agreement State licensees. The NRC sought public comment on these estimates of reduced burden to licensees in the proposed rule published August 6, 2008

(73 FR 45635). No comments were received. More information on this subject is in Section XI, "Paperwork Reduction Act Statement" in the SUPPLEMENTARY INFORMATION section of this document.

IV. Summary of Public Comments on the Proposed Rule

The NRC received 57 comment letters on the proposed rule published August 6, 2008 (73 FR 45635), including many that were form letters. The commenters included professional medical organizations, medical institutions, universities, NRC master material licensees, private physicians, and medical physicists. Copies of the public comments are available for review in the NRC Public Document Room, Room O1F21, 11555 Rockville Pike, Rockville, MD. The NRC considered all of the public comments received on the proposed rule in developing this reproposed rule. A review of the comments and the NRC staff's responses follows:

Comment: Multiple commenters expressed concern that real-time, adaptive, interactive planning manual brachytherapy, where the total source strength to be implanted is based on the actual volume dynamically determined during the procedure rather than based on the pre-implantation volume, would be negatively affected by the rule. Specifically, concerns expressed were that not being able to change the pre-implantation WD would result in unavoidable MEs because of discrepancies in the gland or organ volume at the time of the procedure from the volumes determined during the pre-planning stage.

Response: The NRC disagrees that requiring the AU to document the planned total source strength in the pre-implantation WD would interfere with real-time adaptive planning

implantation. The NRC recognizes that there may be a variance between the planned procedure and the end result. For that reason, as in the current regulations, the proposed rule would allow a 20-percent variance between the planned procedure and the end result for permanent implant brachytherapy. Therefore, AUs may modify their treatment plan during the procedure up to 20-percent of the total source strength documented in the pre-implantation WD without causing an ME to occur. Additionally, § 35.40(c) allows for an existing WD to be revised by an AU prior to beginning the administration to account for any changes in the treatment site (such as organ volume and shape) that may have occurred between the time of the pre-plan and the implantation procedure. This revision to the existing WD, per § 35.40(c)(1), can be oral as long as the AU signs the revised WD within 48 hours.

One criterion for determining if an ME has occurred is the comparison of the total source strength documented in the pre-implantation WD to the total source strength documented in the post-implantation WD. This comparison is important in order to determine whether the administration received by the patient was what the AU intended.

Comment: One commenter stated that the AU who signs the pre-implantation WD as required by § 35.40(a) should not have to be the same AU who signs the post-implantation WD required by § 35.40(b)(6)(ii).

Response: The NRC agrees with this comment and the proposed rule language was changed to reflect that any AU authorized for uses for manual brachytherapy regulated under § 35.400 may sign the post-implantation WD.

Comment: Multiple commenters suggested that the definition for treatment site in § 35.2

was too ambiguous and should be amended to include various descriptions including the gross tumor, the clinical target volume, plus a variable planning target volume.

Response: The proposed rule did not change the definition of treatment site in § 35.2 and the suggested changes are outside the scope of this rulemaking. The comment was forwarded to the NRC's Medical Radiation Safety Team for future consideration.

Comment: One commenter wanted to know how specific the WD needed to be when defining the treatment site.

Response: The AU identifies the treatment site in the WD which, according to § 35.2, includes "the anatomical description of the tissue intended to receive a radiation dose." The treatment site is not defined in more specific terms because different implantation methods, AUs, and therapy planning software packages may define the treatment site differently. This allows the AU to define the treatment site in the WD to best suit the medical needs of the patient.

Comment: Many comments were received related to defining an ME criterion based on implanting sources within 3 cm (1.2 in) of the treatment site. Specifically, the commenters stated that defining the treatment site boundaries and placing a 20 percent limit on sources that could be implanted within the 3 cm boundary of the treatment site would interfere with the clinical judgment of the AU.

Response: In response to the public comments, the NRC reviewed recent advances in technology and other factors and agreed that having an ME criterion based on a 3 cm boundary could create unintended ambiguity and could potentially interfere with the clinical judgment of

the AU. The proposed rule language was therefore changed to remove references to any boundaries beyond the treatment site.

Comment: There were several public comments on the use of microspheres in permanent implant brachytherapy.

Response: Microsphere use in permanent implant brachytherapy is regulated under § 35.1000, which is not part of this rulemaking. The supplementary information in the proposed rule only included the term microsphere as an example in order to distinguish between permanent and temporary brachytherapy, not to imply that microsphere use was regulated under §§ 35.40 or 35.3045. Concerns expressed in the public comments related to microsphere use in permanent implant brachytherapy were sent to the NRC's Medical Radiation Safety Team for future consideration.

Comment: One commenter suggested changes be made to the language in § 35.40(c)(2).

Response: Although § 35.40(c) was administratively restructured, the proposed rule did not change any language in § 35.40(c)(2) and the suggested changes are outside the scope of this rulemaking. The comment was forwarded to the NRC's Medical Radiation Safety Team for future consideration.

Comment: Many commenters did not support the proposed addition of an ME criterion that would require a licensee to report as an ME any administration requiring a WD if a WD was not prepared. Specific objections included the concern that not having a WD or an incomplete

WD should not be an incident that reaches the level of being defined as an ME, and that not preparing a WD was already a violation of NRC regulations. It was also recommended that the NRC re-establish a category of reportable events for incidents when a WD is not prepared.

Response: The NRC partially agrees with the commenters. Information required to be documented on the WD is used for determining if an ME has occurred. If a WD is not prepared when one is required, determining if an ME has occurred may not be possible and determining whether there was potential harm to the patient may be difficult. Requiring reporting of MEs is intended to identify potential quality assurance problems with a licensee's program that have the potential to result in harm to the patient. In addition, having a WD is important in order to determine whether the administration received by the patient was what was intended by the AU.

However, reporting of MEs is not intended to identify minor administrative errors. The basis for determining if an ME has occurred is the comparison of information required to be documented in the WD to what has occurred. In many cases when a WD is not prepared when required, the information required to be in a WD is documented in either an individual's medical records or the licensees' standard written procedures (or both) that existed prior to the administration which can be used to determine if an ME has occurred. Therefore, the proposed rule language has been modified to provide that the licensee may use information documented in an individual's medical records that existed prior to the administration to determine if an ME has occurred when a WD was not prepared. Additionally, for uses of byproduct material requiring a WD that do not involve permanent implant brachytherapy, the licensee's standard written procedures that existed prior to the administration may also be used in determining if an ME has occurred when a WD is not prepared. However, the failure to prepare a WD when

required is still a violation of NRC regulations.

The NRC has never had a category of reportable events for incidents when a WD is not prepared. Establishing such a category is outside the scope of the current rulemaking. The comment was forwarded to the NRC's Medical Radiation Safety Team for future consideration.

Comment: One commenter stated that an ME should be something that has the potential to harm the patient by delivering a significant difference in the dose to the patient.

Response: The NRC partially agrees with the commenter. Threshold criteria for identifying MEs are designed to detect events that have the potential to harm the involved patients. However, the goal of identifying MEs is also to detect possible problems before they rise to that level. The NRC reviews and evaluates MEs for trends and issues that may affect patient or public health and safety. When issues and trends are identified, this information is shared with other licensees to prevent similar occurrences, and avoid potential harm to patients or the public.

Comment: One commenter asserted that the changes to the definition of an ME are inconsistent with the original recommendation made by ACMUI to leave the criteria for modalities other than permanent implant brachytherapy unchanged.

Response: ACMUI, in a letter to the NRC dated July 19, 2005, recommended that: (1) for all permanent implants, most MEs should be defined in terms of 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 should be classified as an ME; (3) the revised “wrong site” ME criterion should distinguish

between tissue or organs adjacent to the treatment site and distant organs; (4) the AU should be required to complete any revisions to the WD for permanent implants before the patient is released from licensee control; and (5) an implant should be considered an ME if the dose calculations used to determine the total source strength documented in the WD are in error by more than 20 percent. Although these recommendations focused upon permanent implant brachytherapy, the ACMUI recommendations did not state that the criteria for modalities other than permanent implant brachytherapy were to remain unchanged.

Further, although ACMUI is the NRC's advisory committee on matters concerning the medical application of isotopes, and, as such, its advice is sought and considered with regard to any changes proposed to the regulations for the medical use of byproduct material, comments and concerns from Agreement States, the public, and NRC's professional staff were also considered in the formulation of the proposed rule. The NRC considered all stakeholders' comments and concerns in developing this reproposed rule.

Comment: One commenter suggested that the NRC should design a WD form to document the regulatory requirements.

Response: Revising the record-keeping requirement for WDs, in 10 CFR 35.2040, is outside the scope of the current rulemaking. The comment was forwarded to the NRC's Medical Radiation Safety Team for future consideration.

Comment: One commenter expressed concern for the lack of care and rigor in the use of terminology exercised in both the current and the proposed regulations, and particularly in the supporting material of the current proposal, with regard to the quantities involved.

Specifically, the commenter stated that the terms "activity" and "strength" are used apparently interchangeably and without clear definition, and that the use of the term "dose" is also somewhat vague.

Response: The proposed rule was reviewed for consistent usage of terms and it was determined that the use of terms was consistent and the terms were clearly defined. Therefore, the proposed rule language was not changed. Reviewing 10 CFR Part 35 in its entirety for consistent usage of terms is outside the scope of this rulemaking. The comment was forwarded to the NRC's Medical Radiation Safety Team for future consideration.

Comment: One commenter disagreed with the recommendation "to single out permanent implant brachytherapy and eliminate the requirement for a written directive for other forms of brachytherapy treatments." The commenter further stated: "Since brachytherapy is not performed on an emergency basis and treatment plans are created for these procedures, all patients should have a written directive prior to treatment."

Response: The NRC has not eliminated the requirement for a WD for any form of brachytherapy. The modifications to § 35.40 do not change the regulatory requirement stated in § 35.40(a) that a WD is required before the administration of all brachytherapy treatments. The information required by § 35.40 for the pre-implantation and the post-implantation WD for manual brachytherapy is changed to clarify the specific requirements unique to permanent implant brachytherapy. Additionally, § 35.3045 is modified to establish ME criteria that are specific to permanent implant brachytherapy. The NRC agrees with the commenter that a WD should be created for all brachytherapy procedures prior to treatment.

Comment: One commenter suggested that, with regard to the criterion for an ME in § 35.3045(a)(2)(iv), i.e., 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 of the dose expected to that site from the administration if carried out as specified in the WD, skin dose is not an issue with brachytherapy. This commenter noted further that for other normal tissues, there is not a clinically accepted parameter used to describe an acceptable versus an unacceptable dose to the two main normal organs at risk, the urethra and rectum. Therefore, the commenter recommended that this criterion for determining whether an ME occurred be deleted.

Response: From the reference to the two main organs at risk, the urethra and rectum, it is assumed the commenter was referring to prostate permanent brachytherapy. The NRC agrees that normally dose to the skin is not an issue in prostate permanent brachytherapy. However, this rule also governs other permanent brachytherapy procedures in which doses to the skin may be of concern. Therefore, the criterion was retained in the proposed rule.

Comment: One commenter suggested that for consistency with § 35.40(b)(6)(i), § 35.40(b)(6)(ii) should be revised to read “the number of sources and the strength of each source implanted, the date ... "

Response: The NRC does not believe that there is any inconsistency between the two paragraphs. The previous paragraph, § 35.40(b)(6)(i), requires that a pre-implantation WD contain the corresponding calculated “total source strength.” Section 35.40(b)(6)(ii) requires that the “the total source strength” implanted be recorded on the post-implantation WD. Therefore, the proposed rule language was not changed.

Comment: One commenter suggested that for clarity, § 35.3045(a)(1)(iii) should be

revised to read "A dose to the skin or an organ or tissue other than the treatment site that is exceeded by ... "

Response: The NRC reviewed the commenter's suggestion and does not agree that the clarity of the regulations would be enhanced if the changes were made. Therefore, the proposed rule language was not changed.

Comment: One commenter suggested that for clarity, § 35.3045(a)(3) should be revised to read "pre-implantation written directive results in a total source strength delivering a dose that differs by more .. ."

Response: The NRC reviewed the commenter's suggestion and does not agree that the clarity of the regulations would be enhanced if the changes were made. Therefore, the proposed rule language was not changed.

Comment: One commenter thought that the term "other sites as applicable" used in § 35.40(b)(6)(i) is too vague and is undefined.

Response: The requirement to document the intended dose to "other sites as applicable" in § 35.40(b)(6)(i) is added to the pre-implantation WD to allow the AU to clarify the intended dose to sites other than the treatment site. Many brachytherapy procedures that are properly conducted result in dose to sites other than the treatment site. The AU may exercise medical judgment in determining which (if any) "other sites" to include in the pre-implantation WD. Allowing the AU to document the dose to these other sites enables the AU to identify and clarify that doses to these sites are necessary in order to deliver the prescribed dose to the treatment site. However, it may not be feasible to more fully describe the intended dose to all

possible tissues and organs outside the treatment site.

Comment: One commenter suggested that requirements on the WD for other administrations of byproduct material or radiation from byproduct material should be similar to what is required on the WD for permanent implant brachytherapy.

Response: The comment was outside the scope of this rulemaking which revises the requirements related to reporting and notifications of MEs to clarify requirements for permanent implant brachytherapy. The comment was forwarded to the NRC's Medical Radiation Safety Team for future consideration.

Comment: One commenter suggested modifying § 35.40(a) to read "A written directive must be dated and signed by an Authorized User before the administration of I-131 sodium iodide greater than 1.11 megabecquerels (MBq) (30 microcuries (mCi)), any therapeutic dosage of unsealed *or sealed implant* byproduct material or any therapeutic dose of radiation from byproduct material."

Response: In accordance with the definitions in § 35.2, the term "dosage" refers to an activity of *unsealed* byproduct material and would not apply to activity from a sealed implant. Rather, the term "dose" refers to, and is applicable to, the energy imparted from sealed byproduct material; i.e., a sealed implant. The current regulation requires that a WD be dated and signed by an AU before any therapeutic "dose" of radiation from byproduct material; therefore, the regulation already requires that a WD be signed and dated prior to administration of radiation from a sealed implant, and the commenter's suggested addition would be redundant, and is not warranted.

V. Summary of Reproposed Revisions

1. Section 35.24 Authority and responsibilities for the radiation protection program.

This section would be amended to add a new paragraph (h) which would require licensees to provide and document additional training to individuals who participate in procedures using byproduct material requiring a WD. The training would include the requirements of § 35.3045, "Reporting and notification of a medical event," and must be provided prior to the first use, annually, and after each revision of § 35.3045. Paragraph (i) would be modified to require records of this training.

This amendment is being proposed in response to the NRC's concern that numerous individuals who had been involved in medical procedures involving MEs, indicated that they were unclear as to the ME requirements and as to their responsibilities when they believed that an ME had occurred. The NRC believes training individuals involved in procedures using byproduct material requiring a WD on the ME requirements, and on recognition of a situation in which a ME may have occurred, is essential to ensure patient health and safety.

2. Section 35.40 Written directives.

This section would be amended to create specific requirements for a WD for permanent implant brachytherapy. Paragraph (b)(5) would be modified to remove the word "or," paragraph (b)(6) would be redesignated as paragraph (b)(7), and a new paragraph (b)(6) would be added to specify the information that must be included in the pre-implantation and post-implantation WD for permanent implant brachytherapy. Additionally, paragraph (c) would be restructured and renumbered.

The information required by the new paragraph (b)(6) would clarify that the WD is divided into two parts; i.e., the pre-implantation WD and the post-implantation WD. The information required by the pre-implantation WD must be documented prior to the start of the administration and cannot be revised once the administration begins. The information required by the post-implantation WD must be documented before the patient leaves the post-treatment recovery area. The term "post-treatment recovery area," as used in paragraph (b)(6) is intended to mean the area or place where a patient recovers immediately following the brachytherapy procedure before being released to a hospital room or, in the case of an out-patient treatment, released from the licensee's facility.

3. Section 35.41 Procedures for administrations requiring a written directive.

This section would add a paragraph (d) which would require the licensee to assess the dose within 60 days of when the patient leaves the post-treatment recovery area. This amendment is proposed because the current regulations do not have a defined time as to when the dose to the treatment site and sites other than the treatment site must be determined. The occurrence of a substantial number of MEs in 2008 underscored the need to add this requirement to the regulations, as some doses related to permanent implant brachytherapy procedures during these events were not determined for more than a year after the patient was treated. The NRC believes that a more rapid assessment of patient doses is necessary to ensure that patients and their physicians can make more timely decisions regarding remedial and prospective health care.

The assessment would have to be done as specified in then-existing current published protocols accepted by nationally recognized professional organizations. A 60-day time frame is

proposed to ensure that the licensee would have ample time to make arrangements to have the dose assessed within the recommended time frames. These assessments would be used to determine if an ME must be reported as required by § 35.3045.

4. Section 35.2024 Records of authority and responsibilities for radiation protection programs.

This section would be amended to add record keeping requirements to support the proposed change to § 35.24. Paragraph (a) would be modified to add record keeping requirements that would require including a list of topics covered, the date of training, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the training. These records would have to be retained for 5 years.

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

This section would be restructured and amended to accommodate the specific criteria for reporting an ME involving permanent implant brachytherapy. Paragraph (a) would be modified to add a requirement to report, as an ME, any administration in which a WD is required and not prepared and documentation in either an individual's medical records or the licensee's standard written procedures (or both) that existed prior to the administration is insufficient to determine if an ME has occurred. Paragraph (a)(1) would accommodate the criteria for reporting as an ME situations involving an administration of byproduct material or radiation from byproduct material that does not involve permanent brachytherapy and would be modified to add language that allows information in either an individual's medical records or the licensee's standard written procedures (or both) to be used to determine if an ME has occurred

when a WD is required and not prepared. For situations involving permanent implant brachytherapy, paragraph (a)(2) would be modified to add language that allows information in an individual's medical records to be used to determine if an ME has occurred when a WD is required and not prepared.

A criterion would be added in new paragraph (a)(1)(ii)(A) for reporting as an ME an administration involving the wrong radionuclide for a brachytherapy procedure. A criterion would also be added in new paragraph (a)(1)(ii)(B) for reporting as an ME an administration using a wrong applicator in a brachytherapy procedure. A requirement would be added in new paragraph (a)(1)(iii) to clarify that the information relied upon to determine whether that specific ME has occurred must be information documented in the pre-administration WD. All other reporting and notification requirements for administrations that require a WD other than permanent implant brachytherapy would be unchanged from the current regulations.

New paragraph (a)(2) would establish separate criteria for reporting MEs involving permanent implant brachytherapy. The proposed amendments to this section would add criteria which are activity-based that focus on errors which can be recognized at the end of the procedure rather than when the dose to the treatment site is assessed at a later time. These activity-based criteria allow for earlier recognition by the licensee that an ME has occurred and allow corrective actions to be taken sooner. Dose-based criteria and exposure limits in the current regulation are being retained to ensure that the patient receives the dose that the physician intended.

Paragraph (c) would be modified to reflect the new NRC Operations Center phone number in the attached footnote.

VI. 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 will be subject to criminal enforcement.

VII. Agreement State Compatibility

Under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" approved by the Commission on June 30, 1997, and published in the *Federal Register* (62 FR 46517; September 3, 1997), this reproposed rule is a matter of compatibility between the NRC and the Agreement States, thereby providing consistency among the Agreement States and the NRC requirements. The NRC staff analyzed the reproposed rule as specified in the procedure established within Part III, "Categorization Process for NRC Program Elements," of Handbook 5.9 to Management Directive 5.9, "Adequacy and Compatibility of Agreement State Programs" (a copy of which may be viewed at http://www.nrc.gov/reading-rm/doc-collections/management-directives/).

NRC program elements (including regulations) are placed into four compatibility categories (See the Compatibility Table in this section). In addition, the NRC program elements can also be identified as having particular health and safety significance or as being reserved solely to the NRC. Compatibility Category A are those program elements that are basic radiation protection standards and scientific terms and definitions that are necessary to understand radiation protection concepts. An Agreement State should adopt Category A

program elements in an essentially identical manner to provide uniformity in the regulation of agreement material on a nationwide basis. Compatibility Category B are those program elements that apply to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. Compatibility Category C are those program elements 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 material on a nationwide basis. An Agreement State should adopt the essential objectives of the Category C program elements. Compatibility Category D are those program elements that do not meet any of the criteria of Category A, B, or C, above, and, thus, do not need to be adopted by Agreement States for purposes of compatibility.

Health and Safety (H&S) are program elements that are not required for compatibility but are identified as having a particular health and safety role (i.e., adequacy) in the regulation of agreement material within the State. Although not required for compatibility, the State should adopt program elements in this H&S category based on those of the NRC that embody the essential objectives of the NRC program elements, because of particular health and safety considerations. Compatibility Category NRC are those program elements that address areas of regulation that cannot be relinquished to Agreement States under the Atomic Energy Act, as amended, or provisions of Title 10 of the Code of Federal Regulations. These program elements are not adopted by Agreement States. The following table lists the Parts and Sections that are revised and their corresponding categorization under the "Policy Statement on

Adequacy and Compatibility of Agreement State Programs." A bracket around a category means that the section may have been adopted elsewhere, and it is not necessary to adopt it again.

Compatibility Table for Reproposed Rule

Section	Change	Subject	Compatibility	
			Existing	New
Part 35				
35.24(h)	New	Authority and responsibilities for the radiation protection program	-	H&S
35.24(i)	Amend	Authority and responsibilities for the radiation protection program	D	D
35.40(b)(5)	Amend	Written directives	H&S	H&S
35.40(b)(6)	New	Written directives	-	H&S
35.40(b)(7)	Amend	Written directives	H&S	H&S
35.40(c)(1)	Amend	Written directives	D	D
35.40(c)(2)	Amend	Written directives	D	D
35.41(d)	New	Procedures for administrations requiring a written directive	-	H&S
35.2024(a)	Amend	Records of authority and responsibilities for the radiation protection programs	D	D
35.3045(a)	Amend	Report and notification of a medical event	C	C
35.3045(a)(1)	Amend	Report and notification of a medical event	C	C
35.3045(a)(2)	Amend	Report and notification of a medical event	C	C
35.3045(c) Footnote 3	Amend	Report and notification of a medical event	C	C

VIII. 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 reproposed 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 of this document.

IX. 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 reproposed rule, the NRC would amend; §§ 35.40 and 35.3045 to revise the criteria for defining MEs, and clarify requirements for WDs for permanent implant brachytherapy; § 35.24 to add a training requirement and § 35.2024 to document the new training requirement; and § 35.41 to add a time frame for assessing a dose to the treatment site.

This action does not constitute the establishment of a standard that establishes generally applicable requirements.

X. Environmental Impact: Categorical Exclusion

The NRC has determined that this reproposed 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 reproposed rule.

XI. Paperwork Reduction Act Statement

This reproposed 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 rule has been submitted to the Office of Management and Budget (OMB) for approval of the information collection requirements.

Type of submission, new or revision: Revision.

The title of the information collection: 10 CFR Part 35, Medical Use of Byproduct Material

The form number if applicable: N/A.

How often the collection is required: As needed.

Who will be required or asked to report: Medical licensees who have occurrences of MEs.

An estimate of the number of annual responses: Increase of 4.

The estimated number of annual respondents: Increase of 4

An estimate of the total number of hours needed annually to complete the requirement or request: 44 hours

Abstract: The amendments would add criteria based on activity (total source strength) for defining some MEs for permanent implant brachytherapy; would add a requirement to report as an ME situations in which a WD is required and not prepared and documentation in either an individual's medical records or the licensee's standard written procedures (or both) that existed prior to the administration is insufficient to determine if an ME has occurred; would clarify

requirements for WDs for permanent implant brachytherapy; would add a requirement that licensees provide and document training to personnel on the requirements of § 35.3045, “Reporting and notification of a medical event;” and would add 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 make certain administrative and clarification changes.

The reproposed amendments would result in an increase of approximately 4 MEs per year. This would be as a result of the new reporting requirements for when a WD is not prepared when required, the new requirement to train personnel to recognize MEs, and the clarification in the reproposed rule that pre-implantation WDs cannot be changed once the administration has begun.

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,

MD 20852. The OMB clearance package and rule are available at the NRC worldwide Website: *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 regulations related to 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 Information 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, Office of Information and Regulatory Affairs, NEOB-10202 (3150-AI26), Office of Management and Budget, Washington, DC 20503. Comments on the proposed information collections may also be submitted via the Federal eRulemaking Portal http://www.regulations.gov, docket # NRC-2008-0071. 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.

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.

XII. Regulatory Analysis

The Commission has prepared a regulatory analysis on the reproposed rule 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 is proposing to amend 10 CFR Part 35 to revise the criteria for defining MEs and clarify requirements for WDs for permanent implant brachytherapy. The amendments would add criteria based on activity (total source strength) for defining some MEs for permanent implant brachytherapy; would add a requirement to report as an ME situations in which a WD is required and not prepared and documentation in either an individual's medical records or the licensee's standard written procedures (or both) that existed prior to the administration is insufficient to determine if an ME has occurred; clarify requirements for WDs for permanent implant brachytherapy; add a requirement that licensees provide and document training to personnel on the requirements of § 35.3045; add 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 make certain administrative and clarification changes.

This reproposed 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 as well as the NRC's evaluation of the circumstances and data from MEs that were reported in 2008. The issues raised by these incidents were discussed in several ACMUI public meetings. Public input was solicited during the development of the reproposed rule language.

1.1 Description of the Action

The reproposed rule would amend § 35.24 to add a paragraph requiring licensees to provide and document training to individuals who participate in procedures using byproduct material requiring a WD. The training would include the requirements of § 35.3045, and must be provided prior to the first use, annually, and after each revision of § 35.3045. Records of the training would have to be kept in accordance with § 35.2024.

This proposed new requirement would be added in response to the NRC's concern that numerous individuals who had been involved in medical procedures involving MEs indicated that they were unclear as to the ME requirements and as to their responsibilities when they believed that an ME had occurred. The NRC believes training individuals involved in procedures using byproduct material requiring a WD on the ME requirements, and on recognition of a situation in which a ME may have occurred, is essential to ensure patient health and safety.

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

Section 35.41 would be amended to add a paragraph (d) which would require the licensee to assess the dose within 60 days of when the patient leaves the post-treatment recovery area. This amendment is proposed because the current regulations do not have a defined time frame within which the dose to the treatment site and sites other than the treatment site must be determined. The occurrence of MEs that were reported in 2008 underscored the need to add this requirement to the regulations, as some doses related to permanent implant brachytherapy procedures during these events were not determined for

more than a year after the patient was treated. The NRC believes that a more rapid assessment of patient doses is necessary to ensure that licensees can complete more timely reviews of the circumstances leading to the ME, identify root causes, and make necessary and prompt corrections to assure that the byproduct material is being used effectively and with minimum risk to the patient and the public.

The assessment would have to be done as specified in then-existing current published protocols accepted by nationally recognized professional organizations. A 60-day time frame is proposed to ensure the licensee has ample time to make arrangements to have the dose assessed within the recommended time frames. These assessments would be used to determine if an ME must be reported as required by § 35.3045.

Section 35.2024 would be amended to add record keeping requirements to support the proposed change to § 35.24. Paragraph (a) would be modified to add record keeping requirements that would require including a list of topics covered, the date of training, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the training. These records would have to be retained for 5 years.

Section 35.3045 would be amended to add criteria for defining some MEs for permanent implant brachytherapy in terms of total source strength implanted rather than in terms of absorbed dose. These activity-based criteria would allow for earlier recognition by the licensee that an ME has occurred, and, therefore, licensees can complete more timely reviews of the circumstances leading to the ME, identify root causes, and make necessary and prompt corrections to assure that the byproduct material is being used effectively and with minimum risk to the patient and the public. As in the current regulations, source migration would be specifically excluded in certain specific circumstances in determining whether an ME has

occurred. 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 and documentation from either an individual's medical records or the licensee's standard written procedures (or both) that existed prior to the administration is insufficient to determine if an ME has occurred.

The reproposed rule would also make certain administrative and clarification changes. These changes would include updating the phone number for the NRC Operations Center; revising the numbering of various paragraphs in §§ 35.24, 35.40, 35.41, 35.2024, and 35.3045; and other minor clarifications.

1.2 Need for the Action

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 into the wrong treatment site by several licensees. Other situations were not reportable as MEs because of lack of clarity as to when and how certain information was to be entered into the WD. Additionally, the evaluation of the circumstances and data related to a substantial number of MEs reported in 2008 prompted the NRC to reevaluate its regulations related to training requirements and time frames for licensees to assess the dose to the treatment site for permanent implant brachytherapy.

Another issue identified from these medical use events was that criteria for most 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 of whether an ME has occurred at the end of the procedure. These activity-based criteria would allow for earlier recognition by the licensee that an ME has occurred; therefore, licensees would be able to complete more timely reviews of the circumstances leading to the ME, identify root causes, and make necessary and prompt corrections to ensure that the byproduct material is being used effectively and with minimum risk to the patient and the public.

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 some MEs for permanent implant brachytherapy would also entail changing the information required in a WD.

2. *Technical Basis for the Rule*

For all medical uses, the variance threshold criterion 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 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 required completion of a WD in 2003, as well as advice from the ACMUI and the NRC's evaluation of the

circumstances and data from recent MEs, 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.

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 most criteria for defining 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. These activity-based criteria allow for earlier recognition by the licensee that an ME has occurred, and, therefore, licensees can complete more timely reviews of the circumstances leading to the ME, identify root causes, and make necessary and prompt corrections to assure that the byproduct material is being used effectively and with minimum risk to the patient and the public.

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 some MEs. Additionally, the evaluation of the circumstances and data related to a substantial number of MEs reported in 2008 prompted the NRC to reevaluate its regulations related to training requirements and time frames for licensees to assess the dose to the treatment site for permanent implant brachytherapy.

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 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. 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.

During late summer and early fall of 2008, a substantial number of MEs were reported to the NRC. The NRC reviewed and analyzed the circumstances and data from these events. Based on its evaluation of this information, including an independent analysis by an NRC's medical consultant, the NRC concluded that an unacceptable number of significant permanent implant brachytherapy errors that occurred in 2008 that were appropriately categorized as MEs would not be MEs under the proposed rule published on August 6, 2008 (73 FR 45635). This was inconsistent with the original regulatory intent. The original regulatory 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. However, the intent was not to adversely impact the detection of errors such that significant errors would not be identified and reported as MEs. The NRC believes that an unacceptable number of

significant permanent implant brachytherapy errors that occurred in 2008 would not be MEs under the proposed rule published on August 6, 2008. Additionally, the evaluation of the circumstances and data prompted the NRC to reevaluate its 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 amended to incorporate this new information and the rule is being reproposed in its entirety for public comment.

3. *Alternatives Considered*

The NRC considered two alternatives for the reproposed rule:

Alternative 1: No Action

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.

Alternative 2: Add some activity-based criteria for defining MEs; clarify requirements for WDs for permanent implant brachytherapy; and add requirements for licensees to provide and document training on § 35.3045 and to assess doses to the treatment site within 60 days.

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 reproposed rule.

Authority and responsibilities for the radiation protection program (§ 35.24)

The proposed change in rule language requiring licensees to provide and document training on the requirements of § 35.3045 to individuals who participate in procedures using byproduct material requiring a WD does not constitute a new training burden. 10 CFR 19.12, "Instructions to workers," already requires individuals who are likely to receive an occupational dose in 1 year in excess of 100 mrem to be "instructed of their responsibility to report promptly to the licensee any condition which may lead to or cause a violation of Commission regulations and licenses or unnecessary exposure to radiation and/or radioactive material." Some individuals who participate in procedures using byproduct material requiring a WD are likely to receive an occupational dose in 1 year in excess of 100 mrem. Additionally, § 35.27 already requires licensees that permit use of byproduct material by an individual under the supervision of an AU to instruct the supervised individuals in the licensee's written procedures, written directive procedures, regulations of this chapter, and license conditions with respect to the use of byproduct material. The proposed change to § 35.24 would only clarify one component of the subject matter required by §§ 19.12 and 35.27. Records of the training would have to be kept in accordance with § 35.2024.

Due to increased awareness resulting from licensees providing training to individuals on the requirements of § 35.3045, the NRC anticipates an annual increase of one reported ME by medical licensees. The burden/cost for this additional ME is estimated to be $1,320 (11 hours x $120/hour).

Written Directives (§ 35.40)

Information Required to be Documented on a Written Directive for Permanent Implant Brachytherapy	
Current Regulations	Reproposed 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 reproposed 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 reproposed rule does not differ greatly from the current regulatory requirements. The reproposed rule adds 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 reproposed rule language and does not constitute a new requirement.

Under both the current regulations and the reproposed rule the WD must be completed after implantation. The requirement in the reproposed rule to have an AU sign and date the WD when the post implantation information is documented is an insignificant change for the medical licensee. Additionally, the reproposed rule would clarify that the pre-implantation WD

cannot be changed after the administration has begun.

Due to increase awareness from licensees that the pre-implantation WD cannot be changed once the administration has begun, the NRC anticipates an annual increase of two reported MEs by medical licensees. The annual burden/cost for these additional ME is estimated to be $2,640 (22 hours x $120/hour).

Procedures for administrations requiring a written directive (§ 35.41)

Requiring licensees to assess the dose to the treatment site within 60 days of when the patient leaves the post-treatment recovery area does not constitute a new burden on licensees. Section 35.41(b)(2) already requires licensees to verify "that the administration is in accordance with the treatment plan, if applicable, and the written directive." Verifying the administration includes determining the dose to the treatment site. The proposed change would only specify the time frame in which this must be accomplished. The result is that there would be no increase of burden or cost to the medical licensees.

Records of authority and responsibilities for radiation protection programs (§ 35.2024)

Record keeping requirements would be added to support the proposed change to § 35.24. Documenting required training on the ME requirements by the licensee is important because numerous individuals who had been involved in medical procedures involving MEs indicated that they were unclear as to the ME requirements and as to their responsibilities when they believed that an ME had occurred. Requiring the licensee to document the training would ensure that all the appropriate individuals have received training.

This record keeping requirement would be a new burden/cost. The annual

recordkeeping burden for documenting the training that would be required by § 35.3024 is estimated to be approximately 0.25 hours per licensee. Based on the number of licensees potentially affected (359 NRC licensees and 2298 Agreement State licensees for a total of 2657 licensees) the annual total number of additional burden hours would be approximately 665 hours (0.25 hours x 2657). The annual increase in burden/cost for documenting the training required by § 35.24 for 2657 licensees would be approximately $79,800 (665 hours x $120/hour). This equates to approximately $30.00 per licensee ($79,800 / 2657 licensees).

Report and Notification of a Medical Events (§ 35.3045)

The addition of new activity-based criteria to the ME reporting requirements should not cause an increase in the number of MEs reported, because it is assumed that any ME identified by the new activity-based criteria would have been identified by the existing dose-based criteria. The addition of activity-based criteria would only allow the licensee to recognize the ME in less time. However, adding the requirement to report as an ME when a WD is not prepared when required would result in an annual increase of one reported ME by medical licensees. The annual burden/cost for this additional ME is estimated to be $1,320 (11 hours x $120/hour).

Based on NRC staff estimates, the number of reported MEs would increase by approximately four per year. This increase would result from the new reporting requirements for when a WD is not prepared when required, the new requirement to train personnel to recognize MEs, and the clarification in the reproposed rule that pre-implantation WDs cannot be changed after the administration has begun. This increase would result in an increase of cost by approximately $5,280 (44 hours x $120/hour). This equates to approximately $2.00 per licensee ($5,280 / 2657 licensees).

The total annual burden/cost for this proposed rulemaking would be approximately $85,080 (665 hours to document training + 44 hours to report MEs x $120/hour). The total annual cost per licensee would be approximately $32.00 ($85,080 / 2657 licensees).

The characteristics in both the public and private sectors that are affected by the reproposed 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 are impacted by this reproposed rule:

Public Health Benefits. Although the number of reported MEs is anticipated to be approximately only four more annually, protection of the health and safety of patients would be increased by this change to the regulation. One example of the change that would increase public health and safety is the addition of some activity-based criteria for determining if an ME has occurred. Having activity-based criteria would allow licensees to determine whether some MEs have occurred before the patient leaves the post-treatment recovery area. This would allow the licensees to complete more timely reviews of the circumstances leading to the ME, identify root causes, and make necessary and prompt corrections to ensure that the byproduct material is being used effectively and with minimum risk to the patient and the public.

Other changes to the regulation that would increase protection of the health and safety of the patient include:

- The addition of a criterion that requires the licensee to report as an ME situations where a WD is required and not prepared, and documentation in either an individual's medical records or the licensee's standard written procedures (or both) that existed prior to the administration is insufficient to determine if an ME has occurred. The failure to prepare a WD in most cases results from a licensee's failure to follow its processes and

procedures. Adding this criterion ensures that the licensees are properly following their processes and procedures.

- Prohibiting modifying the pre-implantation WD after the procedure has begun. This ensures the pre-implantation WD, which is used to determine if certain MEs have occurred, is not changed in order to avoid reporting MEs.
- Requiring an AU to sign and date the post-implantation WD before the patient leaves the post-recovery area. This ensures that the information added to the post-implantation WD has been properly reviewed and approved.
- Requiring licensees to assess the dose within 60 days from when the patient leaves the post-treatment recovery area. Having the dose assessed within 60 days from when the patient leaves the post-recovery area would ensure that licensees complete more timely reviews of the circumstances leading to the ME, identify root causes, and make necessary and prompt corrections to assure that the byproduct material is being used effectively and with minimum risk to the patient and the public.
- Requiring licensees to provide and document training to individuals who participate in procedures using byproduct material requiring a WD. This ensures that MEs are recognized and reported, thus reducing situations where an ME has occurred but has not been recognized and a patient's health and safety may be at risk.

Industry Implementation. 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. However, the NRC anticipates that there would be an increase in the number of reported MEs by approximately four per year. This increase would result from the new reporting requirements for situations when a WD is not prepared when required, the new

requirement to train personnel regarding the requirements for reporting MEs, and the clarification in the reproposed rule that pre-implantation WDs cannot be changed after the administration has begun. Therefore, the industry would have an increase in expenses from implementation of this reproposed rule

The proposed requirements for licensees to provide and document additional training to individuals who participate in procedures using byproduct material requiring a WD and to assess the dose to the treatment site within 60-days of treatment would not create any implementation issues, because both actions are already required under current regulations. Training is currently required by §§ 19.12 and 35.27 and assessing dose is currently required by § 35.41.

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

Other Government. Agreement State governments would incur a one-time cost for adopting rule changes 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 Part 35.

Each Agreement State has 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 as a final rule. On average each State would be expected to expend approximately 0.1 FTE to amend their State regulation, which, based on an average of approximately $76,000 per FTE, would equal approximately $7,600 per State. With 38 Agreement States, the total cost would be approximately $288,800.

Other Considerations. Public confidence in the 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, requiring training on recognizing MEs, and requiring doses to the treatment site to be assessed with 60 days from the patient leaving the post-treatment recovery area.

5. *Decision Rationale and Implementation*

The assessment of costs and benefits discussed previously leads the NRC to the conclusion that the reproposed rule would not have a significant economical impact on medical licensees who are performing therapeutic procedures using byproduct material. The reproposed 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 it easier to determine whether an ME has occurred during the procedure, and therefore, improve the reliability of ME recognition and reporting. A requirement for an AU for § 35.400 uses for

manual brachytherapy to sign the WD after administration, but before the patient leaves the post-treatment recovery area, would ensure that the information added to the post-implantation WD has been properly reviewed and approved.

Requiring licensees to provide and document training to individuals who participate in procedures using byproduct material requiring a WD on the requirements of § 35.3045 would ensure that MEs are recognized and reported, thus reducing situations in which an ME has occurred but has not been recognized and a patient's health and safety may be at risk. Having the dose assessed within 60 days of the patient leaving the post-recovery area would ensure that licensees complete more timely reviews of the circumstances leading to the ME, identify root causes, and make necessary and prompt corrections to assure that the byproduct material is being used effectively and with minimum risk to the patient and the public.

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

XIII. Regulatory Flexibility Certification

Under 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. The majority of companies that own these facilities do not fall within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act or the size standards established by the NRC (10 CFR 2.810).

XIV. Backfit Analysis

The NRC has determined that the backfit rule, which is found in the regulations at §§ 50.109, 70.76, 72.62, 76.76, and in 10 CFR Part 52, does not apply to this reproposed rule because this amendment does 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 In 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 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 § 35.24, paragraph (h) is revised and redesignated as paragraph (i) and a new paragraph (h) is added to read as follows:

§ 35.24 Authority and responsibilities for the radiation protection program.

* * * * *

(h) A licensee shall provide training on the requirements of § 35.3045, Reporting and notification of a medical event, to all individuals who participate in procedures using byproduct material requiring a written directive prior to the first use, annually, and after each revision of § 35.3045.

(i) A licensee shall retain a record of actions taken under paragraphs (a), (b), (e) and (h) of this section in accordance with § 35.2024.

3. 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 (pre-implantation): the treatment site, the radionuclide, the intended dose to the treatment site and other sites as applicable, and the corresponding calculated total source strength required; and

(ii) After administration (post-implantation) but before the patient leaves the post-treatment recovery area: the total source strength implanted, the date, and the signature of an Authorized User for § 35.400 uses for manual brachytherapy; 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.

* * * * *

4. In § 35.41, a new paragraph (d) is added to read as follows:

§ 35.41 Procedures for administrations requiring a written directive.

* * * * *

(d) 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 written directive in accordance with then-existing current published protocols accepted by nationally recognized professional organizations and no later than 60 days from the date that the patient left the post-treatment recovery area. These assessments must be used to determine if a

medical event must be reported as required by § 35.3045.

5. In § 35.2024, paragraph (a) is revised to read as follows:

§ 35.2024 Records of authority and responsibilities for radiation protection programs.

(a) A licensee shall retain a record of actions taken by the licensee's management in accordance with § 35.24(a) and (h) for 5 years. The record for § 35.24(a) must include a summary of the actions taken and a signature of licensee management. The record for § 35.24(h) must include a list of topics covered, the date of training, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the training.

* * * * *

6. 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 and documentation from either an individual's medical records or the licensee's standard written procedures (or both) that existed prior to the administration is insufficient to determine if a medical event has occurred 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 to the treatment site that differs from the prescribed dose, or dose that would have resulted from the prescribed dosage, or dose or dosage supported by either an individual's medical records or the licensee's standard written procedures (or both) that existed prior to the administration when no written directive was prepared, 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, or dose supported by either an individual's medical records or the licensee's standard written procedures (or both) that existed prior to the administration when no written directive was prepared, by 20 percent or more;

(B) The total dosage delivered differs from the prescribed dosage, or dosage supported by either an individual's medical records or the licensee's standard written procedures (or both) that existed prior to the administration when no written directive was prepared, by 20 percent or more or falls outside the prescribed dosage range; or

(C) The fractionated dose delivered differs from the prescribed dose, or dose supported by either an individual's medical recordsor the licensee's standard written procedures (or both) that existed prior to the administration when no written directive was prepared, 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 from the administration defined in the pre-administration written directive or dose supported by either an individual's medical records or the licensee's standard written procedures (or both) that existed prior to the administration when no written directive was prepared.

(2) The administration of byproduct material or radiation from byproduct material for permanent implant brachytherapy results in —

(i) The total dose delivered to the treatment site differing by 20 percent or more from the intended dose documented in the pre-implantation written directive or supported by an individual's medical records that existed prior to the administration when no written directive was prepared.

(ii) The total source strength administered differing by 20 percent or more from the intended total source strength documented in the pre-implantation written directive or supported by an individual's medical records that existed prior to the administration when no written directive was prepared.

(iii) The total source strength administered differing by 20 percent or more from the total source strength documented in the post-implantation written directive.

(iv) The total source strength administered outside the treatment site exceeding 20 percent of the total source strength administered (excluding sources that were implanted in the correct site but migrated outside the treatment site).

(v) 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 from the administration defined in the pre-implantation written directive or supported by an individual's medical records that existed prior to the administration when no written directive was prepared (excluding sources that were implanted in the correct site but migrated outside the treatment site).

(vi) 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.

* * * * *

(c) * * *

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

* * * * *

Dated at Rockville, Maryland, this day of , 2010.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,
Secretary of the Commission.

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 § 35.24, paragraph (h) is revised and redesignated as paragraph (i) and a new paragraph (h) is added to read as follows:

§ 35.24 Authority and responsibilities for the radiation protection program.

* * * * *

(h) A licensee shall provide training on the requirements of § 35.3045, Reporting and notification of a medical event, to all individuals who participate in procedures using byproduct material requiring a written directive prior to the first use, annually, and after each revision of § 35.3045.

(i) A licensee shall retain a record of actions taken under paragraphs (a), (b), (e) and (h) of this section in accordance with § 35.2024.

3~~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 (pre-implantation): the treatment site, the radionuclide, the intended dose to the treatment site and other sites as applicable ~~necessary~~, and the corresponding calculated total source strength required; and

(ii) After administration (post-implantation) but before the patient leaves the post-treatment recovery area: the total source strength implanted, the date, and the signature of ~~AU~~ an authorized user for § 35.400 uses for manual brachytherapy; 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~~4. In § 35.41, a new paragraph (d) is added to read as follows:

§ 35.41 Procedures for administrations requiring a written directive.

* * * * *

(d) 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 written

directive in accordance with then existing current published protocols accepted by nationally recognized professional organizations and no later than 60 days from the date that the patient left the post-treatment recovery area. These assessments must be used to determine if a medical event must be reported as required by § 35.3045.

5. In § 35.2024, paragraph (a) is revised to read as follows:

§ 35.2024 Records of authority and responsibilities for radiation protection programs.

(a) A licensee shall retain a record of actions taken by the licensee's management in accordance with § 35.24(a) and (h) for 5 years. The record for § 35.24(a) must include a summary of the actions taken and a signature of licensee management. The record for § 35.24(h) must include a list of topics covered, the date of training, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the training.

6. 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 and documentation from either an individual's medical records or the licensee's standard written procedures (or both) that existed prior to the administration is insufficient to determine if a medical event has occurred 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 to the treatment site that differs from the prescribed dose, or dose that would have resulted from the prescribed dosage, or dose or dosage supported by either an individual's

medical records or the licensee's standard written procedures (or both) that existed prior to the administration when no written directive was prepared, 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, or dose supported by either an individual's medical records or the licensee's standard written procedures (or both) that existed prior to the administration when no written directive was prepared, by 20 percent or more;

(B) The total dosage delivered differs from the prescribed dosage, or dosage supported by either an individual's medical records or the licensee's standard written procedures (or both) that existed prior to the administration when no written directive was prepared, by 20 percent or more or falls outside the prescribed dosage range; or

(C) The fractionated dose delivered differs from the prescribed dose, or dose supported by either an individual's medical records or the licensee's standard written procedures (or both) that existed prior to the administration when no written directive was prepared, 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~~ from the administration ~~had been carried out as specified~~ defined in the pre-administration written directive or dose supported by either an individual's medical records or the licensee's standard written procedures (or both) that existed prior to the administration when no written directive was prepared.

(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.~~

(i) The total absorbed dose delivered to the treatment site differing by 20 percent or more from the intended dose documented in the pre-implantation written directive or supported by an individual's medical records that existed prior to the administration when no written directive was prepared.

~~(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.~~

(ii) The total source strength administered differing by 20 percent or more from the intended total source strength documented in the pre-implantation written directive or supported by an individual's medical records that existed prior to the administration when no written directive was prepared.

~~(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.~~

(iii) The total source strength administered differing by 20 percent or more from the total source strength documented in the post-implantation written directive.

(iv) The total source strength administered outside the treatment site exceeding 20 percent of the total source strength administered (excluding sources that were implanted in the correct site but migrated outside the treatment site).

(i~~v~~v) 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~~ from the administration ~~had been carried out as specified~~ defined in the pre-implantation written directive or supported by an individual's medical records that existed prior to the administration when no written directive was prepared (excluding sources that were implanted in the correct site but migrated outside the treatment site).

(~~v~~vi) 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.~~

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(c) * * *

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

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