[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:** Final rule.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) is amending its regulations governing medical use of byproduct material related to reporting and notifications of medical events (MEs) to clarify requirements for permanent implant brachytherapy. The amendments will change most criteria for defining MEs for permanent implant brachytherapy from dose-based to activity-based; add a requirement to report as an ME situations when a written directive (WD) is required and not prepared and documentation in medical records is insufficient to determine if an ME has occurred; clarify requirements for WDs for permanent implant brachytherapy; and make certain administrative and clarification changes.

These amendments regarding permanent implant brachytherapy are being made in response to several incidents involving therapeutic use of byproduct material. The changes are based in part on recommendations from NRC's Advisory Committee on the Medical Use of

Isotopes (ACMUI) and the NRC staff. This rule will affect all medical licensees that perform procedures using byproduct material that require completion of a WD.

**EFFECTIVE DATE:** This final rule is effective on (**insert date 90 days from date of publication in the Federal Register**)

**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.

**SUPPLEMENTARY INFORMATION:**

## I. Background

MEs are events that meet the criteria in 10 CFR 35.3045(a) or (b). These events are incidents in which the end result of a medical use of radioactive material is significantly different from what was 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 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 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 medical events because of lack of clarity as to when and how certain information was to be entered into the WD.

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

ACMUI, in considering the issue of defining MEs involving permanent implant brachytherapy, concluded that the 20 percent variance from the prescription criterion in the existing rule continued to be appropriate for permanent implant brachytherapy if both the prescription and the variance could be expressed in units of activity, rather than in units of dose, because there is no suitable clinically used dose metric available for judging the occurrence of MEs. The NRC staff agrees that, for permanent implant brachytherapy, total source strength (activity-based) is an acceptable alternative to total dose (dose-based) for the purpose of determining the occurrence of most MEs.

In March 2004, the NRC staff began its interactions with the ACMUI on issues relating to the adequacy of ME criteria for permanent implant brachytherapy. ACMUI 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 final 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 the Summary of Public Comments on the Proposed Rule section in the Supplementary Information of this document.

## II. Discussion

### *A. What Action is the NRC Taking?*

The NRC is amending 10 CFR 35.40 and 35.3045 to establish separate ME criteria and WD requirements for permanent implant brachytherapy. This amendment adds a requirement

to report as an ME instances when a written directive is required, but not prepared, and documentation in medical records is insufficient to determine if an ME has occurred and, additionally, makes minor administrative and clarification changes.

Section 35.3045 is 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. Additionally, minor changes have been made to the language in the regulations to accommodate this revision.

*B. Who Will This Action Affect?*

This final rule will 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. Public input was solicited on the preliminary draft rule language via http://www.regulations.gov (Docket ID # NRC-2008-0071) on February 8, 2008, and published 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 out on the NRC's Medical List Server on February 8, 2008. All public input on the preliminary draft rule language received was considered in formulating this final rule.

The NRC published a proposed rule (73 FR 45635) 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) per 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 the Summary of Public Comments on the Proposed Rule section in the Supplementary Information of this document.

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

The final rule defines most ME criteria in terms of the total source strength (activity-based) rather than dose or dosage (dose-based). This change focuses on what the AU can control; namely, into which organ or treatment site the sources are implanted, instead of the absorbed dose distribution, over which AU control is limited. Additionally, for the most commonly practiced forms of image-guided source implantation, definitive dose distributions may not be available until several weeks after completion of the procedure. On the other hand, the number

of sources implanted in the treatment site (and hence total source strength) can be assessed before the patient leaves the post-recovery area (e.g., via intraoperative imaging for prostate implants.)

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

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

No. The final rule retains dose-based criteria in two situations in which an activity-based criterion cannot be applied. One situation relates to determining if an error in calculations had occurred. Specifically, prior to implantation, an AU prescribes his or her treatment intention in units of absorbed dose to the treatment site, and the intended dose along with the corresponding calculated total source strength is documented in the pre-implantation WD. However, an error may be made in the calculations used to determine the total source strength that will deliver the desired dose. As a result, although the prescribed total source strength is delivered, the intended dose to the treatment site is not achieved. The second situation relates to exposure to the skin, organs, and tissues other than the treatment site. The exposure limits in the current regulations for these areas are retained in the final rule because dose is a necessary factor in making a determination as to whether an excess exposure has occurred.

*F. 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 medical records and licensees' standard written procedures which can be used to determine if an ME has occurred.

Therefore, the final rule provides that the licensee may use medical records and licensees' standard written procedures to determine if an ME has occurred when a WD was not prepared. If a WD was not prepared and the documentation from medical records and licensees' standard written procedures is sufficient to determine an ME has not occurred, the event is not reportable as an ME. This requirement ensures that the health and safety of medical patients are protected. Not preparing a WD when required is still a violation of NRC regulations.

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

The WD requirements for permanent implant brachytherapy in the final rule are changed to support both the activity-based and dose-based ME criteria. The requirement to document the intended dose to the treatment site and other sites as necessary is 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 AU to identify and clarify that doses to these sites are necessary in order to deliver the prescribed dose to the treatment site.

The permanent implant brachytherapy post-implantation WD requirements include specifying at what point a permanent implant brachytherapy procedure is considered to be complete, i.e., before the patient leaves the post-treatment recovery area; the total source strength implanted; the date; and the signature of an AU for § 35.400 uses for manual brachytherapy.

Current regulations specify that after implantation but before completion of the procedure, certain information required by the regulations must be added to the WD. The current regulations do not clearly define "completion of the procedure" for permanent implant brachytherapy and as a result, there has been confusion as to when the required information must be added to the post-implantation WD. The final rule removes the term “completion of the procedure” and clarifies that post-implantation information must be documented in the WD after administration but before the patient leaves the post-treatment recovery area.

The requirement in the current regulation to document the treatment site and nuclide 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 is added to ensure that the information added to the post-implantation WD has been properly reviewed and approved. This change clarifies the intent of the current regulation that an AU must approve all required information on the WD.

*H. 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.

*I. What is the 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.

*J. Why Was Reference to a 3 cm Boundary Removed From the Final 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 limit on sources that could be implanted within the 3 cm boundary of the treatment site would interfere with clinical judgment of the AU. Based on recent advances in technology and other factors stated in the

public comments, including ACMUI reconsideration of its original recommendation, the final rule language was changed to remove references to any boundaries beyond the treatment site.

*K. 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.

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

No. The final 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.

*M. Has NRC Prepared a Cost-Benefit Analysis?*

NRC staff has prepared a regulatory analysis for this rulemaking. This analysis shows a reduction in cost by approximately $5,211 annually from this final rule. More detailed information on this subject is in Section X. of this document.

*N. Has NRC Evaluated the Paperwork Burden to Licensees?*

This final 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 final rule will 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 IX., Paperwork Reduction Act Statement of this document.

## III. Summary of Public Comments on the Proposed Rule

The NRC received 57 comment letters on the proposed rule, 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, Public File Area O1F21, 11555 Rockville Pike, Rockville, MD. 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 will 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 final rule allows for 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 final 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 written directive 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:* This ME criterion was based on recommendations from ACMUI to the NRC in 2005. During the public comment period, ACMUI reconsidered its original recommendation (i.e., to use a 3 cm boundary as a criterion for determining whether an ME as occurred) and, based on recent advances in technology and other factors, ACMUI recommended that the 3 cm boundary not be used as a criterion for defining an ME. Many other comments from the public supported this new ACMUI position. After reviewing the public comments the NRC agrees that

having an ME criterion based on a 3 cm boundary creates unintended ambiguity and may interfere with the clinical judgment of the AU. The final rule language was 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.

*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 patients. 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 medical records and licensees' standard written procedures which can be used to determine if a ME has occurred. Therefore, the final rule language has been modified to provide that the licensee may use information documented in medical records and licensees' standard written procedures to determine if an ME has occurred when a WD was not prepared. If a WD was not prepared when required and the documentation from medical records and licensees' standard written procedures is sufficient to allow for a determination that an ME has not occurred, the event is not reportable as an ME. However, the failure to prepare a WD when required is still a violation of NRC regulations.

*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 thus, to potentially avoid harm to patients or the public.

*Comment:* One commenter asserted that the changes to the definition of a medical event are inconsistent with the original recommendation made by ACMU 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 written directive 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.

Furthermore, while 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 considers all stakeholders' comments and concerns in developing the final 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 final 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 final 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 written directive, 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, such as the uses of mesh grids, in which doses to the skin may be of concern. Therefore, the criterion was retained in the final 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 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 final 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 final 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 final 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 necessary" 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 written directive. 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 written directive for

other administrations of byproduct material or radiation from byproduct material should be similar to what is required on the written directive 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:* A therapeutic dosage refers to the use of radiopharmaceuticals, such as pills and liquids that contain byproduct material. A sealed implant consists of radioactive sources, such as seeds and other sealed sources used in brachytherapy. It does not include radiopharmaceuticals. Therefore adding the term "sealed implant" as part of a therapeutic dosage is not the proper use of the term and was not added to the final rule language.

## IV. Summary of Final Revisions

1. Section 35.40 Written directives.

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

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

This section is restructured and amended to accommodate the specific criteria for reporting an ME involving permanent implant brachytherapy. Paragraph (a) is modified to add a requirement to report as an ME any administration in which a WD is required and not prepared and documentation in medical records and licensees' standard written procedures is insufficient to determine if an ME has occurred. Paragraph (a)(1) accommodates the criteria for reporting as an ME situations involving an administration of byproduct material or radiation from byproduct material except permanent brachytherapy. Paragraphs (a)(1) through (a)(2) are 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 is 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 is also 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 is added in new paragraph (a)(1)(iii) to clarify that the information relied upon to determine whether that specific ME has occurred must be that information documented in the pre-administration WD. All other reporting and notification requirements for administrations that require a WD other than permanent implant brachytherapy are unchanged.

New paragraph (a)(2) separately establishes the criteria for reporting MEs involving permanent implant brachytherapy. The amendments revise most criteria for defining MEs for permanent implant brachytherapy from dose-based to activity-based. Dose-based criteria is retained in two situations in which an activity-based criterion cannot be applied; i.e., in determining if an error in calculations occurred, and with regard to exposure limits to the skin, organs, and tissues other than the treatment site.

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

## V. Criminal Penalties

For the purpose of Section 223 of the Atomic Energy Act (AEA), the Commission is issuing the final rule 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.

## VI. 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 final 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 final rule in accordance with 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 Final Rule

| Section | Change | Subject | Compatibility | |
|---|---|---|---|---|
| | | | Existing | New |
| Part 35 | | | | |
| 35.40(b) | Amend | | H&S | H&S |
| 35.40(c) | Amend | | D | D |
| 35.3045 | Amend | | C | C |

VII. Voluntary Consensus Standards

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

## VIII. Environmental Impact: Categorical Exclusion

The NRC has determined that this final 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 final rule.

## IX. Paperwork Reduction Act Statement

This final rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These requirements were approved by the Office of Management and Budget, approval number 3150-0010.

Because the rule will reduce the burden for existing/modified information collection requirements, the public burden for these information collections is expected to be decreased by 10.1 hours per licensee. This reduction includes the time required for reviewing instructions,

searching existing data sources, gathering and maintaining the data needed and completing and reviewing the information collection. Send comments on any aspect of these information collections, including suggestions for further reducing the burden, to the Records and FOIA/Privacy Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet electronic mail to INFOCOLLECTS@NRC.GOV; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0010), Office of Management and Budget, Washington, DC 20503.

Public Protection Notification

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

## X. Regulatory Analysis

The Commission has prepared a regulatory analysis on the final 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 amending 10 CFR 35.40 and 35.3045 to revise the criteria for defining MEs and clarify requirements for WDs for permanent implant brachytherapy. The amendments will change the criteria for defining most MEs for permanent implant brachytherapy from dose-based to activity-based; add a requirement to report as an ME when a written directive is

required and not prepared and documentation in medical records is insufficient to determine if an ME has occurred; clarify requirements for WDs for permanent implant brachytherapy; and make certain administrative and clarification changes.

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

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

## 1.1 Description of the Action

The final rule amends § 35.3045 to change the criteria for defining most MEs for permanent implant brachytherapy in terms of total source strength implanted rather than in terms of absorbed dose. The final rule retains dose-based criteria for two situations where activity-based criterion cannot be applied. One criterion relates to determining if an error in calculations had occurred. The second criterion relates to the exposure to the skin, organs, and tissues other than the treatment site. As in the current regulations, source migration is specifically excluded in certain specific circumstances in determining whether an ME has occurred. One additional ME criterion is added that requires a medical licensee to report, as an

ME, any administration requiring a WD if a WD was not prepared and the documentation from medical records is insufficient to determine if a medical event has occurred.

Section 35.40 is 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.

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

1.2 Need for the Action

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

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

Another issue identified from these medical use events was that criteria for MEs for permanent implant brachytherapy are dose-based. Under current regulations, determining

whether an ME had occurred for permanent implant brachytherapy was not done until the dose to the treatment site was determined and often was not done for some time after the procedure. ACMUI recommended that the criteria for defining most MEs for permanent implant brachytherapy be based on activity which allows for a determination of whether an ME has occurred at the end of the procedure. Activity-based criteria allow for earlier recognition by the licensee that an ME has occurred and allow corrective actions to be taken sooner which results in an increase in the health and safety of the patient. Additionally, because the AU can control where the brachytherapy sources are implanted, activity-based ME criteria will result in less occurrences of MEs for permanent implant brachytherapies.

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

2. *Technical Basis for the Rule*

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

Several medical use events involving therapeutic use of byproduct material that require completion of a WD in 2003, as well as advice from the ACMUI, prompted the NRC to

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

In March 2004, the NRC staff began its interactions with the ACMUI on the issues related to the adequacy of ME definitions. ACMUI established a 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.

3. *Alternatives Considered*

The NRC considered two alternatives for the final 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: Revise the criteria for defining MEs and clarify requirements for WDs for permanent implant brachytherapy.

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 final rule.

Report and Notification of a Medical Events (§ 35.3045)

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

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

The net result is that the amendments to § 35.3045 will decrease cost to medical

licensees by $5,211.

Written Directives (§ 35.40)

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

Under both the current regulations and the final rule, the WD must be completed after implantation. The requirement in the final rule to have the AU sign and date the WD when the

post implantation information is documented is an insignificant change for the medical licensee.

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

The characteristics, in both the public and private sectors that are affected by the final 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 final rule:

*Public Health Benefits.* Although the number of reported MEs is anticipated to be approximately two less annually, protection of the health and safety of patients is increased by this change to the regulation. One example of the change that increases public health and safety is the change in most criteria for determining if an ME has occurred from dose-based to activity-based. Having activity-based criteria allows licensees to determine in most cases whether MEs have occurred before the patient leaves the post-recovery area. This allows the patient and physician to make timely medical decisions related to the procedure and corrective actions can be taken sooner by the licensee.

Other changes to the regulation that 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 medical records 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 the 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.

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

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

*Other Government*. Agreement State governments will incur a one-time cost for adopting this final rule into their State regulations governing the use of radioactive material. Under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" approved by the Commission on June 30, 1997 (62 FR 46517), specific requirements within this rule should be adopted by Agreement States for purposes of compatibility or because of health and safety

significance. Implementing procedures for the Policy Statement establish specific categories which have been applied to categorize the requirements in Parts 35. The final rule amends the following sections and paragraphs that are covered under the Policy Statement:

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

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

3. § 35.40(b), which has a Compatibility Category H&S designation under the Policy Statement. The Compatibility Category Health & Safety (H&S) identifies program elements that are not required for purposes of compatibility, but have particular health and safety significance. States should adopt the essential objectives of such program elements in order to maintain an adequate program.

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 final rule. On average each State will expend 0.1 FTE to amend their State regulation, which, based on $76,000 per FTE, will equal $7,600 per State. With 36 Agreement States, the total cost will be $273,600.

The Agreement States are required to report MEs that occur under their jurisdiction to the NRC. As noted in Section 4 of this Regulatory Analysis, the amendments to § 35.3045 will

decrease the cost to medical licensees and the amendments to § 35.40 will have a negligible increase of in burden or cost to the medical licensees. Also, there is no additional burden to the Agreement States for licensing or inspections.

*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.

5. *Decision Rationale and Implementation*

The assessment of costs and benefits discussed previously leads the NRC to the conclusion that the final rule will not have a significant economical impact on medical licensees who are performing therapeutic procedures using byproduct material. The final rule will 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 will 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 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, ensures that the information added to the post-implantation WD has been properly reviewed and approved.

The Commission requested public comment on this regulatory analysis as part of the proposed rule published on August 6, 2008 (73 FR 45635). No comments were received during the public comment period.

## XI. Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the Commission certifies that this rule does not 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

## XII. Backfit Analysis

The NRC has determined that the backfit rule (§§ 50.109, 70.76, 72.62, or 76.76) does not apply to this final 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.

## XIII. Congressional Review Act

In accordance with the Congressional Review Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

List of Subjects In 10 CFR Part 35

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. 552 and 553; the NRC is adopting the following amendments to 10 CFR Part 35.

PART 35--MEDICAL USE OF BYPRODUCT MATERIAL

1. The authority citation for Part 35 continues to read as follows:

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

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

**§ 35.40 Written directives.**

* * * * *

(b) * * *

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

(6) For permanent implant brachytherapy:

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

(ii) After administration (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

(7) * * * * *

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

(2) If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by the authorized user within 48 hours of the oral revision.

* * * * *

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

**§ 35.3045 Report and notification of a medical event.**

(a) A licensee shall report as a medical event any administration requiring a written directive if a written directive was not prepared and the documentation from medical records 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 that differs from the prescribed dose, or dose that would have resulted from the prescribed dosage, or dose or dosage supported by an individual's medical records 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 an individual's medical records 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 an individual's medical records 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 an individual's medical records 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 an individual's medical records 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 source strength administered differing by 20 percent or more from the total source strength documented in the pre-implantation written directive or supported by an individual's medical records when no written directive was prepared.

(ii) The total source strength administered outside the treatment site exceeding 20 percent of the total source strength documented in the post-implantation written directive or supported by an individual's medical records when no written directive was prepared (excluding sources that were implanted in the correct site but migrated outside the treatment site).

(iii) 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 when no written directive was prepared (excluding sources that were implanted in the correct site but migrated outside the treatment site).

(iv) 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 pre-implantation written directive or dose supported by an individual's medical records when no written directive was prepared that resulted in an administered total source strength that delivered a dose differing by more than 20 percent from the intended dose to the treatment site.

* * * * *

(c) * * *

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

* * * * *

Dated at Rockville, Maryland, this_____ day of_____, 2009.

For the Nuclear Regulatory Commission.

_____
Annette Vietti-Cook,
Secretary of the Commission.