was published in June 3, 2013; 78 FR 33117. The notice provided an opportunity to submit comments on the Commission's proposed NSHC determination. No comments have been received. The notice also provided an opportunity to request a hearing by August 2, 2013, but indicated that if the Commission makes a final NSHC determination, any such hearing would take place after the issuance of the amendment.

The Commission's related evaluation of the amendment, finding of exigent circumstances, state consultation, and final NSHC determination are contained in a safety evaluation dated June 22, 2013.

Attorney for licensee: General Counsel, Tennessee Valley Authority, 400 West Summit Hill Drive, ET 11A, Knoxville, Tennessee 37902.

NRC Branch Chief: Jessie F. Quichocho.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated June 19, 2013.

No significant hazards consideration comments received: No.

Dated at Rockville, Maryland, this 28th day of June 2013.

For the Nuclear Regulatory Commission.

Michele G. Evans,

Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2013–16293 Filed 7–8–13; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2013–0114]

Interim Enforcement Policy for Permanent Implant Brachytherapy Medical Event Reporting

AGENCY: Nuclear Regulatory Commission.

ACTION: Policy statement; revision.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing an interim Enforcement Policy that allows the staff to exercise enforcement discretion for certain violations of regulations for reporting medical events occurring under an NRC licensee's permanent implant brachytherapy program. This interim policy affects NRC licensees that are authorized to perform permanent implant brachytherapy.

DATES: This policy revision is effective July 9, 2013. The NRC is not soliciting comments on this revision to its Enforcement Policy at this time.

ADDRESSES: Please refer to Docket ID NRC–2013–0114 when contacting the NRC about the availability of information regarding this document. You may access information related to this document, which the NRC possesses and is publicly available, using any of the following methods:

- Federal Rulemaking Web site: Go to *http://www.regulations.gov* and search for Docket ID NRC–2013–0114. Address questions about NRC dockets to Carol Gallagher; telephone: 301–492–3668; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- NRC's Agencywide Documents Access and Management System (ADAMS): You may access publicly available documents online in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*ADAMS Public Documents*'' and then select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced in this document (if that document is available in ADAMS) is provided the first time that a document is referenced. The Enforcement Policy is available in ADAMS under Accession No. ML12340A295.
- NRC's PDR: You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

The NRC maintains the *Enforcement Policy* on its Web site at *http://www.nrc.gov;* select ''Public Meetings and Involvement,'' then ''Enforcement,'' and then ''Enforcement Policy.''

FOR FURTHER INFORMATION CONTACT: Kerstun Day, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–1252; email: *Kerstun.Day@nrc.gov.*

SUPPLEMENTARY INFORMATION:

Background

In SECY–05–0234, ''Adequacy of Medical Event Definitions in 10 CFR [Title 10 of the Code of *Federal Regulations*] 35.3045, and Communicating Associated Risks to the Public,'' (ADAMS Accession No. ML041620583), dated December 27, 2005, the staff recommended that the Commission approve the staff's plan to revise the medical event definition and the associated requirements for written directives to be source strength-based instead of dose-based. The Commission directed the staff to proceed directly with the development of a proposed rule to modify both the written directive requirements in § 35.40(b)(6) and the medical event reporting requirements in § 35.3045 for permanent implant brachytherapy. The modified medical event reporting requirements would allow the medical event criteria to be based on source strength as opposed to dose. In SRM–SECY–08–0080, ''Proposed Rule: Medical Use of Byproduct Material—Amendments/ Medical Events Definitions'' (ADAMS Accession No. ML082100074), dated July 25, 2008, the Commission approved publication of a proposed rule to (1) amend sections in 10 CFR part 35 involving medical event reporting and (2) clarify requirements for permanent implant brachytherapy programs.

The proposed rule was published for public comment in the **Federal Register** on August 6, 2008 (73 FR 45635). The vast majority of commenters offered no objection to converting the medical event criteria from dose-based to source strength-based. However, following an evaluation of a number of medical events in 2008, the staff recognized that an unintended effect of the proposed rule would have been that some significant events would not be identified, categorized, and reported as medical events, which would have been contrary to the original regulatory intent. Therefore, in SECY–10–0062, ''Reproposed Rule: Medical Use of Byproduct Material—Amendments/ Medical Event Definitions'' (ADAMS Accession No. ML100890121), dated May 18, 2010, the staff recommended that the NRC publish a revised proposed rule to retain dose-based criteria. However, following a Commission meeting in which members of the NRC's Advisory Committee on the Medical Use of Isotopes (ACMUI) and certain stakeholders opposed this approach, the Commission disapproved the staff's recommendation and directed the staff to work closely with the ACMUI and stakeholders to develop a revised medical event definition that would protect patients' interests and allow physicians necessary flexibility, while enabling the agency to detect failures and misapplication of byproduct materials. The staff worked closely with the ACMUI and held stakeholder workshops to discuss issues associated with the medical event definition. The meeting summaries from the stakeholder workshops are available in ADAMS under Accession Nos. ML111930470 and ML112510385.

Following these outreach efforts, the NRC staff developed recommendations

in SECY–12–0053, ''Recommendations on Regulatory Changes for Permanent Implant Brachytherapy Programs'' (ADAMS Accession No. ML12072A306), dated April 5, 2012, defining separate medical event reporting criteria exclusively for permanent implant brachytherapy and, for permanent implant brachytherapy, changing from a dose-based criterion to a hybrid definition using primarily source-strength based criteria but also retaining certain dose-based criteria for assessing whether a medical event occurred. In SRM–SECY–12–0053, ''Recommendations on Regulatory Changes for Permanent Implant Brachytherapy Programs,'' issued on August 13, 2012 (ADAMS Accession No. ML122260211), the Commission approved these recommendations and directed that modifications be developed as part of a so-called ''expanded'' rulemaking that had begun in July 2010 to amend 10 CFR part 35. The NRC staff is currently revising the regulations in 10 CFR part 35 for permanent implant brachytherapy programs which may eliminate dose-based medical event reporting requirements for treatment sites. In the interim, the NRC has developed this policy with regard to permanent implant brachytherapy for the reasons explained below in the Discussion section of this document.

Discussion

Section 35.40, *Written directives,* provides that for permanent implant brachytherapy, the written directive must contain, before implantation, the treatment site, radionuclide, and dose; and after implantation but before completion of the procedure, the radionuclide, treatment site, number of sources, and total source strength and exposure time or the total dose.

Section 35.41, *Procedures for administrations requiring a written directive,* requires that a licensee performing medical administrations must develop, implement, and maintain written procedures to provide high confidence that, among other things, each administration is in accordance with the treatment plan, if applicable, and the written directive.

Section 35.3045, *Report and notification of a medical event,* provides the criteria that must be met for a medical administration to be reported as a medical event. Among the criteria, there is a criterion for reporting a medical event involving dose to the treatment site in § 35.3045(a)(1) which specifies a threshold based on absorbed dose variance (i.e., a comparison of the dose delivered as a result of the medical administration with the prescribed dose) as measured in sieverts (Sv) or in rem, and a threshold for percent variance (i.e., the difference between delivered dose and prescribed dose measured as a percentage). Section 35.3045(a)(1) includes limits for both of these dose thresholds. If both limits are exceeded, a medical administration would be required to be reported as a medical event, based on an evaluation of the dose to the treatment site.

With regard to these criteria, § 35.3045(a)(1) does not currently provide separate criteria for permanent implant brachytherapy, and does not explicitly state whether, for permanent implant brachytherapy, the comparison of delivered dose to prescribed dose can be done with doses expressed as total source strength and exposure time for determining percent dose variance for the treatment site. The definition of prescribed dose for manual brachytherapy in § 35.2, *Definitions,* permits the doses to be expressed as total source strength and exposure time as well as absorbed dose. However, § 35.3045(a)(1) specifies the threshold for delivered absorbed dose variance from prescribed dose in sieverts (Sv) or in rem. Therefore, § 35.3045(a)(1) requires that this comparison of delivered absorbed dose to prescribed dose must be performed in terms of absorbed dose to determine whether a medical event has occurred. Section 35.3045(a)(1) therefore does not provide licensees with the option to use total source strength and exposure time instead of absorbed dose when evaluating the difference between the delivered absorbed dose and the prescribed dose.

When completing the written directive after permanent implant brachytherapy implantation, the delivered dose (for the treatment site) may be expressed as total source strength and exposure time. In such a situation, in order to allow a comparison to be made between the delivered dose and the dose prescribed in the written directive, the preimplantation entry in the written directive for prescribed dose must also have been expressed as total source strength and exposure time. However, in accordance with § 35.3045(a)(1), medical use licensees must currently perform a treatment site medical event evaluation with both the delivered dose and the prescribed dose expressed in sieverts or rem for determination of absorbed dose variance. Therefore, if the licensee specifies treatment site doses in the written directive as total source strength and exposure time, then the licensee must also provide enough information to allow for the absorbed dose calculation (in sieverts or rem) to ensure compliance with § 35.3045(a)(1). This creates an unnecessary burden for licensees.

The treatment site doses for therapeutic uses are large enough that if the percent variance of delivered dose from prescribed dose for the treatment site exceeds the threshold for reporting a medical event (i.e., 20 percent), then the threshold for absorbed dose variance for the treatment site (i.e., 0.5 Sv (50 rem)), will also be exceeded. Hence, the two linked criteria for a treatment site medical event in § 35.3045(a)(1) will both have been met. Therefore, the staff recognizes the need to provide regulatory relief to licensees from the current requirement, so a comparison of delivered dose to prescribed dose for determination of absorbed dose variance, with both doses expressed in sieverts or rem, is not necessary.

This interim enforcement policy provides enforcement discretion for both existing and future violations of the current § 35.3045(a)(1) requirement relating to treatment site dose comparisons for permanent implant brachytherapy. Under this interim enforcement policy, the staff will typically exercise enforcement discretion and not cite a violation for failure to use a dose-based calculation if the authorized treatment mode is permanent implant brachytherapy and licensees use total source strength and exposure time for evaluating the existence of a medical event. This approach will allow for an effective and objective criterion for medical event reporting. In order for enforcement discretion to be exercised, however, the event cannot result in the misapplication of byproduct material. This policy does not provide regulatory relief from complying with any other aspect of § 35.3045, including the requirements for evaluation of dose to normal tissue.

Enforcement discretion would only apply in this situation if the licensee had entered both the prescribed dose and the delivered dose into the written directive in terms of total source strength and exposure time. Also, this dose comparison could only be made if the licensee's documented procedures required under § 35.41 specify use of total source strength and exposure time as the basis for the required treatment site dose comparison.

In addition, the NRC will normally exercise enforcement discretion for violations of current § 35.3045(a)(1) when the total dose to the permanent implant brachytherapy treatment site equals or exceeds 120 percent of the

prescribed dose. This enforcement discretion would only apply if: (1) The licensee used absorbed dose to compare the dose delivered to the treatment site with the prescribed dose; (2) doses to normal tissues and structures did not exceed the regulatory dose limits for reporting medical events specified in current § 35.3045(a)(3); and (3) the total dose for the treatment site was expressed in the written directive as absorbed dose. Section 35.3045(a)(1)(i) limits the variance of delivered dose from prescribed dose to less than 20 percent, so if the delivered dose variance from prescribed dose equals 20 percent or more, the delivered dose equals 120 percent or more of the prescribed dose.

As part of the ongoing 10 CFR part 35 proposed rulemaking, stakeholders have informed the NRC that variables in post-implant dosimetry studies cause calculated absorbed dose to be an unreliable metric for regulatory purposes; however, licensees have more control over delivery of the prescribed dose when using source strength and exposure time. As a result, this enforcement discretion will not apply if the total dose for the treatment site was expressed in the written directive as total source strength and exposure time. This does not change the physician's current ability to make intraoperative adjustments in the quantity of source strength implanted based on the conditions encountered during the surgical procedure and to document such adjustments in the portion of the written directive required after implantation but before completion of the procedure.

This regulatory relief does not pose a safety concern because the NRC recognizes that the overall clinical objective of permanent implant therapies is to deliver as much radiation dose as possible to the treatment site without exceeding medically-recognized dose limits for nearby normal tissues and structures (i.e., organs at risk). Licensees using this regulatory relief must evaluate dose to nearby normal tissues and structures in accordance with the requirements in § 35.3045(a)(3) to determine if a medical event has occurred. In addition, this policy is not intended to grant discretion for doses less than 80 percent of the prescribed dose. The intent of permanent implant brachytherapy is to deliver at least a minimum dose in accordance with the physician's direction; therefore, exercising enforcement discretion for an underdose would not further this intent.

Licensees shall comply with all other requirements, as applicable, unless explicitly replaced or amended in this interim policy.

The NRC will keep this interim policy in place until the implementation date of a final rule associated with the medical event reporting requirements.

Accordingly, the NRC has revised its Enforcement Policy to read as follows:

Interim NRC Enforcement Policy

9.3 Enforcement Discretion for Permanent Implant Brachytherapy Medical Event Reporting (10 CFR 35.3045)

This section sets forth the interim policy that the NRC will use for medical event reporting violations under current 10 CFR 35.3045. Enforcement discretion will typically be exercised for reporting violations in the following scenarios, subject to criteria specified below, when the authorized treatment mode is permanent implant brachytherapy: (1) the licensee uses total source strength and exposure time for evaluating the existence of a treatment site medical event; or (2) the total absorbed dose to the treatment site equals or exceeds 120 percent of the prescribed dose. This policy does not provide regulatory relief from complying with any other aspect of §§ 35.41 or 35.3045, including the requirements related to the evaluation of dose to normal tissue.

The interim policy applies to violations that result from an otherwise appropriate use of total source strength and exposure time when determining the existence of a medical event and when the use of these values does not result in the misapplication of byproduct material by the licensee.

Specifically, under this interim Enforcement Policy, the NRC will normally not take enforcement action for using total source strength and exposure time to compare the dose delivered to the treatment site with the prescribed dose when evaluating whether a medical administration is a medical event under § 35.3045(a)(1) if the authorized treatment mode is permanent implant brachytherapy and all of the following criteria are met:

a. The licensee's documented procedures required under § 35.41 specify total source strength and exposure time as the regulatory evaluation values for treatment site dose comparisons;

b. The licensee entered both the prescribed dose and the delivered dose into the written directive as total source strength and exposure time; and

c. Per § 35.3045, the licensee timely reported the event based on that treatment site dose comparison, if applicable.

In addition, the NRC will normally not take enforcement action against a licensee for not submitting a medical event report when the permanent implant brachytherapy treatment site total dose equals or exceeds 120 percent of the prescribed dose. This enforcement discretion would only apply if: (1) The licensee used absorbed dose to compare the dose delivered to the treatment site with the prescribed dose; (2) doses to normal tissues and structures did not exceed the regulatory dose limits for reporting medical events specified in current § 35.3045(a)(3); and (3) the total dose for the treatment site was expressed in the written directive as absorbed dose.

This discretion will not be exercised for licensees using source strength and exposure time to compare the dose delivered to the treatment site with the prescribed dose, since it is expected that the licensee has more control over delivery of the prescribed dose when using source strength and exposure time. However, this is not intended to limit the physician's current ability to make intraoperative adjustments in the quantity of source strength to be implanted based on the conditions encountered during the surgical procedure and to document such adjustments in the portion of the written directive required after implantation but before completion of the procedure.

Licensees shall comply with all other requirements, as applicable, unless explicitly replaced or amended in this interim policy.

This interim policy will remain in place until the implementation date of a final rule associated with the medical event reporting requirements.

Procedural Requirements

Paperwork Reduction Act Statement

This policy statement does not contain new or amended information collection requirements subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). Existing requirements were approved by the Office of Management and Budget, approval numbers 3150–0010 and 3150–0136.

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.

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 OMB Office of Information and Regulatory Affairs.

Dated at Rockville, MD, this 3rd day of July, 2013.

For the Nuclear Regulatory Commission.

Rochelle C. Bavol,

Acting Secretary of the Commission.

[FR Doc. 2013–16435 Filed 7–8–13; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2013–0001]

Sunshine Act Meetings

AGENCY HOLDING THE MEETINGS: Nuclear Regulatory Commission.

DATES: Weeks of July 8, 15, 22, 29, August 5, 12, 2013.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

Week of July 8, 2013

Tuesday, July 9, 2013

9:30 a.m. Briefing on Security Issues (Closed—Ex. 1).

Wednesday, July 10, 2013

9:00 a.m. Briefing on NRC International Activities (Part 1) (Public Meeting) (Contact: Karen Henderson, 301–415–0202).

This meeting will be webcast live at the Web address—*www.nrc.gov.*

10:30 a.m. Briefing on NRC International Activities (Part 2) (Closed—Ex. 1 & 9) (Contact: Karen Henderson, 301–415–0202).

Thursday, July 11, 2013

9:30 a.m. Meeting with the Advisory Committee on Reactor Safeguards. (ACRS) (Public Meeting). (Contact: Ed Hackett, 301–415–7360).

This meeting will be webcast live at the Web address—*www.nrc.gov.*

Week of July 15, 2013—Tentative

There are no meetings scheduled for the week of July 15, 2013.

Week of July 22, 2013—Tentative

There are no meetings scheduled for the week of July 22, 2013.

Week of July 29, 2013—Tentative

There are no meetings scheduled for the week of July 29, 2013.

Week of August 5, 2013—Tentative

There are no meetings scheduled for the week of August 5, 2013.

Week of August 12, 2013—Tentative

There are no meetings scheduled for the week of August 12, 2013.

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* The schedule for Commission meetings is subject to change on short notice. To verify the status of meetings, call (recording)—301–415–1292. Contact person for more information: Rochelle Bavol, 301–415–1651.

* * * * *

The NRC Commission Meeting Schedule can be found on the Internet at: *http://www.nrc.gov/public-involve/public-meetings/schedule.html.*

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The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (e.g. braille, large print), please notify Kimberly Meyer, NRC Disability Program Manager, at 301–287–0727, or by email at *kimberly.meyer-chambers@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

* * * * *

This notice is distributed electronically to subscribers. If you no longer wish to receive it, or would like to be added to the distribution, please contact the Office of the Secretary, Washington, DC 20555 (301–415–1969), or send an email to *darlene.wright@nrc.gov.*

July 3, 2013.

Rochelle C. Bavol,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2013–16575 Filed 7–5–13; 4:15 pm]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket No. MT2013–2; Order No. 1771]

Market Test of International Merchandise Return Service

AGENCY: Postal Regulatory Commission.

ACTION: Notice

SUMMARY: The Commission is noticing a recently-filed Postal Service proposal to conduct a market test of a competitive experimental product called International Merchandise Return Service-Non-Published Rates (IMRS–NPR). This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* July 15, 2013.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

On July 1, 2013, the Postal Service filed a notice, pursuant to 39 U.S.C. 3641, announcing its intent to conduct a market test of a competitive experimental product called International Merchandise Return Service—Non-Published Rates (IMRS–NPR).[1] IMRS–NPR is comprised of Air Parcels or Express Mail Service packages returning to the United States that originate from a foreign territory served by another postal operator with which the Postal Service has made an arrangement for a return service. *Id.* at 2. The market test is scheduled to begin on or shortly after August 15, 2013 and continue for two calendar years. *Id.* at 6.

II. Background

IMRS–NPR items consist of returned merchandise that consumers purchased through online retailers in the United States. *Id.* at 2. IMRS–NPR will enable foreign consumers to create return labels and postage payment to return products back to the United States. *Id.* The consumer can create his or her own shipping label and send it to the merchant through the consumer's postal channel.

The Postal Service explains that many shipping companies create methods to improve ease of use by creating labels for the merchants and either sending the labels by email to their customers or providing labels for use if an item is returned. *Id.* It states that returns are an inevitable part of international online commerce, and customers consider returns as an important part of

[1] Notice of the United States Postal Service of Market Test of Experimental Product—International Merchandise Return Service—Non-Published Rates (IMRS–NPR) and Notice of Filing IMRS–NPR Model Contract and Application for Non-Public Treatment of Materials Filed Under Seal, July 1, 2013 (Notice).