POLICY ISSUE
(Notation Vote)

April 22, 2013 SECY-13-0044

FOR: The Commissioners

FROM: R. W. Borchardt
Executive Director for Operations

SUBJECT: INTERIM ENFORCEMENT POLICY FOR PERMANENT IMPLANT BRACHYTHERAPY MEDICAL EVENT REPORTING

PURPOSE:

The purpose of this paper is to request Commission approval of an interim enforcement policy that will allow the staff to exercise enforcement discretion for certain violations of current regulations in 10 CFR Part 35, "Medical Use of Byproduct Material," for reporting medical events occurring under a licensee's permanent implant brachytherapy program. This paper does not address any new commitments or resource implications.

SUMMARY:

This SECY paper responds to SRM-SECY-12-0053, "Recommendations on Regulatory Changes for Permanent Implant Brachytherapy Programs," (Agencywide Documents Access and Management System (ADAMS) Accession No. ML122260211), dated August 13, 2012. Specifically, the Commission directed the staff to develop an interim enforcement policy that would allow the staff to exercise enforcement discretion for both existing and future violations of current 10 CFR Part 35 that do not result in the misapplication of byproduct material by those licensees that use total source strength and treatment time for determining the existence of a medical event, provided certain conditions are met. Additionally, this SECY paper provides, for Commission consideration, a recommendation to exercise enforcement discretion for medical event reporting violations when the total dose to the permanent implant brachytherapy treatment site equals or exceeds 120 percent of the prescribed dose. 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

CONTACT: Kerstun J. Day, OE/EB
(301) 415-1252

regulatory dose limits for reporting medical events specified in current 10 CFR 35.3045(a)(3); and (3) the total dose for the treatment site was expressed in the written directive as absorbed dose.

BACKGROUND:

In SECY-05-0234, "Adequacy of Medical Event Definitions in 10 CFR 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. In SRM-SECY-05-0234 (ADAMS Accession No. ML060460594), dated February 15, 2006, the Commission directed the staff to proceed directly with the development of a proposed rule to modify both the written directive requirements in 10 CFR 35.40(b)(6) and the medical event reporting requirements in 10 CFR 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 10 CFR Part 35 sections 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. 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 (ADAMS Accession Nos. ML111930470 and ML112510385).

Following these outreach efforts, the NRC staff developed recommendations in SECY-12-0053, dated April 5, 2012,"Recommendations on Regulatory Changes for Permanent Implant Brachytherapy Programs," (ADAMS Accession No. ML12072A306) 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, 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 staff has developed this interim Enforcement Policy.

DISCUSSION:

10 CFR 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.

10 CFR 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.

10 CFR 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 10 CFR 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). 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, 10 CFR 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 10 CFR 35.2, "Definitions," states "either the total source strength and exposure time or the total dose, as documented in the written directive." This definition therefore permits the doses to be expressed as total source strength and exposure time as well as absorbed dose. However, 10 CFR 35.3045(a)(1) specifies the threshold for delivered absorbed dose variance from prescribed dose in sieverts (Sv) or in rem. Therefore, 10 CFR 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. 10 CFR 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 10 CFR 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 10 CFR 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 10 CFR 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.

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 10 CFR 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 10 CFR 35.41 specify use of total source strength and exposure time as the basis for the required treatment site dose comparison.

In addition, the staff is proposing to exercise enforcement discretion for violations of current 10 CFR 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 10 CFR 35.3045(a)(3); and (3) the total dose for the treatment site was expressed in the written directive as absorbed dose. 10 CFR 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 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 10 CFR 35.3045(a)(3) to determine if a medical event has occurred.

This proposed policy is not intended to grant discretion for doses less than 80 percent of the intended 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.

RECOMMENDATIONS:

Approve the enclosed *Federal Register* Notice for publication.

COORDINATION:

The Office of General Counsel has reviewed this paper and has no legal objection.

/RA by Michael F. Weber for/

R. W. Borchardt
Executive Director
for Operations

Enclosure:
Draft *Federal Register* Notice

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 10 CFR 35.3045(a)(3) to determine if a medical event has occurred.

This proposed policy is not intended to grant discretion for doses less than 80 percent of the intended 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.

RECOMMENDATIONS:

Approve the enclosed *Federal Register* Notice for publication.

COORDINATION:

The Office of General Counsel has reviewed this paper and has no legal objection.

/RA by Michael F. Weber for/

R. W. Borchardt
Executive Director
for Operations

Enclosure:
Draft *Federal Register* Notice

ADAMS ACCESSION NO.: ML13063A207 **WITS 201200140/EDATS: SECY-2012-0416**

OFFICE	OE:ES	OE:BC	Tech Editor	OIS:IRSD	OGC:GCLR/RMR
NAME	KDay	NHilton	CHsu[1]	TDonnell[2]	SChidakel[3]
DATE	3/1/2013	3/12/2013	12/28/2012	3/8/2013	4/11/2013
OFFICE	OGC:GCHEA/MLE	FSME:OD	OE: OD	EDO	
NAME	MSimon[4]	MSatorius	RZimmerman	RWBorchardt	
DATE	4/19/2013	4/22/2013	4/22/2013	4/22/2013	

OFFICIAL RECORD COPY

[1] Quality Tech Editor concurrence received electronically from C. Hsu on December 28, 2012.
[2] OIS concurrence received electronically from T. Donnell on March 8, 2013.
[3] No Legal Objection received electronically from S. Chidakel (OGC/GCLR/RMR) on April 11, 2013.
[4] No Legal Objection received electronically from M. Simon (OGC/GCHEA/MLE) on April 29, 2013.