UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF FEDERAL AND STATE MATERIALS AND
ENVIRONMENTAL MANAGEMENT PROGRAMS
WASHINGTON, DC 20555

July 30, 2013

NRC REGULATORY ISSUE SUMMARY 2013-10 PERMANENT IMPLANT BRACHYTHERAPY MEDICAL EVENT REPORTING UNDER 10 CFR PART 35

ADDRESSEES

All U.S. Nuclear Regulatory Commission (NRC) medical-use licensees, NRC master material licensees (MMLs), Agreement State Radiation Control Program Directors, and State Liaison Officers.

INTENT

The NRC is issuing this regulatory issue summary (RIS) to: (1) supply information to assist licensees in complying with the current NRC requirements related to permanent implant brachytherapy; and (2) announce that an Interim Enforcement Policy[1](IEP), has been developed and published and explain the enforcement discretion NRC will use to provide regulatory relief to licensees until the implementation date of a revised final rule (10 CFR Part 35, Medical Use of Byproduct Material) associated with the Medical Event (ME) reporting requirements.

No specific action or written response is required. The NRC is providing this RIS to Agreement States for their information and for distribution to their medical licensees, as appropriate.

BACKGROUND

In SRM-SECY-12-0053[2], dated August 13, 2012, the Commission approved the staff's recommendations for modifying the regulatory requirements that appear in 10 CFR 35.3045 for permanent implant brachytherapy ME reporting and conforming changes to the current written directive (WD) requirements in 10 CFR 35.40(b)(6), to convert from dose-based to source-strength-based ME criteria for the treatment site. The Commission also directed the staff to clarify ME reporting for permanent implant brachytherapy under the existing rule and provide insights about compliance with the current NRC requirements. Finally, the Commission directed the staff to develop an IEP that would allow the staff to exercise enforcement discretion for both existing and future violations of current Part 35 that do not result in the misapplication of byproduct material by those licensees that use total source strength and treatment (exposure) time for determining the existence of a treatment site ME.

ML13156A195

[1] Docket ID NRC-2013-0114. Available on the Federal Rulemaking Web site at: http://www.regulations.gov.

[2] Available on the NRC public Web site in the Agencywide Documents Access Management System at: http://www.nrc.gov/reading-rm/adams.html. Use search number ML12228A606.

SUMMARY OF ISSUE

Compliance With Current Regulations

In 10 CFR 35.2, *Definitions,* "prescribed dose" for manual brachytherapy is defined as "either the total source strength and exposure time or the total dose, as documented in the written directive," and "treatment site" is defined as "the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive." In 10 CFR 35.40, Written Directives (WD), the information required for the WD when the treatment mode is manual brachytherapy includes the patient's or human research subject's name and the following: Before implantation, the treatment site, the radionuclide, and the dose (i.e., the prescribed dose); and after implantation but before completion of the procedure, the treatment site, the radionuclide, the number of sources (implanted), and "the total source strength and exposure time (or the total dose)."

The regulations reference many different terms all linked to the WD: total source strength; total dose; treatment site; and dose. These terms may have variable meanings and uses for licensees. For instance, in manual prostate brachytherapy, treatment site may mean the prostate only for one licensee and may mean the prostate plus a volume of tissue surrounding the prostate for another licensee. Therefore, licensees are reminded to be consistent in their use of terms when documenting in the pre-implantation and post-implantation portions of the WD all components of the implant that will ultimately be used when evaluating the adequacy of the implant.

10 CFR 35.41, *Procedures for administrations requiring a written directive,* states that a medical use licensee authorized for permanent implant brachytherapy 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 with the WD. Therefore, licensees should have checks in place to ensure that each component of the WD is met. The NRC notes that some licensees' procedures were developed when the predecessor to 10 CFR 35.41, called Quality Management Program, was initiated (1990's) and licensees have not updated these procedures even though their implant style and assessments may have changed. For instance, prior to 1990, many licensees implanted sources for prostate treatments without pre-planning or post-planning dosimetry. Today, many licensees perform extensive imaging and dosimetry to prescribe and evaluate doses to not only intended tissue (e.g., prostate), but also to nearby tissue (e.g., rectum, bladder, or urethra). Therefore, licensees are reminded that procedures should correctly document the program currently in place, and for purposes of determining whether medical event reporting is required, provide definitive criteria for evaluating the adequacy of the dose delivered to the intended treatment site, compared to the prescribed dose, and the acceptability of the dose delivered to any other organ or tissue, compared to the dose expected from the administration defined in the written directive.

10 CFR 35.3045, *Report and notification of a medical event,* provides the criteria for ME reporting and uses terms like dose, prescribed dose, organ or tissue other than the treatment site, and migrated seeds. These terms again may have variable meanings and uses for licensees. In addition, differences in prescribing doses among licensees makes it difficult for some licensees to assess if an ME has occurred.

For instance, in manual prostate brachytherapy, some licensees develop a treatment plan that includes expected doses to organs or tissues near the prostate and perform post-treatment planning after the implant with this same data. However, some licensees do not perform treatment planning at all, but instead rely on a nomogram approach for performing implants and review of post-implant images for assessing the adequacy of the placement of the sources. Therefore, the first category of licensees may have data to assess whether an "organ or tissue other than the treatment site" received a dose (in terms of gray (Gy) or rads) in excess of the ME reporting criteria, but the second category of licensees would not readily have the data available to make this assessment. NRC has noted that both categories of licensees frequently do not document their post-treatment assessments in detail. In addition, the second category of licensees should develop mechanisms for collecting definitive data to perform an assessment of the adequacy of the implant. For instance, a conventional x-ray taken immediately after the implant and reviewed may not be sufficient for determining where the sources are implanted. Therefore, all licensees are reminded that their procedures, developed in accordance with 10 CFR 35.41, should be robust enough to allow the licensee to definitively evaluate the dose to the defined treatment site and the doses to other organs or tissues in performing an assessment of whether an ME may have occurred.

Total Dose Variance Determination

For the treatment site, the ME reporting criteria in 10 CFR 35.3045(a)(1) includes a threshold for delivered total dose variance from prescribed dose, in sieverts (Sv) or in rem, and a threshold for percent variance of delivered dose from prescribed dose. Both of these dose thresholds (delivered total dose variance and percent dose variance) must be exceeded for a medical use procedure to be deemed an ME based on treatment site dose variance.

As stated above, "prescribed dose" is defined as "either the total source strength and exposure time, or the total dose, as documented in the written directive." Section 35.3045 does not explicitly state whether the comparison of delivered total dose to prescribed dose for the treatment site, for determination of the percent dose variance, can be done with these doses expressed as total source strength and exposure time, consistent with one of the options in the definition of prescribed dose, or whether the prescribed dose (and the delivered total dose) must be expressed as total dose, the other option in the definition of prescribed dose. However, because 10 CFR 35.3045(a)(1) specifies that the threshold for delivered total dose variance from prescribed dose is expressed in sieverts (Sv) or in rem in 10 CFR 35.3045(a)(1), section 35.3045 requires that this comparison of delivered dose to prescribed dose must be performed in terms of total dose to determine whether a ME has occurred. Thus, Section 35.3045 does not provide licensees with the option to use total source strength and exposure time in lieu of total dose for the total dose variance determination.

Medical use licensees authorized for permanent implant brachytherapy are advised that for completing the WD after implantation, the delivered dose (for the treatment site) may be expressed as total source strength and exposure time as long as the prescribed dose was also expressed in terms of total source strength and exposure time for the pre-implantation entries of the WD. However, as noted above, the determination under section 35.3045(a)(1) that a particular procedure is or is not an ME based on treatment site dose variance must be done with both the delivered dose and the intended (prescribed) dose expressed in Sv or rem for determination of total dose variance.

Therefore, in order for the licensee to be in compliance with the requirements in section 35.3045(a)(1), if specifying treatment site doses in the WD in terms of total source strength and exposure time, the licensee should also provide sufficient information to allow for the calculation of the total doses (prescribed and delivered) in Sv or rem. Of course, for the WD, medical use licensees authorized for permanent implant brachytherapy can also continue to express both the prescribed dose and the delivered dose as total doses, and make the determination under section 35.3045 as to whether a treatment site ME has occurred based on the total dose values (prescribed and delivered) in the WD. Note that an implant that is considered ME reportable based on the percent dose variance for a comparison of delivered total dose to prescribed total dose might not be considered ME reportable if the comparison of delivered dose to intended dose was performed based on total source strength and exposure time.

As interim guidance to NRC inspectors when reviewing permanent implant brachytherapy programs, in 2012 the NRC developed Appendix B, *Reviewing Licensees' Implementation of Procedures for Permanent Implant Brachytherapy Administrations*, and Appendix C, *Questions & Answers for Inspecting Manual Brachytherapy Prostate Implants*, to its Inspection Procedure (IP) 87132, *Brachytherapy Programs*. Licensees may find these guidelines and examples, along with the IEP described below, useful in reviewing their permanent implant programs and procedures. These Appendices are enclosed, as well as being available on the NRC public web site. Note that the IEP may supersede some of the information in IP 87132, including some of the responses to the questions and answers in Appendix C, until IP 87132 is revised to reflect it.

However, note that, because the prescribed dose is large and is intended to be therapeutic, if the percent variance of delivered total dose from prescribed dose for the treatment site exceeds the threshold for reporting an ME, which is 20 percent, in every case the threshold for total dose variance (delivered from prescribed) for the treatment site, at 0.5 Sv (50 rem), will also be exceeded, so the two linked criteria for a treatment site ME will both have been met. This fact is the basis for part of the enforcement discretion in the IEP described below.

Interim Enforcement Policy

Based on the information in the paragraph above, NRC recognized the need to provide regulatory relief to licensees from the current requirement that a comparison of delivered dose to prescribed dose for determination of total dose variance for the treatment site be done with both doses expressed in Sv or rem. Specifically, provision of regulatory relief would be justifiable in the case in which a licensee's procedure identifies use of total source-strength and exposure time for the entire process, including determining percent variation of delivered total dose from prescribed dose as a criterion to identify a treatment site ME.

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 developed an IEP.

On July 9, 2013, the IEP was published in the *Federal Register* (78 FR 41125). The effective date of the IEP is July 9, 2013. The NRC Enforcement Policy can be found at: http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. Via the *Federal Register* Notice, the NRC provided notice of its revised Enforcement Policy. To review the IEP, please refer to Enclosure 3.

The IEP applies to violations that result from an otherwise appropriate use of total source strength and treatment time for determining the existence of a treatment site ME, and if use of these values does not result in the misapplication of byproduct material by the licensee. Under the IEP, enforcement discretion for existing and future violations of the ME reporting requirement will be considered if the authorized treatment mode is permanent implant brachytherapy and licensees uses total source strength and exposure time for determining the percent variation between delivered total dose and intended (prescribed) dose (for the treatment site), for determining under current 10 CFR 35.3045 whether a treatment site ME has occurred.

Enforcement discretion will only be considered if the licensee entered both the prescribed dose and the delivered total dose into the WD in terms of total source strength and exposure time; the licensee's documented procedures required under section 35.41 specify total source strength and exposure time as the regulatory evaluation values for treatment site dose comparisons; and the licensee timely reported the event based on that treatment site dose comparison, if applicable.

The IEP also provides enforcement discretion for existing and future violations of the current section 35.3045(a)(1)(i) ME reporting requirement when a treatment site total dose exceeds 120 percent of the prescribed dose. This enforcement discretion will apply if the licensee used absorbed dose to compare the dose delivered to the treatment site with the prescribed dose; doses to normal tissues and structures do not exceed the regulatory dose thresholds for reporting MEs in current section 35.3045(a)(3); and the total dose for the treatment site was expressed in the WD as absorbed dose. This additional regulatory relief is being offered because variables in post-implant dosimetry studies cause calculated absorbed dose to be an unreliable metric for regulatory purposes.

This regulatory relief does not pose a safety concern because the permanent implant therapies planned by many practitioners have as their objective delivering 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.

Also, the NRC recognizes that the current ME reporting of delivered total dose to the treatment site exceeding 120 percent, compared to the prescribed dose, inappropriately limits the medical practitioner’s ability to provide optimum medical care and treatment to his/her patients by maximizing the delivered total dose to the treatment site. Note that the revisions to 10 CFR 35.3045 that are now under development for permanent implant brachytherapy would eliminate all treatment site dose variance threshold criteria present in the current 10 CFR 35.3045 ME reporting requirements.

This enforcement discretion for treatment site total dose exceeding 120 percent of the prescribed dose 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 is because licensees have more control over delivery of the prescribed dose when using source strength and exposure time. This policy 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 policy does not provide enforcement discretion for a delivered dose to the treatment site that is less than 80 percent of the intended dose, the lower limit for treatment site dose variance in the current section 35.3045(a)(1)(i). 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.

BACKFIT DISCUSSION

This RIS requires no action or written response. Any action on the part of addressees in accordance with the guidance contained in this RIS is strictly voluntary and, therefore, is not a backfit under any regulatory requirement. Consequently, the staff did not perform a backfit analysis.

FEDERAL REGISTER NOTIFICATION

A notice of opportunity for public comment on this RIS was not published in the *Federal Register* because this RIS is informational and does not represent a departure from current regulatory requirements.

CONGRESSIONAL REVIEW ACT

This RIS is not a rule as defined in the Congressional Review Act (5 U.S.C. §§ 801-808).

PAPERWORK REDUCTION ACT STATEMENT

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

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.

CONTACT

This RIS requires no specific action or written response. Please direct any questions to the technical contact listed below or the appropriate regional office.

/RA PHenderson for/

Brian J. McDermott, Director
Division of Materials Safety and State Agreements
Office of Federal and State Materials
and Environmental Management Programs

Technical Contact: Ronald Zelac, Ph.D., FSME
(301) 415-7635
Email: Ronald.Zelac@nrc.gov

Enclosures:
1. Appendix B - Inspection Procedure 87132
2. Appendix C - Inspection Procedure 87132
3. Interim Enforcement Policy
4. FSME Generic Communications

CONTACT

This RIS requires no specific action or written response. Please direct any questions to the technical contact listed below or the appropriate regional office.

/RA PHenderson for/

Brian J. McDermott, Director
Division of Materials Safety and State Agreements
Office of Federal and State Materials
and Environmental Management Programs

Technical Contact: Ronald Zelac, Ph.D., FSME
(301) 415-7635
Email: Ronald.Zelac@nrc.gov

Enclosures:
1. Appendix B - Inspection Procedure 87132
2. Appendix C - Inspection Procedure 87132
3. Interim Enforcement Policy
4. FSME Generic Communications

DISTRIBUTION: WITS 201200139 EDATS-SECY-2012-0415
MSSA r/f

ML13156A195

OFFICE	MSSA/RMSB	MSSA/RMSB	MSSA/RMSB	MSSA/RMSB	OE
NAME	RZelac	SGabriel	AMcIntosh	SGabriel for CEinberg	NHilton
DATE	6/4/13	6/19/13	6/13/13	6/19/13	7/2/13
OFFICE	OIS	OGC-NLO	OGC-CRA	MSSA	MSSA
NAME	TDonnell	BJones	JAdler for BAmmon	PHenderson	**PHenderson for** BMcDermott
DATE	7/10/13	7/23/13	7/23/13	7/30/13	7/30/13

OFFICIAL RECORD COPY