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DRAFT REGULATORY GUIDE

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DRAFT REGULATORY GUIDE DG-6003

(Proposed Revision 2 to Regulatory Guide 6.1, dated July 1974)

LEAK TESTING RADIOACTIVE BRACHYTHERAPY SOURCES

A. INTRODUCTION

This regulatory guide directs the reader to methods and procedures acceptable to the staff of the U.S. Nuclear Regulatory Commission (NRC) for leak testing radioactive brachytherapy sources. Possession and use of brachytherapy sources is an activity requiring a license pursuant to Title 10, Section 30.3, "Activities Requiring License," of the *Code of Federal Regulations* (10 CFR 30.3). The requirements in 10 CFR 35.67, "Requirements for Possession of Sealed Sources and Brachytherapy Sources," state that the sources are to be periodically leak tested and that the test be capable of detecting the presence of 185 becquerel (Bq) (0.005 microcurie (μCi)) of radioactive material in the sample. The regulations also require that the source be immediately withdrawn from use if the test reveals the presence of 185 Bq (0.005 μCi) or more of removable contamination.

This regulatory guide endorses the methods and procedures for leak testing radioactive brachytherapy sources contained in the current revisions of Volume 3 of NUREG-1556, "Consolidated Guidance about Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration," and Volume 9 of NUREG-1556, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Medical Use Licenses," as a process that the NRC has found to be acceptable for meeting the regulatory requirements.

The NRC revised the requirements for the medical use of byproduct materials, found in 10 CFR Part 35, "Medical Use of Byproduct Material," to implement a risk-informed, performance-based approach to regulation. Volume 3 of NUREG-1556 provides information on applying for sealed source and device evaluation and registration while Volume 9 of NUREG-1556 provides information on applying for a medical use license.

This regulatory guide is being issued in draft form to involve the public in the early stages of the development of a regulatory position in this area. It has not received final staff review or approval and does not represent an official NRC final staff position.

Public comments are being solicited on this draft guide (including any implementation schedule) and its associated regulatory analysis or value/impact statement. Comments should be accompanied by appropriate supporting data. Written comments may be submitted to the Rulemaking, Directives, and Editing Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; e-mailed to NRCREP@nrc.gov; submitted through the NRC's interactive rulemaking Web page at http://www.nrc.gov; faxed to (301) 415-5144; or hand delivered to the Rulemaking, Directives, and Editing Branch, Office of Administration, U.S. Nuclear Regulatory Commission, 11555 Rockville Pike, Rockville, MD 20852, between 7:30 a.m. and 4:15 p.m. on Federal workdays. Copies of comments received may be examined at the NRC's Public Document Room, 11555 Rockville Pike, Rockville, MD. Comments will be most helpful if received by April 18, 2008.

Electronic copies of this draft regulatory guide are available through the NRC's interactive rulemaking Web page (see above); the NRC's public Web site under Draft Regulatory Guides in the Regulatory Guides document collection of the NRC's Electronic Reading Room at http://www.nrc.gov/reading-rm/doc-collections/; and the NRC's Agencywide Documents Access and Management System (ADAMS) at http://www.nrc.gov/reading-rm/adams.html, under Accession No. ML073310340.

Licensees must perform leak testing of sealed sources (e.g., calibration, transmission, and reference sources) or brachytherapy sources in accordance with 10 CFR 35.67. Appendix Q to Volume 9 of NUREG-1556 provides an example procedure that is an acceptable method of performing the leak testing.

The NRC issues regulatory guides to describe to the public methods that the staff considers acceptable for use in implementing specific parts of the agency's regulations, to explain techniques that the staff uses in evaluating specific problems or postulated accidents, and to provide guidance to applicants. Regulatory guides are not substitutes for regulations and compliance with them is not required.

This regulatory guide contains information collections that are covered by the requirements of 10 CFR Part 35 and that the Office of Management and Budget (OMB) approved under OMB control number 3150-0010. The NRC may neither conduct nor sponsor, and a person is not required to respond to, an information collection request or requirement unless the requesting document displays a currently valid OMB control number.

B. DISCUSSION

As part of its redesign of the materials license program, the NRC consolidated and updated numerous guidance documents for material licenses into the multivolume NUREG-1556. Various volumes in the NUREG-1556 series provide current, program-specific guidance on testing, licensing, decommissioning, and terminating materials licenses.

Volume 3 of NUREG-1556 provides applicants with guidance on how to submit a request to the NRC for a safety evaluation or registration of a sealed source. It also provides reviewers of such requests with the information and materials necessary to determine that the products are acceptable for registration and certification purposes. It provides the applicants and reviewers with information concerning how to file a request, a listing of the applicable regulations and industry standards, policies affecting evaluation and registration, administrative procedures to be followed, information on how to perform the evaluation and write a registration certificate, and the responsibilities of the registration certificate holder.

Volume 9 of NUREG-1556 contains information to assist applicants for licenses for the medical use of byproduct material in preparing their license applications. In particular, it describes the types of information needed to complete NRC Form 313, "Application for Material License," and NRC Form 313A, "Training and Experience and Preceptor Statement." Because of the wide variety in the types of medical uses of byproduct material, NUREG-1556 includes indicators to alert applicants for particular types of medical uses to information that pertains to those uses.

Many of the volumes of NUREG-1556 also contain appendices that include (1) copies of necessary forms, (2) sample applications and completed examples for different types of applications, and (3) examples of the types of supporting information, such as implementing procedures that the applicant may need to prepare. The NRC is placing added emphasis on conducting its regulatory activities in a risk-informed and performance-based manner. This approach is intended to be less prescriptive and to allow licensees the flexibility to implement the agency's regulations in a manner that is more specific to their needs yet still meets the regulatory requirements. By supplying examples, the NRC seeks to provide information to meet the needs of applicants for licensure, without being prescriptive. Guidance in the NUREG represents one means of complying with NRC regulations and is not intended to be the only means of satisfying the regulatory requirements.

NUREG-1556 is available electronically through the Electronic Reading Room on the NRC's public Web site, at http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556. Copies are also available for inspection or copying for a fee from the NRC's Public Document Room (PDR) at 11555 Rockville Pike, Rockville, MD; the mailing address is USNRC PDR, Washington, DC 20555; telephone (301) 415-4737 or (800) 397-4209; fax (301) 415-3548; and e-mail PDR@nrc.gov. In addition, copies are available at current rates from the U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20402-9328, telephone (202) 512-1800, or from the National Technical Information Service (NTIS), at 5285 Port Royal Road, Springfield, VA 22161, online at http://www.ntis.gov, by telephone at (800) 553-NTIS (6847) or (703) 605-6000, or by fax to (703) 605-6900.

C. REGULATORY POSITION

This regulatory guide endorses the method described in Volumes 3 and 9 of NUREG-1556 as a process that the NRC has found to be acceptable for meeting the regulatory requirements for leak testing of radioactive brachytherapy sources.

D. IMPLEMENTATION

The purpose of this section is to provide information to applicants and licensees regarding the NRC's plans for using this draft regulatory guide. No imposition or backfit is intended or approved in connection with its issuance.

The NRC has issued this draft guide to encourage public participation in its development. The NRC will consider all public comments received in development of the final guidance document. Except in those cases in which an applicant or licensee proposes or has previously established an acceptable alternative method for complying with specified portions of the NRC's regulations, the methods described in the active guide will be used in evaluating compliance with the regulations as discussed in this guide for license applications, license amendment applications, and exemption requests.

REGULATORY ANALYSIS

1. Statement of the Problem

The NRC published Revision 1 of Regulatory Guide 6.1 in July 1974 to provide licensees with agency-approved guidance for complying with the then current version of 10 CFR 35.65. As a result of the NRC's implementation of a risk-informed, performance-based approach, combined with multiple updates and revisions to the regulations, Regulatory Guide 6.1 is outdated.

2. Objective

As part of its redesign of the materials licensing process, the NRC consolidated and updated numerous materials license guidance documents into a single comprehensive repository—the multivolume NUREG-1556. Each volume of the NUREG contains program-specific guidance for various materials licenses and licensee activities. The NRC developed and issued the multiple volumes of NUREG-1556 to provide both the licensee and NRC staff with current guidance.

This action is being undertaken to provide clear and up-to-date information to support consolidated guidance about leak testing radioactive brachytherapy sources.

3. Alternative Approaches

The NRC staff considered the following alternative approaches:

- Do not revise Regulatory Guide 6.1.
- Withdraw Regulatory Guide 6.1.
- Revise Regulatory Guide 6.1 to match or replace Volumes 3 and 9 of NUREG-1556.
- Revise Regulatory Guide 6.1 to endorse portions of Volumes 3 and 9 of NUREG-1556.

3.1 Alternative 1: Do Not Revise Regulatory Guide 6.1

Under this alternative, the NRC would not revise this document and the original version of this regulatory guide would continue to be used. However, this alternative would leave conflicting guidance in place and could cause unnecessary confusion. This alternative is considered the baseline or "no action" alternative and, as such, involves no value/impact considerations.

3.2 Alternative 2: Withdraw Regulatory Guide 6.1

Withdrawing this regulatory guide would eliminate the duplicative and somewhat contradictory information that currently exists in NUREG-1556 and the current version of Regulatory Guide 6.1. However, this action would leave a void in the regulatory guide system and provide no quick means for interested parties to identify a method for leak testing radioactive brachytherapy sources that the NRC finds to be acceptable. Although this alternative would be relatively low cost, it may impede the public's accessibility to the most current information.

3.3 Alternative 3: Revise Regulatory Guide 6.1 to Match or Replace Volumes 3 and 9 of NUREG-1556

NUREG-1556 is a multivolume document first published in May 1997 to provide consolidated guidance about materials licenses in accordance with the most current regulatory requirements. Regulatory Guide 6.1 contains specific guidance about only one of the many areas covered in Volumes 3 and 9 of NUREG-1556. Revising the regulatory guide to match the information in the existing NUREG would create duplicate sources of information and would require continuing staff resources to ensure that the separate documents continued to contain duplicate information. Revising this regulatory guide to replace the NUREG would require substantial expansion of the current guide and a large expenditure of labor without a noticeable enhancement in performance or efficiency for the NRC or its licensees. This alternative is considered to be an unnecessary use of staff resources.

3.4 Alternative 4: Revise Regulatory Guide 6.1 to Endorse Portions of Volumes 3 and 9 of NUREG-1556

The July 1974 version of the regulatory guide no longer represents a method that is acceptable to the NRC for satisfying the requirements of 10 CFR Part 35. Failure to revise the regulatory guide will result in conflicting guidance documents and possible confusion to interested parties. Therefore, the staff has opted to revise the regulatory guide to direct any interested parties to the most current guidance which is provided in Volumes 3 and 9 of NUREG-1556.

4. Conclusion

Based on this regulatory analysis, the staff recommends that the NRC revise Regulatory Guide 6.1 to endorse the methods and procedures for leak testing radioactive brachytherapy sources as described in Volumes 3 and 9 of NUREG-1556. The staff has concluded that the proposed action will reduce unnecessary burden on both the NRC and its licensees and will result in an improved and more uniform process. Moreover, the staff sees no adverse effects associated with issuing this regulatory guide.