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DRAFT REGULATORY GUIDE

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DRAFT REGULATORY GUIDE DG-6004

(Proposed Revision 2 of Regulatory Guide 6.2, dated July 1974)

INTEGRITY AND TEST SPECIFICATIONS FOR SELECTED BRACHYTHERAPY SOURCES

A. INTRODUCTION

This guide directs the reader to the type of information acceptable to the U.S. Nuclear Regulatory Commission (NRC) to evaluate the integrity and test specifications of selected brachytherapy sources. The manufacture of brachytherapy sources containing byproduct material requires a license pursuant to Title 10, Section 30.3, "Activities Requiring License," of the *Code of Federal Regulations* (10 CFR 30.3). Brachytherapy sources manufactured under such license must meet certain integrity requirements and pass certain tests. The regulation at 10 CFR 32.74(a)(2)(iii) requires that an application for a specific license to manufacture and distribute brachytherapy sources and devices containing byproduct material include a description of the procedures for, and results of, prototype tests performed to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents. Additionally, 10 CFR 32.74(a)(2)(v) requires that the application also include details of quality control procedures to ensure that production sources and devices meet the standards of the design and prototype tests.

This regulatory guide endorses the methods and procedures for integrity and test specifications of selected 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.

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. ML073331052.

Since the initial publication of RG 6.2 in 1974, the NRC has revised the requirements for the medical use of byproduct materials in 10 CFR Part 32, "Manufacture and Distribution of Sources or Devices Containing Byproduct Material for Medical Use," and 10 CFR Part 35, "Medical Use of Byproduct Material," to implement a risk-informed, performance-based approach to regulation. Volumes 3 and 9 of NUREG-1556 incorporate this revised approach.

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. Guidance in this regulatory guide represents one means acceptable to the NRC staff of complying with NRC regulations and is not intended to be the only means of satisfying requirements for a license. 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 Parts 32 and 35 and that the Office of Management and Budget (OMB) approved under OMB control numbers 3150-0001 and 3150-0010, respectively. 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 has 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 describes how to file a request with the NRC for radiation safety evaluation and registration of sealed sources and devices containing byproduct material. It also lists the applicable regulations and industry standards as well as the policies affecting evaluation and registration. Volume 3 contains administrative procedures to be followed, information on how to perform the evaluation and how to prepare a registration certificate, and the responsibilities of the registration certificate holder. In addition, it is designed to provide the reviewer of such requests with guidance, information, and materials necessary to perform a complete and thorough evaluation of the submittal.

Volume 9 of NUREG-1556 provides guidance for licensing under 10 CFR Part 35. It contains information that is intended to assist applicants with the preparation of license applications for the medical use of byproduct material. In particular, it describes the types of information needed to complete NRC Form 313, "Application for Material License," and the NRC Form 313A, series of forms. Volume 9 provides an overview of the types of licenses issued by the NRC and the commitments and responsibilities that a licensee must undertake. In addition, it identifies the applicable regulations, the process for filing a license application, and the contents of applications for different types of medical uses of byproduct material. Because of the wide variety in the types of medical uses of byproduct material, Volume 9 contains indicators to alert applicants to information pertinent to particular types of medical uses.

In addition, Volume 9 of NUREG-1556 contains appendices that include (1) copies of necessary forms, (2) a sample license application and completed licenses for different types of medical uses of byproduct materials, and (3) examples of the types of supporting documents, such as implementing procedures, that applicants may need to prepare and (4) information required by regulation for requesting authorization for preparation of Positron Emission Tomography (PET) radioactive drugs for

noncommercial distribution to other members of a consortium. The NRC is placing added emphasis on conducting its regulatory activities in a risk-informed and performance-based manner to be less prescriptive and to allow for the implementation by licensees that may be specific to their needs while meeting the regulatory requirements. By supplying examples, the NRC seeks to provide information to meet the needs of applicants for licensure without being prescriptive.

NUREG-1556 is available electronically through the Public 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 for the PDR is USNRC PDR, Washington, DC 20555; telephone (301) 415-4737 or (800) 397-4209; fax (301) 415-3548; and email 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, 5285 Port Royal Road, Springfield, Virginia 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 has been found acceptable to the NRC for meeting the regulatory requirements for integrity and test specifications for selected 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 6.2 in July 1974 to provide licensees with agency-approved guidance for complying with the then current versions of 10 CFR 32.74, "Manufacture and Distribution of Sources or Devices Containing Byproduct Material for Medical Use." The NRC's implementation of a risk-informed, performance-based approach, combined with multiple updates and revisions to the regulations, makes the current regulatory guide 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. This

comprehensive repository is 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.

The objective of this action is to provide clear and up-to-date information to support consolidated guidance about materials licenses in general and integrity and test specifications for selected brachytherapy sources in particular.

3. Alternative Approaches

To meet this objective, the staff considered the following alternative approaches:

- Do not revise Regulatory Guide 6.2.
- Withdraw Regulatory Guide 6.2.
- Revise Regulatory Guide 6.2 to match or replace Volumes 3 and 9 of NUREG-1556.
- Revise Regulatory Guide 6.2 to endorse Volumes 3 and 9 of NUREG-1556.

3.1 Alternative 1: Do Not Revise Regulatory Guide 6.2

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 6.2

Withdrawing this regulatory guide would eliminate the problem of NUREG 1556 and this regulatory guide containing duplicate and occasionally contradictory information. However, this action would leave a void in the regulatory guide system and provide no quick means for interested parties to identify the method(s) that the NRC finds acceptable for integrity and test specifications of selected brachytherapy sources. Although this alternative would cost relatively little, it may impede the public's accessibility to the most current information.

3.3 Alternative 3: Revise Regulatory Guide 6.2 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 6.2 contains specific guidance about only one of the many areas covered in Volumes 3 and 9 of NUREG-1556. Revising Regulatory Guide 6.2 to match the existing guidance for integrity and test specifications of selected brachytherapy sources in Volumes 3 and 9 of NUREG-1556 would result in creating duplicate sources of information and would require future staff resources to ensure that the separate documents continue to contain duplicate information. Revising this regulatory guide to replace the guidance in the NUREG volumes would involve 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 6.2 to Endorse 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 32 and 10 CFR Part 35. Failure to revise the regulatory guide would result in conflicting guidance documents and possible confusion to interested parties. Therefore, the staff has chosen to revise the regulatory guide to direct any interested parties to the most current guidance for integrity and test specifications of selected brachytherapy sources 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 6.2 to endorse the methods and procedures for integrity and test specifications of selected brachytherapy sources contained in the current revisions of 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.