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REGULATORY GUIDE

OFFICE OF NUCLEAR REGULATORY RESEARCH

REGULATORY GUIDE 6.1

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LEAK TESTING RADIOACTIVE BRACHYTHERAPY SOURCES

A. INTRODUCTION

This 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) (Ref. 1). The requirements in 10 CFR 35.67, "Requirements for Possession of Sealed Sources and Brachytherapy Sources" (Ref. 2), state, in part, 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 The regulations also require that the source be immediately withdrawn from use if the test reveals the presence of 185 Bq (0.005 μCi) or more of removable contamination.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 NUREG-1556, Volume 3, "Consolidated Guidance about Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration" (Ref. 3), and NUREG-1556, Volume 9, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Medical Use Licenses" (Ref. 4), 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 the

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The NRC issues regulatory guides to describe and make available to the public methods that the NRC staff considers acceptable for use in implementing specific parts of the agency's regulations, techniques that the staff uses in evaluating specific problems or postulated accidents, and data that the staff needs in reviewing applications for permits and licenses. Regulatory guides are not substitutes for regulations, and compliance with them is not required. Methods and solutions that differ from those set forth in regulatory guides will be deemed acceptable if they provide a basis for the findings required for the issuance or continuance of a permit or license by the Commission.

This guide was issued after consideration of comments received from the public.

Regulatory guides are issued in 10 broad divisions—1, Power Reactors; 2, Research and Test Reactors; 3, Fuels and Materials Facilities; 4, Environmental and Siting; 5, Materials and Plant Protection; 6, Products; 7, Transportation; 8, Occupational Health; 9, Antitrust and Financial Review; and 10, General.

Electronic copies of this guide and other recently issued guides are available through the NRC's public Web site under the Regulatory Guides document collection of the NRC's Electronic Reading Room at http://www.nrc.gov/reading-rm/doc-collections/ and through the NRC's Agencywide Documents Access and Management System (ADAMS) at http://www.nrc.gov/reading-rm/adams.html, under Accession No. ML081140467.

NRC criteria for evaluating a medical use license application which includes the use of radioactive sources for brachytherapy.

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.

This regulatory guide contains information collection requirements covered by 10 CFR Part 35 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 includes a discussion of the NRC's criteria for evaluating a medical use license application. Appendix Q, "Model Leak Test Program" of Volume 9, contains procedures for leak testing of brachytherapy sources that the NRC has found to be an acceptable method of demonstrating compliance with the requirements of 10 CFR 35.67.

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 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 (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 regulatory guide. The NRC does not intend or approve any imposition or backfit in connection with its issuance.

In some cases, applicants or licensees may propose or use a previously established acceptable alternative method for complying with specified portions of the NRC's regulations. Otherwise, the methods described in this guide will be used in evaluating compliance with the applicable regulations for license applications, license amendment applications, and amendment requests.

REFERENCES

1. 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," U.S. Nuclear Regulatory Commission, Washington, DC.[1]

2. 10 CFR Part 35, "Medical Use of Byproduct Material," U.S. Nuclear Regulatory Commission, Washington, DC.[1]

3. NUREG-1556, Volume 3, "Consolidated Guidance about Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration," Washington DC, U.S. Nuclear Regulatory Commission, most current date and revision.[2] (http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/)

4. NUREG-1556, Volume 9, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Medical Use Licenses," U.S. Nuclear Regulatory Commission, Washington DC, most current date and revision.[2] (http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/)

[1] All NRC regulations listed herein are available electronically through the Electronic Reading Room on the NRC's public Web site, at http://www.nrc.gov/reading-rm/doc-collections/cfr/. 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 email PDR@nrc.gov.

[2] The multivolume NUREG-series report listed herein was published by the U.S. Nuclear Regulatory Commission. These volumes are available electronically through the Electronic Reading Room on the NRC's public Web site, at http://www.nrc.gov/reading-rm/doc-collections/nuregs/. 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 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 (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.