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REGULATORY GUIDE

OFFICE OF NUCLEAR REGULATORY RESEARCH

REGULATORY GUIDE 6.2

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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 for 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) (Ref. 1). Brachytherapy sources manufactured under such a license must meet certain integrity requirements and pass certain tests. The regulation at 10 CFR 32.74(a)(2)(iii) (Ref. 2) 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 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 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. ML081140471.

Since the initial publication of Regulatory Guide 6.2 in 1974, the NRC has revised the requirements for the medical use of byproduct materials in 10 CFR Part 32, "Specific Domestic Licenses To Manufacture or Transfer Certain Items Containing Byproduct Material," and 10 CFR Part 35, "Medical Use of Byproduct Material" (Ref. 5), to implement a risk-informed, performance-based approach to regulation. Volumes 3 and 9 of NUREG-1556 incorporate this revised approach.

This regulatory guide contains information collections covered by 10 CFR Parts 32 and 35 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 Materials License," and the series of forms under NRC Form 313A, "Training and Experience and Preceptor Statement." 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.

Volume 9 of NUREG-1556 includes a discussion of the NRC's criteria for evaluating a medical use license application. Complementary guidance on inspection procedures for inspections of medical use licensees is contained in documents available at the NRC's web page on the medical use of byproduct material (Ref. 6) (http://www.nrc.gov/materials/miau/med-use-toolkit.html).

In addition, Volume 9, like 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 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 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 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material," U.S. Nuclear Regulatory Commission, Washington, DC.

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

5. 10 CFR Part 35, "Medical Use of Byproduct Material," U.S. Nuclear Regulatory Commission, Washington, DC.

6. Medical Uses Licensee Toolkit, U.S. Nuclear Regulatory Commission, Washington DC, NRC Web site: (http://www.nrc.gov/materials/miau/med-use-toolkit.html).

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[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.