[7590-01-P]

U.S. NUCLEAR REGULATORY COMMISSION

Notice of Issuance of Regulatory Guide

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of Issuance and Availability of Regulatory Guide 6.2, Revision 2.

FOR FURTHER INFORMATION CONTACT: Mark Orr, Regulatory Guide Development Branch, Division of Engineering, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-6373 or e-mail to Mark.Orr@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

The U.S. Nuclear Regulatory Commission (NRC) has issued revisions to existing guides in the agency's "Regulatory Guide" series. This series was developed to describe and make available to the public information such as methods that are acceptable to the NRC staff for 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 its review of applications for permits and licenses.

Revision 2 of Regulatory Guide 6.2, "Integrity and Test Specifications for Selected Brachytherapy Sources," was issued with a temporary identification as Draft Regulatory Guide DG-6004. This guide directs the reader to the type of information acceptable to the NRC staff 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). 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) 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" and NUREG-1556, Volume 9, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Medical Use Licenses" as a process that the NRC staff has found to be acceptable for meeting the regulatory requirements.

II. Further Information

In December 2007, DG-6004 was published with a public comment period of 60 days from the issuance of the guide. No comments were received and the public comment period closed on April 18, 2008. Electronic copies of Regulatory Guide 6.2, Revision 2 are available through the NRC's public Web site under "Regulatory Guides" at http://www.nrc.gov/reading-rm/doc-collections/.

In addition, regulatory guides are available for inspection at the NRC's Public Document Room (PDR), which is located at Room O-1F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852-2738. The PDR's mailing address is USNRC PDR, Washington, DC 20555-0001. The PDR can also be reached by telephone at (301) 415-4737 or (800) 397-4209,

by fax at (301) 415-3548, and by e-mail to pdr@nrc.gov.

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Dated at Rockville, Maryland, this 11th day of July, 2008.

For the Nuclear Regulatory Commission.

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