[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 10.8, Revision 3.

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) is issuing a revision to an existing guide 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 3 of Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Use Programs," was previously issued with a temporary identification as Draft Regulatory Guide, DG-0018 and an opportunity for public comments. This regulatory guide directs the reader to the type of information acceptable to the NRC staff for review of an application for a medical use license. Title 10, Part 35, "Medical Use of Byproduct Material," of the *Code of Federal Regulations* (10 CFR Part 35) regulates the medical use of byproduct material. In addition to the requirements of 10 CFR Part 35, medical use licensees may be subject to those portions of 10 CFR Part 20, "Standards for Protection Against Radiation," that relate to radiation safety and the sections of 10 CFR Part 30, "Rules of General Applicability to

Domestic Licensing of Byproduct Material," that relate to licensing and the noncommercial transfer of specific radioactive drugs to medical use licensees within a consortium.

This regulatory guide endorses the methods and procedures for medical licensing applications contained in the current revision of NUREG–1556, Volume 9, "Consolidated Guidance about Material Licenses: Program-Specific Guidance about Medical Use Licenses," as a process that the NRC staff finds acceptable for meeting the regulatory requirements.

II. Further Information

In April 2008, DG-0018 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 June 30, 2008. Electronic copies of Regulatory Guide 10.8, Revision 3 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.resource@nrc.gov

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Dated at Rockville, Maryland, this 10th day of September, 2008.

For the Nuclear Regulatory Commission.

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Stephen C. O'Connor, Acting Chief,
Regulatory Guide Development Branch,
Division of Engineering,
Office of Nuclear Regulatory Research.