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REGULATORY GUIDE

OFFICE OF NUCLEAR REGULATORY RESEARCH

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GUIDE FOR THE PREPARATION OF APPLICATIONS FOR THE USE OF SELF-CONTAINED DRY SOURCE-STORAGE GAMMA IRRADIATORS

A. INTRODUCTION

This regulatory guide directs the reader to the type of information acceptable to the U.S. Nuclear Regulatory Commission (NRC) staff for the preparation and review of an application for the use of a self-contained dry source-storage gamma irradiator. Title 10, Part 36, "Licenses and Radiation Safety Requirements for Irradiators," of the *Code of Federal Regulations* (10 CFR Part 36) (Ref. 1) contains the licensing, design, and radiation safety requirements for irradiators. In addition, licensees and applicants may be subject to portions of the requirements in 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material" (Ref. 2), and 10 CFR Part 20, "Standards for Protection Against Radiation" (Ref. 3).

This regulatory guide endorses the methods and procedures describing how to apply for a license to use a self-contained dry source-storage gamma irradiator that are contained in the current revision of NUREG-1556, Volume 5, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Self-Shielded Irradiator Licenses" (Ref. 4), as a process that the NRC staff finds acceptable for meeting the regulatory requirements.

Volume 5 of NUREG-1556 addresses the issues that an applicant must respond to when preparing a license application on NRC Form 313, "Application for Materials License." The NUREG also includes guidance on amending a license and terminating operations.

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. ML081960560.

This regulatory guide contains information collection requirements covered by 10 CFR Parts 20, 30, and 36 and NRC Form 313 that the Office of Management and Budget (OMB) approved under OMB control numbers 3150-0014, 3150-0017, 3150-0158, and 3150-0120, 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 licensing program, the NRC consolidated and updated numerous guidance documents for materials 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 5 of NUREG-1556 provides program-specific guidance on applying for a license to use a self-contained dry source-storage gamma irradiator and identifies the information needed to complete NRC Form 313. Additionally, the NUREG provides an overview of the types of irradiator licenses issued by the NRC, the commitments and responsibilities that a licensee must undertake, applicable regulations, the process for filing a license application, and the contents of applications for different types of irradiators. In particular, Volume 5 of NUREG-1556 gives an item-by-item description of the information to be provided by an applicant. Because of the wide variety in the types of irradiators, the NUREG contains indicators to alert applicants for particular types of irradiators to information that pertains to those types. 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 NUREG-1556 represents one means of complying with NRC regulations and is not intended to be the only means of satisfying the regulatory requirements.

C. REGULATORY POSITION

This regulatory guide endorses the guidance for applying for a license to use a self-contained dry source-storage gamma irradiator or revising an existing license for a self-contained source-storage gamma irradiator described in the current revision of NUREG-1556, Volume 5, as a process that the NRC has found to be acceptable for meeting the regulatory requirements.

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 36, "Licenses and Radiation Safety Requirements for Irradiators," U.S. Nuclear Regulatory Commission, Washington, DC.[1]

2. 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," U.S. Nuclear Regulatory Commission, Washington, DC.

3. 10 CFR Part 20, "Standards for Protection Against Radiation," U.S. Nuclear Regulatory Commission, Washington, DC.

4. NUREG-1556, Volume 5, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Self-Shielded Irradiator 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 e-mail PDR@nrc.gov.

[2] All NUREG-series reports listed herein have been published by the U.S. Nuclear Regulatory Commission. They 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 e-mail 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.