



# REGULATORY GUIDE

OFFICE OF NUCLEAR REGULATORY RESEARCH

## REGULATORY GUIDE 6.5

(Draft was issued as DG-6006, dated January 2008)

# GENERAL SAFETY STANDARDS FOR INSTALLATIONS USING NONMEDICAL SEALED GAMMA-RAY SOURCES

## A. INTRODUCTION

This guide directs the reader to the type of information acceptable to the U.S. Nuclear Regulatory Commission (NRC) to approve the initial transfer of devices containing byproduct material to persons generally licensed under Title 10, Section 31.5, “Certain Detecting, Measuring, Gauging, or Controlling Devices, and Certain Devices for Producing Light or an Ionized Atmosphere,” of the *Code of Federal Regulations* (10 CFR 31.5) (Ref. 1) or equivalent regulations of an Agreement State.

The requirements for transferring gamma-ray sources to general licensees appear in 10 CFR 32.51, “Byproduct Material Contained in Devices for Use Under § 31.5; Requirements for License to Manufacturer, or Initially Transfer” (Ref. 2). One method of complying with the requirements of 10 CFR 32.51 appears in NUREG-1556, Volume 3, “Consolidated Guidance about Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration” (Ref. 3).

This regulatory guide endorses the description of the information to be submitted in the application for the initial transfer and installation of sealed gamma-ray sources contained in the current revision of Volume 3 of NUREG-1556 as a method acceptable to the NRC staff.

Volume 3 of NUREG-1556 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.

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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. ML081140498.

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Radiation safety programs for sealed gamma-ray sources or devices are structured on two key points. First, the byproduct material will not breach its containment and contaminate the environment or unnecessarily expose individuals to radiation. Second, the sealed source or device will be installed and operated correctly and in accordance with the manufacturer's instructions. Regulatory Guide 6.4, "Verification of Containment Properties of Sealed Radioactive Sources," discusses verification of the byproduct containment system. This guide directs the reader to the type of information necessary for the NRC to review the safety standards for the installation of the source or device.

This regulatory guide contains information collection requirements covered by 10 CFR Parts 31, and 32 that the Office of Management and Budget (OMB) approved under OMB control numbers 3150-0016, 3150-0001, 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 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 guidance to applicants for requests for sealed source or device safety evaluations and registrations. It also provides reviewers of such requests with the information and materials necessary to determine that the products are acceptable for licensing purposes. It provides the applicants and reviewers with information concerning how to file a request, a list of the applicable regulations, industry and consensus 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.

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 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 description of the information to be submitted in the application for the initial transfer and installation of sealed gamma-ray sources contained in the current revision of NUREG-1556, Volume 3, as a process that the NRC has found to be acceptable.

## **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 31, “General Domestic Licenses for Byproduct Material,” U.S. Nuclear Regulatory Commission, Washington, DC.<sup>1</sup>
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.<sup>2</sup> (<http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/>)

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<sup>1</sup> 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](mailto:PDR@nrc.gov).

<sup>2</sup> 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](mailto: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.