



REGULATORY GUIDE

OFFICE OF NUCLEAR REGULATORY RESEARCH

REGULATORY GUIDE 6.4

(Draft was issued as DG-6005, dated January 2008)

VERIFICATION OF CONTAINMENT PROPERTIES OF SEALED RADIOACTIVE SOURCES

A. INTRODUCTION

This guide directs the reader to the type of information acceptable to the U.S. Nuclear Regulatory Commission (NRC) to evaluate and verify the containment properties of sealed radioactive sources. The NRC licenses the manufacture and distribution of devices containing radioactive byproduct material under Title 10, Part 32, “Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material,” of the *Code of Federal Regulations* (10 CFR Part 32) (Ref. 1). The regulations require, in part, that each application for a specific license to distribute devices containing byproduct material include information on procedures for prototype tests and the results of such tests to demonstrate that the source or device will maintain its integrity during the most severe conditions that are likely to be encountered under normal or accidental conditions of handling, storage, use, and disposal of the sealed radioactive source.

The provisions of 10 CFR Part 32 address the specific licensing requirements for containment of byproduct material in sealed radioactive sources by product type. The following regulations delineate the requirements for licensing major product categories and specific exempt products:

- 10 CFR 32.14, “Certain Items Containing Byproduct Material; Requirements for License To Apply or Initially Transfer,”
- 10 CFR 32.15, “Same: Quality Assurance, Prohibition of Transfer, and Labeling,”
- 10 CFR 32.16, “Certain Items Containing Byproduct Material: Records and Reports of Transfer,”

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/reg-guides/> and through the NRC’s Agencywide Documents Access and Management System (ADAMS) at <http://www.nrc.gov/reading-rm/adams.html> under Accession No. ML081140487.

- 10 CFR 32.18, “Manufacture, Distribution and Transfer of Exempt Quantities of Byproduct Material: Requirements for License,”
- 10 CFR 32.19, “Same: Conditions of Licenses,”
- 10 CFR 32.20, “Same: Records and Material Transfer Reports,”
- 10 CFR 32.21, “Radioactive Drug: Manufacture, Preparation, or Transfer for Commercial Distribution of Capsules Containing Carbon-14 Urea Each for ‘In Vivo’ Diagnostic for Humans to Persons Exempt from Licensing; Requirements for a License,”
- 10 CFR 32.21a, “Same: Conditions of License,”
- 10 CFR 32.22, “Self-Luminous Products Containing Tritium, Krypton-85, or Promethium-147: Requirements for License To Manufacture, Process, Produce, or Initially Transfer,”
- 10 CFR 32.23, “Same: Safety Criteria,”
- 10 CFR 32.25, “Conditions of Licenses Issued Under § 32.22: Quality Control, Labeling, and Reports of Transfer,”
- 10 CFR 32.26, “Gas and Aerosol Detectors Containing Byproduct Material: Requirements for License To Manufacture, Process, Produce, or Initially Transfer,”
- 10 CFR 32.27, “Same: Safety Criteria,”
- 10 CFR 32.28, “Same: Table of Organ Doses,”
- 10 CFR 32.29, “Conditions of Licenses Issued Under § 32.26: Quality Control, Labeling, and Reports of Transfer,”
- 10 CFR 32.74, “Manufacture and Distribution of Sources or Devices Containing Byproduct Material for Medical Use,” and
- 10 CFR 32.210, “Registration of Product Information” (for specifically licensed items).

Additionally, vendors under other material licenses may be required to submit similar qualification testing information when requesting approvals for standardized source or device designs. Retention of radioactive material within a device or source is dependent on the containment properties of the source.

Radiation safety programs for the use of byproduct material in a sealed source or device are structured on the presumption that the byproduct material will not breach its containment and contaminate the environment or unnecessarily expose individuals to radiation. This presumption depends largely upon the adequacy of the containment properties of the sealed sources or devices in withstanding the stresses imposed by the environment in which they are possessed and used.

This regulatory guide endorses the methods and procedures for evaluation and verification of the containment properties of sealed radioactive sources contained in the current revision of NUREG-1556, Volume 3, “Consolidated Guidance about Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration” (Ref. 2), as a process that has been found acceptable to the NRC staff for meeting the regulatory requirements. Since the publication of Revision 2 of Regulatory Guide 6.4 in August 1980, the NRC has revised the requirements for byproduct material containments in 10 CFR Part 32 to implement a risk-informed, performance-based approach to regulation. NUREG-1556 incorporates this revised approach.

This regulatory guide contains information collection requirements covered by 10 CFR Part 32 that the Office of Management and Budget (OMB) approved under OMB control number 3150-0001. 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 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.

C. REGULATORY POSITION

This regulatory guide endorses the methods and procedures for evaluation and verification of the containment properties of sealed radioactive sources described in the current revision of Volume 3 of NUREG-1556 as a process that has been found acceptable to the NRC 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 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material," U.S. Nuclear Regulatory Commission, Washington, DC.¹
2. 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/>)

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.