



# DRAFT REGULATORY GUIDE

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## DRAFT REGULATORY GUIDE DG-7008 (Proposed Revision 1 to Regulatory Guide 7.4, dated June 1975)

# LEAKAGE TESTS ON PACKAGES FOR SHIPMENT OF RADIOACTIVE MATERIALS

## A. INTRODUCTION

This guide describes an approach that the staff of the U.S. Nuclear Regulatory Commission (NRC) considers acceptable for meeting the containment criteria for Type B packages in Title 10, Section 71.51, "Additional Requirements for Type B Packages," of the *Code of Federal Regulations* (10 CFR 71.51) (Ref. 1). The regulations at 10 CFR 71.51 require licensees to ensure that Type B packages, following tests for normal conditions of transport and hypothetical accident conditions, meet the containment criteria to minimize radioactive contamination and dose rates to the public. The NRC staff developed and published this guidance to help licensees meet these objectives, ensure package integrity, and minimize the distribution of contamination to the environment.

This regulatory guide endorses the methods and procedures developed by the Standards Committee on Packaging and Transportation of Radioactive and Nonnuclear Hazardous Materials, N14, Subcommittee of the American National Standards Institute (ANSI) in ANSI N14.5-1997, "Radioactive Materials - Leakage Tests on Packages for Shipment," issued 1997 (Ref. 2), as a process that the NRC staff considers acceptable for meeting the regulatory requirements.

The NRC issues regulatory guides to describe to the public methods that the NRC staff considers acceptable for use in implementing specific parts of the agency's regulations, to explain techniques that the NRC staff uses in evaluating specific problems or postulated accidents, and to provide guidance to applicants. Regulatory guides are not substitutes for regulations and compliance with them is not required.

This regulatory guide contains information collection requirements covered by 10 CFR Part 71 that the Office of Management and Budget (OMB) approved under OMB control number 3150-0008. 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. The NRC has determined that this Regulatory Guide is not a major rule as designated by the Congressional Review Act and has verified this determination with the OMB.

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This regulatory guide is being issued in draft form to involve the public in the early stages of the development of a regulatory position in this area. It has not received final staff review or approval and does not represent an official NRC final staff position. Public comments are being solicited on this draft guide (including any implementation schedule) and its associated regulatory analysis or value/impact statement. Comments should be accompanied by appropriate supporting data. Written comments may be submitted to the Rules, Announcements, and Directives Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; submitted through the NRC's interactive rulemaking Web page at <http://www.nrc.gov>; or faxed to (301) 492-3446. Copies of comments received may be examined at the NRC's Public Document Room, 11555 Rockville Pike, Rockville, MD. Comments will be most helpful if received by April 26, 2011.

Electronic copies of this draft regulatory guide are available through the NRC's interactive rulemaking Web page (see above); the NRC's public Web site under Draft Regulatory Guides in the Regulatory Guides document collection of the NRC's Electronic Reading Room at <http://www.nrc.gov/reading-rm/doc-collections/>; and the NRC's Agencywide Documents Access and Management System (ADAMS) at <http://www.nrc.gov/reading-rm/adams.html>, under Accession No. ML102350572. The regulatory analysis may be found in ADAMS under Accession No. ML102350573.

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## **B. DISCUSSION**

The regulations at 10 CFR Part 71, “Packaging and Transportation of Radioactive Material,” establish the requirements for the packaging, preparation for shipment, and transportation of licensed material in such a manner that the total dose to an individual (including doses resulting from licensed and unlicensed radioactive material and from radiation sources other than background radiation) does not exceed the standards for protection against radiation prescribed in 10 CFR Part 20, “Standards for Protection against Radiation” (Ref. 3). The regulation describes package release limits, methods for relating package release limits to allowable and reference leakage rates, and minimum requirements for leakage rate test procedures. The regulation also provides requirements for the design, fabrication, maintenance, periodic testing, and preshipment leakage rate tests of packages that contain radioactive material.

## **C. REGULATORY POSITION**

This regulatory guide endorses the methods described in ANSI N14.5-1997 and constitutes a procedure generally acceptable by the NRC staff for assessing the containment properties of packages for the shipment of radioactive material to satisfy the provisions of 10 CFR Part 71.51.

## **D. IMPLEMENTATION**

This implementation section is in two parts. The first part addresses applicants, licensees, and holders of certificates of compliance for nuclear power reactors and certain materials facilities including fuel facilities, spent fuel and radioactive waste storage facilities, and uranium enrichment facilities subject to the requirements of the backfitting regulations in 10 CFR 50.109, or 10 CFR 70.76, or 10 CFR 72.62, or 10 CFR 76.76. The second part of this section addresses implementation of this guide for other applicants, licensees, or holders of certificates of compliance that are not subject to the backfitting regulations and requirements identified above.

This implementation section provides information on how applicants, licensees, and certificate of compliance holders, may voluntarily use this regulatory guide. This section also provides information on how the NRC plans to use this regulatory guide and how the NRC implements the backfit regulatory requirements in 10 CFR 50.109 (or 70.76, 72.62, or 76.76, as appropriate), “Backfitting,” and any applicable finality provisions in 10 CFR Part 52.

### **1. Power Reactors and Certain Materials Facilities Including Fuel Facilities, Spent Fuel and Radioactive Waste Storage Facilities, and Uranium Enrichment Facilities**

#### **Applicant and Licensee Use**

Applicants, licensees, and holders of certificate of compliance who are currently subject to the backfitting regulations in 10 CFR 50.109, or 10 CFR 70.76, or 10 CFR 72.62, or 10 CFR 76.76, “Backfitting” may voluntarily use the information in this regulatory guide to develop applications for initial licenses, amendments to licenses, or other requests for NRC regulatory approval (e.g., exemptions). Licensees may use the information in this regulatory guide for actions which do not require prior NRC review and approval (e.g., changes to a facility design under 10 CFR 50.59 or equivalent regulations which do not require prior NRC review and approval). Licensees may use the information in this Regulatory Guide or applicable parts to resolve regulatory or inspection issues (e.g., by committing to comply with provisions in the regulatory guide).

Current licensees may continue to use any existing guidance the NRC has previously found to be acceptable for complying with the specific portions of the regulations addressed in this regulatory guide. This previously acceptable guidance may be a previous version of this regulatory guide.

A licensee who believes that the NRC staff is inappropriately imposing the voluntary guidance in this regulatory guide as part of a request for a license amendment or request for a change to a previously issued NRC regulatory approval may file a backfitting appeal with the NRC in accordance with applicable procedures.

### **NRC Staff Use**

The NRC staff does not intend or approve any imposition or backfitting of the guidance in this Regulatory Guide in the absence of a licensee-initiated change to its licensing basis. The NRC staff does not expect or plan to request licensees to voluntarily adopt this Regulatory Guide to resolve a generic regulatory issue. The NRC staff does not expect or plan to initiate NRC regulatory action which would require the use of this regulatory guide (e.g. issuance of an order requiring the use of the Regulatory Guide, requests for information under NRC regulations such as 10 CFR 50.54(f) as to whether a licensee intends to commit to use of this regulatory guide, generic communication, or promulgation of a rule requiring the use of this Regulatory Guide) without further backfit consideration. The NRC staff intends to consider the information contained within this Regulatory Guide when evaluating whether a licensee's program and their implementation meet applicable NRC requirements.

During inspections of specific facilities, the staff may suggest or recommend that licensees consider various actions consistent with staff positions in this regulatory guide. Such suggestions and recommendations would not ordinarily be considered backfitting even if prior versions of this Regulatory Guide are part of the licensing basis of the facility with respect to the subject matter of the inspection. However, the staff may not represent to the licensee that: (i) the licensee's failure to comply with the positions in this Regulatory Guide constitutes a violation; (ii) the licensee may avoid the violation by agreeing to comply with this Regulatory Guide; or (iii) the only acceptable way for the licensee to address the NRC-identified non-compliance or violation is to commit to this Regulatory Guide (i.e., including this Regulatory Guide in the facility's licensing basis).

If an existing licensee seeks a license amendment or change to an existing approved area of NRC regulatory concern and (1) the NRC staff's consideration of the request involves a regulatory issue that is directly relevant to this new or revised regulatory guide and (2) the specific subject matter of this regulatory guide is an essential consideration in the staff's determination of the acceptability of the licensee's request, then, as a prerequisite for NRC approval of the license amendment or change, the staff may require the licensee to follow the guidance in this regulatory guide or provide an equivalent alternative method to demonstrate compliance with the underlying NRC regulatory requirement. This is not considered backfitting as defined in 10 CFR 50.109(a)(1) (or 70.76(a)(1), or 72.62(a), or 76.76(a)(1), as appropriate) or a violation of any of the issue finality provisions in 10 CFR Part 52.

### **Conclusion**

For nuclear power reactors and certain material facilities including fuel facilities, spent fuel and radioactive waste storage facilities and uranium enrichment facilities, this regulatory guide is not being imposed upon applicants, current licensees, or holders of certificates of compliance and any use by any of these groups is purely voluntary. In addition, this regulatory guide is issued in conformance with all internal NRC policies and procedures governing backfitting. Accordingly, issuance of this regulatory guide by the NRC staff is not considered backfitting as defined in 10 CFR 50.109(a)(1) (or 70.76(a)(1), or

72.62(a), or 76.76(a)(1), as appropriate) or a violation of any of the issue finality provisions in 10 CFR Part 52.

**2. Other Applicants, licensees, and holders of certificates of compliance NOT subject to the requirements of the backfitting regulations in 10 CFR 50.109, 70.76, 72.62, or 76.76**

**Introduction**

The purpose of this section is to provide information to other applicants, licensees, and holders of certificates of compliance regarding the NRC's plans for using this regulatory guide.

**Applicant, Licensee, and NRC Staff Use**

This regulatory guide describes one method the NRC has determined to be acceptable for the applicant, licensee, or certificate holder to demonstrate compliance with the regulatory requirements identified in this regulatory guide. This regulatory guide is not a substitute for the regulations and compliance with this regulatory guide is not required.

In some cases, applicants or licensees may propose an equivalent alternative method 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<sup>1</sup>

1. 10 CFR Part 71, “Packaging and Transportation of Radioactive Material,” U.S. Nuclear Regulatory Commission, Washington, DC.
2. ANSI N14.5-1997, “Radioactive Materials—Leakage Tests on Packages for Shipment,” American National Standards Institute, New York, NY, 1997.<sup>2</sup>
3. 10 CFR Part 20, “Standards for Protection against Radiation,” U.S. Nuclear Regulatory Commission, Washington, DC.

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<sup>1</sup> All publicly available NRC documents 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/>. The documents can also be viewed on-line for free or printed for a fee in 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.resource@nrc.gov](mailto:pdr.resource@nrc.gov).

<sup>2</sup> Copies of American National Standards Institute (ANSI) standards may be purchased from ANSI, 1819 L Street, NW., Washington, DC 20036, on their Web site at <http://webstore.ansi.org/>; telephone (202) 293-8020; fax (202) 293-9287; or e-mail [storemanager@ansi.org](mailto:storemanager@ansi.org).