

U.S. NUCLEAR REGULATORY COMMISSION

DRAFT REGULATORY GUIDE DG-7010



Proposed Revision 2 to Regulatory Guide 7.4

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Technical Lead: JoAnn Ireland

LEAKAGE TESTS ON PACKAGES FOR SHIPMENT OF RADIOACTIVE MATERIAL

A. INTRODUCTION

Purpose

This regulatory guide (RG) describes methods and procedures acceptable to the U.S. Nuclear Regulatory Commission (NRC) staff to meet the requirements in 10 CFR Part 71, “Packaging and Transportation of Radioactive Material” (Ref. 1), for leakage tests of packages to ensure the integrity of radioactive materials containers and to minimize the distribution of contamination to the environment.

It endorses the American National Standards Institute (ANSI) Standards Committee on Packaging and Transportation of Radioactive and Nonnuclear Hazardous Materials (N14), Subcommittee on Leakage Tests on Packages for Shipment of Radioactive Materials (N14.5), developed in ANSI N14.5-2014, “Radioactive Materials—Leakage Tests on Packages for Shipment,” dated June 19, 2014 (Ref. 2), which contains the most current information on meeting the requirements in 10 CFR Part 71.

Applicability

This RG applies to NRC licensees that transport a Type B quantity of radioactive materials or that deliver a Type B quantity of radioactive materials to a carrier for transport (10 CFR Part 71.4, “Definitions,” provides a definition for a Type B package) under 10 CFR Part 71, as well as holders of or applicants for a Type B transportation certificate of compliance (CoC) for the design and fabrication of packages for the transport of a Type B quantity of radioactive materials under 10 CFR Part 71.

Applicable Regulations

- 10 CFR Part 71 provides requirements for the packaging, preparation for shipment, and transportation of licensed material, and procedures and standards for NRC approval of packaging and shipping procedures for fissile material and for a quantity of other licensed material in excess of a Type A quantity.

This RG is being issued in draft form to involve the public in the development of regulatory guidance in this area. It has not received final staff review or approval and does not represent an NRC final staff position. Public comments are being solicited on this DG and its associated regulatory analysis. Comments should be accompanied by appropriate supporting data. Comments may be submitted through the Federal rulemaking Web site, <http://www.regulations.gov>, by searching for draft regulatory guide DG-7010. Alternatively, comments may be submitted to the Rules, Announcements, and Directives Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Comments must be submitted by the date indicated in the *Federal Register* notice.

Electronic copies of this DG, previous versions of DGs, and other recently issued guides are available through the NRC’s public Web site under the Regulatory Guides document collection of the NRC Library at <https://nrcweb.nrc.gov/reading-rm/doc-collections/reg-guides/>. The DG is also available through the NRC’s Agencywide Documents Access and Management System (ADAMS) at <http://www.nrc.gov/reading-rm/adams.html>, under Accession No. ML19042A172. The regulatory analysis may be found in ADAMS under Accession No. ML19042A183.

- 10 CFR 71.43(f) requires a package to be designed, constructed, and prepared for shipment so that, under the tests specified in 10 CFR 71.71, “Normal Conditions of Transport,” there would be no loss or dispersal of radioactive contents, no significant increase in external surface radiation levels, and no substantial reduction in the effectiveness of the packaging.
- 10 CFR 71.43(h) provides that a package may not incorporate a feature intended to allow continuous venting during transport.
- 10 CFR 71.51 requires licensees to ensure that Type B packages, by following tests for normal conditions of transport and hypothetical accident conditions, meet the containment criteria to minimize radioactive contamination and ensure that dose rates to the public do not exceed the standards for protection against radiation in 10 CFR Part 20, “Standards for Protection Against Radiation” (Ref. 3).
 - 10 CFR 71.51(a) requires that a Type B package must satisfy the requirements of §§ 71.41 through 71.47 and be designed, constructed, and prepared for shipment subject to the following tests:
 1. 10 CFR 71.51(a)(1) states that there would be no loss or dispersal of radioactive contents as demonstrated to a sensitivity of 10^{-6} A₂ per hour, under 10 CFR 71.71, “Normal Conditions of Transport.” An A₂ is the maximum activity of radioactive material, other than special form material, low specific activity (LSA), and surface contaminated object (SCO) material permitted in a Type A package. This value is either listed in Appendix A, “Determination of A₁ and A₂,” Table A-1, “A₁ and A₂ Values for Radionuclides,” of 10 CFR 71, or may be derived in accordance with the procedures in Appendix A of 10 CFR 71.
 2. 10 CFR 71.51(a)(2) states that there would be no escape of krypton-85 exceeding 10 A₂ in 1 week, and no escape of other radioactive material exceeding a total amount A₂ in 1 week, and no external radiation dose rate exceeding 10 mSv/h (1 rem/h) at 1 m (40 in) from the external surface of the package under 10 CFR 71.73, “Hypothetical Accident Conditions.”
 - 10 CFR 71.51(c) requires that compliance with the permitted activity release limits of 10 CFR 71.51(a) may not depend on filters or on a mechanical cooling system.
- 10 CFR 71.85(a) requires the certificate holder to ascertain that the packaging has no cracks, pinholes, uncontrolled voids, or other defects that could significantly reduce its effectiveness before the first use of packaging for the shipment of licensed material.
- 10 CFR 71.87, “Routine Determinations,” requires the licensee to ensure that a package with its contents satisfies the following applicable requirements before each shipment of the licensed material:
 - 10 CFR 71.87(c) states that each closure device of the packaging, including any required gasket, is properly installed and secured and free of defects.
 - 10 CFR 71.87(f) states that the package has been loaded and closed in accordance with written procedures.
- 10 CFR Part 20 establishes the dose limits for occupational workers and members of the public.

Purpose of Regulatory Guides

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

Paperwork Reduction Act

This RG provides voluntary guidance for implementing the mandatory information collections in 10 CFR Part 71 that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These information collections were approved by the Office of Management and Budget (OMB), approval number 3150-0008. Send comments regarding this information collection to the Information Services Branch (T6-A10M), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocollects.Resource@nrc.gov, and to the OMB reviewer at: OMB Office of Information and Regulatory Affairs (3150-0008), Attn: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street, NW Washington, DC 20503; e-mail: oira_submission@omb.eop.gov.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.

B. DISCUSSION

Reason for Revision

This revision of RG 7.4 (Revision 2) endorses ANSI N14.5-2014, which has been updated and contains new information, corrections, and clarifications. Revision 2 of RG 7.4 includes best practices in leakage rate testing to ensure the integrity of radioactive materials containers and minimize the distribution of radioactive contamination to the environment.

Background

The NRC originally published RG 7.4 in June 1975 (Ref. 4) to endorse the guidance in ANSI N14.5-1973 (Ref. 5) as an acceptable industry standard for leakage tests on Type B packages for shipment in accordance with the requirements in 10 CFR Part 71. Since that time, the NRC has revised 10 CFR Part 71 a number of times. The staff issued RG 7.4, Revision 1, in 2012 to endorse ANSI N14.5-1997 (Ref. 6), which was reaffirmed in 2008. ANSI updated ANSI N14.5 again in 2014, and the staff has revised this RG to endorse the 2014 ANSI standard.

The regulations in 10 CFR Part 71 establish the requirements for the packaging, preparation for shipment, and transportation of licensed materials in such a manner that the total dose to an individual does not exceed the standards for protection against radiation in 10 CFR Part 20. The limits in 10 CFR Part 20 apply to doses resulting from licensed and unlicensed radioactive material and from radiation sources other than background radiation. The regulations in 10 CFR Part 71 describe package release limits and the need to demonstrate the integrity of the package to meet these release limits.

ANSI N14.5-2014 describes leakage rate testing of radioactive materials containers, methods for relating release limits to allowable and reference leakage rates, and minimum requirements for leakage rate test procedures. The standard describes the design, fabrication, maintenance, periodic, and pre-shipment leakage rate tests to demonstrate package containment integrity.

Harmonization with International Standards

The International Atomic Energy Agency (IAEA) works with member states and other partners to promote the safe, secure, and peaceful use of nuclear technologies. The IAEA develops safety standards for protecting people and the environment from harmful effects of ionizing radiation. These standards provide a system of safety fundamentals, safety requirements, and safety guides reflecting an international consensus on what constitutes a high level of safety. This RG incorporates similar design and performance guidelines and is consistent with the safety principles provided in the below publications.

- IAEA Specific Safety Guide No. SSG-26, “Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material (2012 Edition),” issued 2014 (Ref. 7)
- IAEA Safety Requirements No. TS-R-1, “Regulations for the Safe Transport of Radioactive Material,” issued 2009 (Ref. 8)

Documents Discussed in Staff Regulatory Guidance

This RG endorses the use of one or more codes or standards developed by external organizations, and other third party guidance documents. These codes, standards and third party guidance documents may contain references to other codes, standards or third party guidance documents (“secondary

references”). If a secondary reference has itself been incorporated by reference into NRC regulations as a requirement, then licensees and applicants must comply with that standard as set forth in the regulation. If the secondary reference has been endorsed in a RG as an acceptable approach for meeting an NRC requirement, then the standard constitutes a method acceptable to the NRC staff for meeting that regulatory requirement as described in the specific RG. If the secondary reference has neither been incorporated by reference into NRC regulations nor endorsed in a RG, then the secondary reference is neither a legally-binding requirement nor a “generic” NRC approved acceptable approach for meeting an NRC requirement. However, licensees and applicants may consider and use the information in the secondary reference, if appropriately justified, consistent with current regulatory practice, and consistent with applicable NRC requirements.

C. STAFF REGULATORY GUIDANCE

This RG endorses the methods described in ANSI N14.5-2014. The NRC staff has determined that the methods described in ANSI N14.5-2014 are acceptable to the NRC staff for use in assessing the containment properties of packages for the shipment of radioactive material. The standard specifies methods for demonstrating that Type B packages designed for transport of normal form radioactive material comply with the containment requirements of 10 CFR Part 71, and that the leakage rate testing confirms that the containment system is properly assembled for each shipment.

D. IMPLEMENTATION

The purpose of this section is to provide information on how applicants, CoC holders, and licensees may use this guide and the NRC's plans for using this RG. Backfitting and issue finality considerations do not apply to licensees, CoC holders, and applicants when performing activities under 10 CFR Part 71. The NRC staff does not intend or approve any imposition or backfitting of the guidance in this RG.

Applicants and licensees may voluntarily¹ use the guidance in this document to demonstrate compliance with the underlying NRC regulations. Methods that differ from those described in this RG may be acceptable if they provide sufficient basis and information for the NRC staff to verify that the proposed alternative demonstrates compliance with the appropriate NRC regulations. Current licensees may continue to use guidance the NRC found acceptable for complying with the identified regulations as long as their current licensing basis remains unchanged.

If a CoC holder or licensee believes that the NRC is using this RG in a manner inconsistent with the discussion in this Implementation section, then the CoC holder or licensee may file a backfit appeal with the NRC in accordance with the guidance in NRC Management Directive 8.4, "Management of Facility-Specific Backfitting and Information Collection" (Ref. 9), and in NUREG-1409, "Backfitting Guidelines" (Ref. 10).

¹ In this section, "voluntary" and "voluntarily" means that the licensee is seeking the action of its own accord, without the force of a legally binding requirement or an NRC representation of further licensing or enforcement action.

REFERENCES²

1. *U.S. Code of Federal Regulations (CFR)*, “Packaging and Transportation of Radioactive Material,” Part 71, Chapter 1, Title 10, “Energy.”
2. American National Standards Institute (ANSI) N14.5-2014, “Radioactive Materials—Leakage Tests on Packages for Shipment,” New York, NY, June 19, 2014.³
3. CFR, “Standards for Protection against Radiation,” Part 20, Chapter 1, Title 10, “Energy.”
4. NRC, RG 7.4, (1975), “Leakage Tests on Packages for Shipment of Radioactive Materials,” Washington, DC (ADAMS Accession No. ML003739407).
5. ANSI N14.5-1973, “Leakage Tests on Packages for Shipment of Radioactive Materials,” New York, NY, December 1974.
6. ANSI N14.5-1997, “Radioactive Materials—Leakage Tests on Packages for Shipment,” New York, NY, January 1997.
7. International Atomic Energy Agency (IAEA) Specific Safety Guide SSG-26 “Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material (2012 Edition),” Vienna, Austria, 2014.⁴
8. IAEA Safety Requirements TS-R-1 “Regulations for the Safe Transport of Radioactive Material,” (TS-R-1), Vienna, Austria, 2009.
9. U.S. Nuclear Regulatory Commission (NRC), Management Directive 8.4, “Management of Facility-Specific Backfitting and Information Collection,” Washington, DC.
10. NRC, NUREG-1409, “Backfitting Guidelines,” Washington, DC.

2 Publicly available NRC published documents are available electronically through the NRC Library on the NRC’s public Web site 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>. The documents can also be viewed online or printed for a fee in the NRC’s Public Document Room (PDR) at 11555 Rockville Pike, Rockville, MD. For problems with ADAMS, contact the PDR staff at 301-415-4737 or (800) 397-4209; fax (301) 415-3548; or e-mail pdr.resource@nrc.gov.

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

4 Copies of International Atomic Energy Agency (IAEA) documents may be obtained through its Web site at WWW.IAEA.Org/ or by writing the International Atomic Energy Agency, P.O. Box 100 Wagramer Strasse 5, A-1400 Vienna, Austria; telephone (+431) 2600-0; fax (+431) 2600-7; or e-mail Official.Mail@IAEA.Org.