



REGULATORY GUIDE

OFFICE OF NUCLEAR REGULATORY RESEARCH

REGULATORY GUIDE 7.7

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ADMINISTRATIVE GUIDE FOR VERIFYING COMPLIANCE WITH PACKAGING REQUIREMENTS FOR SHIPPING AND RECEIVING OF RADIOACTIVE MATERIAL

A. INTRODUCTION

This guide describes an approach that the staff of the U.S. Nuclear Regulatory Commission (NRC) considers acceptable for meeting the administrative requirements associated with shipment and receipt of radioactive material in Title 10, of the *Code of Federal Regulations*, Part 71, “Packaging and Transportation of Radioactive Material” (10 CFR Part 71) (Ref. 1) and 10 CFR Part 20, “Standards for Protection Against Radiation (Ref. 2). The regulations in 10 CFR Part 71 apply to NRC licensees that transport licensed material or that deliver licensed material to a carrier for transport. The requirements in 10 CFR Part 20 apply to NRC licensees that receive, possess, use, transfer, or dispose of byproduct, source, or special nuclear material. The staff developed and published this guidance to provide licensees with an acceptable method to satisfy the administrative requirements in 10 CFR Part 71 and Part 20 for transferring, shipping, and receiving radioactive material.

Subpart J of 10 CFR Part 20, “Precautionary Procedures,” provides requirements designed to protect licensees during the use of radioactive material. Specifically, 10 CFR 20.1906 provides requirements for licensees that are designed to minimize the potential for receiving unplanned exposure to radiation when receiving and opening radioactive material packages.

Subpart C of 10 CFR Part 71, “General Licenses,” provides general licenses for NRC licensees to transport, or to deliver to a carrier to transport, licensed material in a package that either the NRC or a competent foreign authority has approved, or for fissile material transported in a Type AF package that meets the requirements in the U.S. Department of Transportation’s (DOT’s) radioactive material regulations. In addition to following the terms of the general license, the licensee must ensure that the package is appropriate for the contents and has been properly prepared, transported, received, and opened. In addition to NRC regulations, the licensee must conform to certain DOT standards and requirements.

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.

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 Library 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. ML112160407. The regulatory analysis may be found in ADAMS under Accession No. ML112160410.

This guide was issued after consideration of comments received from the public. The public comments and NRC staff response to them may be found in ADAMS under Accession No. ML112160411.

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This regulatory guide contains information collection requirements covered by 10 CFR Part 20 and 10 CFR Part 71 that the Office of Management and Budget (OMB) approved under OMB control numbers 3150-0014 and 3150-0008, 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. 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.

B. DISCUSSION

The regulations in 10 CFR Part 71 establish the requirements for packaging, preparing for shipment, and transporting licensed material. The regulations in 10 CFR Part 20 describe the requirements for controlling the handling of radioactive material.

C. STAFF REGULATORY GUIDANCE

This regulatory guide provides licensees with a method the NRC considers acceptable for meeting the administrative requirements for transporting licensed material under 10 CFR Part 71 either in a Type B radioactive material or a Type AF (fissile material) package and receipt and opening of the package under 10 CFR Part 20. The NRC's administrative requirements for the shipment, receipt, and opening of a Type B package appear in Subpart J, "Precautionary Procedures" of 10 CFR Part 20 and Subpart G, "Operating Controls and Procedures," of 10 CFR Part 71, and specifically include the following seven regulations:

- 10 CFR 20.1906, "Procedures for receiving and opening packages,"
- 10 CFR 71.83, "Assumptions as to Unknown Properties,"
- 10 CFR 71.85, "Preliminary Determinations,"
- 10 CFR 71.87, "Routine Determinations,"
- 10 CFR 71.89, "Opening Instructions,"
- 10 CFR 71.91, "Records," and
- 10 CFR 71.95, "Reports."

In addition to these requirements, licensees transporting or preparing either a Type AF or a Type B package for transport should perform the necessary administrative requirements, as appropriate for the package design, before, during, and after shipment to ensure that shipments are completed in a safe, secure, and timely manner. This regulatory guide provides licensees with an approach that the NRC considers acceptable for completing administrative requirements when preparing and shipping radioactive material. Rather than following the NRC regulations by section number (as listed above), this regulatory guide follows the sequence of steps involved in making a shipment, from planning, performing, receipt and opening the shipment through verification of shipment and package recordkeeping.

1.0 Planning a Shipment

An NRC licensee should, to the extent practical, plan each shipment as far in advance as necessary to complete the shipment in the timeframe needed for the use or disposition of the radioactive material. Shipments of hazardous materials, including radioactive materials and the regulations that govern them, may be complex, regulated by multiple agencies (e.g., the NRC and DOT), and varied in nature. Organizations with little or no experience in transporting or providing radioactive material to a carrier for transport should consult a specialist to address factors such as vehicle restrictions; nuclear safety; package selection; contamination control; and, if needed, physical protection of the material during transit, to ensure that materials are shipped safely and securely and in compliance with applicable NRC and DOT regulations. Planning is especially necessary when multiple component packages are required; when there is a need to apply for a special permit; or when additional hazards, such as flammables or explosives, are present.

The first step in planning a shipment of radioactive material is to identify the radionuclides present and their activity content in curies. The contents dictate whether a Type A, Type AF, or Type B package is required. (Appendix A to Part 71, “Determination of A_1 and A_2 ” contains instructions and tables of radionuclides to assist the shipper in determining the package type.) Once the package type is known, NRC regulations (e.g., 10 CFR 30.41, “Transfer of Byproduct Material”; 10 CFR 40.51, “Transfer of Source or Byproduct Material”; or 10 CFR 70.42, “Transfer of Special Nuclear Material,” as applicable) require the shipper to verify that the consignee is authorized to receive the type, form, and quantity of material to be shipped.

If any properties of the contents to be shipped are unknown, the shipper should bound or bracket the contents (i.e., identify the range of values) based on known information about them. If the activity content is not known or cannot be measured directly, the shipper can estimate it by conversion calculations using weight, radiation dose rate measurements, or other suitable means. The shipper should also know the physical form of the material or details of its encapsulation to determine whether it qualifies as special form material. In the event that the unknown properties are for fissile material, 10 CFR 71.83 identifies the requirements for the licensee to package the material as if the unknown properties (including moderator within the contents) have credible values that will cause maximum reactivity.

2.0 Packaging

If the contents are determined to be either Type AF or Type B material, the shipper should select an NRC-approved packaging (typically authorized by a certificate of compliance) that authorizes the contents (quantity and form of material) to be shipped. If there is not an NRC-approved package for the contents to be shipped, the licensee should choose a package authorizing similar contents and, if the licensee is not the certificate holder, request the certificate holder to obtain an amendment from the NRC for the contents to be transported. Regulatory Guide 7.9, “Standard Format and Content of Part 71 Applications for Approval of Packages for Radioactive Material” (Ref. 3) contains a standard format for a safety analysis report that is acceptable to the NRC for submitting an application for an amendment to or a new certificate of compliance for approval. Finally, if this has not already been done, the shipper must register as a user of the package pursuant to the conditions of the general license for NRC-approved packages in 10 CFR 71.17. Note that the general license for use of an approved package applies only to licensees who have an NRC-approved quality assurance program, a copy of the certificate of compliance and documents referenced in the approval relating to the use and maintenance of the packaging, and comply with the terms and conditions of the package approval.

2.1 Preliminary Determinations

If the package to be used for shipment is newly fabricated, 10 CFR 71.85 requires three preliminary determinations that should be included in the package acceptance tests (typically Section 8 of the application for approval). Note that NUREG/CR-3854, (Ref. 4) "Fabrication Criteria for Shipping Containers," may be useful for selection fabrication criteria for certain aspects, such as welding, shielding installation and acceptance testing of newly fabricated packages. In accordance with 10 CFR 71.85, "Preliminary Determinations," before the first use of any packaging for the shipment of licensed material the licensee shall --

- a. ascertain that there are no cracks, pinholes, uncontrolled voids, or other defects that could significantly reduce the effectiveness of the packaging;
- b. when the maximum normal operating pressure (MNOP) will exceed 35 kPa (5 lbf/in²) gauge, test the containment system at an internal pressure at least 50 percent higher than the MNOP to verify the capability of the system to maintain its structural integrity at that pressure; and
- c. conspicuously and durably mark the packaging with its model number, serial number, gross weight, and a package identification number assigned by NRC. Before applying the model number, the licensee shall determine that the packaging has been fabricated in accordance with the design approved by the NRC.

In addition to these three items, and depending on the package type, the acceptance tests may also include fabrication leak test(s) on the containment system (in addition to the pressure test) and neutron absorber tests for boron density and porosity. The leakage tests ensure that the fabricated package will meet the Type B containment requirements in 10 CFR 71.51, "Additional Requirements for Type B Packages." The package neutron poisons are tested to ensure that the components contain the minimum amount of boron.

2.1.1 Elimination of Voids

Air bubbles or incomplete package shielding may occur during some manufacturing processes. Therefore, per the requirements of 10 CFR 71.107, the licensee, certificate holder or applicant for a certificate must establish measures to assure that the package design as specified in the certificate of compliance is correctly translated into specifications, drawings, procedures, and instructions. Additionally, the licensee is responsible for verifying the adequacy of the design. The licensee can demonstrate compliance with these requirements by ensuring that the package is built in accordance with the drawings referenced in the certificate of compliance. Typically, to ensure that the package shielding is in place and is the minimum thickness required by the drawings, the licensee should measure the effectiveness of the package shielding using a calibrated radioactive source. The licensee may calculate the dose rate on the surface of the package, based on the application's shielding evaluation and source strength, and then confirm the calculation by measurements.

One acceptable method of determining the shielding effectiveness and identifying the existence of potential voids is by partitioning the surface of the packaging into a grid pattern, measuring the dose in each square of the grid, and comparing it to the estimated dose. The size of the grid pattern should be such that the detector being used can easily measure essentially the entire area of an individual block of grid at one time. Note that a source of sufficient strength and radioactive emission consistent with the package contents should be used for the shielding integrity test. Licensees should determine the cause of the discrepancy (e.g., voids, streaming paths, or a localized reduction in shielding) by further evaluating

areas on the surface of the package where the measured and estimated dose rates are inconsistent. The licensee should measure shielding effectiveness for both gamma and neutron radiation, as applicable to the package.

2.1.2 Packaging Defects

To ensure that the package has been fabricated in accordance with the drawings, the licensee should:

- a. Perform a visual examination of the packaging.
- b. Measure packaging components and compare the measurement with the drawing dimensions and tolerances.
- c. Inspect any welds, using the examinations cited in the drawings.

2.1.3 Pressure Tests

Under 10 CFR 71.85(b), packages that have an MNOP greater than a 35-kPa (5-lbf/in.²) gauge shall be pressure-tested to a pressure that is at least 50 percent higher than the MNOP of the package. The NRC staff accepts pressure tests performed in accordance with the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel (B&PV) Code, Section III, Subsection NB, Paragraph NB-6200 or NB-6300 (Ref. 5).

2.1.4 Package Marking

The licensee should mark each Type AF and Type B package with a steel plate that is securely affixed (e.g., welded onto metal) to the outermost portion of the packaging. The markings serve to identify a specific packaging, in the event of issues related to its fabrication or use. The plate should be inscribed with the following four items:

- a. model number,
- b. serial number,
- c. gross weight, and
- d. identification number (assigned by NRC).

2.1.5 Leakage Test

Regulatory Guide 7.4, "Leakage Tests on Packages for Shipment of Radioactive Materials," (Ref. 6) provides a method acceptable to the Commission to perform the fabrication leakage test.

2.1.6 Neutron Absorber Tests

The NRC accepts the neutron-absorbing material qualification tests in Section 5.2.6 of the American Society for Testing and Materials International (ASTM) Standard C1671-2007, "Standard Practice for Qualification and Acceptance of Boron Based Metallic Neutron Absorbers for Nuclear Criticality Control for Dry Cask Storage Systems and Transportation Packaging" (Ref. 7), with the following clarifications and exceptions:

- a. If, during the testing specified in Section 5.2.6.2 of C1671, a coupon contiguous to every plate of neutron-absorbing material is not examined during acceptance testing, the neutron attenuation program should contain a sufficient number of samples to ensure that the neutron-absorbing properties of the materials meet the minimum required areal density of the neutron absorber. In the past, the staff has accepted the following methods:
 1. A wet chemistry analysis of mixed powder batches is followed by additional neutron-attenuation testing of a minimum of 10 percent of the neutron poison plates (for a neutron-absorbing material with a significant qualification program and nonstatistically derived minimum guaranteed properties).
 2. Sampling plans which call for at least one neutron-transmission measurement to be taken for 2,000 square inches of neutron poison plate material in each lot.
 3. A sampling plan requiring neutron attenuation testing of each of the first 50 sheets (or coupons from the first 50 sheets) of every batch of neutron absorber material. Thereafter, randomly selected coupons from 10 out of every 50 sheets of neutron absorber material are sampled in the same manner. The 20 percent sampling frequency continues until there is a change in the lot or batch of constituent materials for the sheets (i.e., boron carbide powder or aluminum powder) or a process change. A single measured value of less than the allowed minimum density of boron-10 during the 20 percent sampling period is classified as a nonconformance and mandates a return to 100 percent sampling frequency for the next 50 sheets of material.
- b. The minimum areal density of boron-10 present in each type of neutron-absorbing material used in the calculation of the effective neutron multiplication factor (k_{eff}) should be clearly stated in the acceptance tests typically located in Chapter 8 of a transportation application, as specified in Regulatory Guide 7.9.
 1. If the criticality analysis uses 90-percent credit for the efficacy of the neutron absorber, then methods other than neutron attenuation should be used only as verification or partial substitution for attenuation tests. Benchmarking of other methods against neutron-attenuation testing should be done periodically throughout acceptance testing, under appropriate attenuation conditions and with proper sample sizes. This should be done to confirm the adequacy of the proposed methods, as the most reliable method of measuring the expected neutron-absorbing behavior of the poison plates is by direct measurements of neutron attenuation.
 2. For neutron-absorbing materials for which 75-percent credit is taken, direct neutron-attenuation measurements should be required only as part of a qualification program, which should include benchmarking for other methods

used to determine the boron-10 areal density. Once qualified and benchmarked, the alternative methods that have been validated by attenuation measurements, such as wet chemistry analyses, are sufficient to verify the minimum areal density of the neutron-absorbing material during acceptance testing.

- c. A clarification to Section 5.2.6.2(1) of ASTM Standard C1671 is that only homogenous neutron-absorbing materials such as zirconium diboride with uniform absorption properties should be considered for neutron-attenuation testing standards because homogenous materials preclude, or at least minimize, any neutron-streaming effects that may occur in heterogeneous materials. This exception to C1671 precludes the use of materials, such as boron carbide reinforced aluminum matrix composites, as calibration standards for neutron absorption.
- d. When performing the attenuation tests discussed in Section 5.2.6.2(2) of C1671, the licensee should specify the size of the collimated neutron beam for attenuation testing, limiting it to a maximum of 2.54 centimeters in diameter with a 10-percent tolerance.
- e. In addition to the inspections described in Section 5.2.6.3 of C1671, the acceptance tests should describe a visual inspection procedure and the tests' inspection criteria. The licensee should conduct a visual inspection on all the neutron-absorbing components intended for service. The acceptance tests and their criteria should be sufficient to ensure the quality of plate materials that contain more than 30-volume-percent boron carbide, because plate materials with high loadings of boron carbide (greater than 30-volume percent) are subject to edge-cracking during rolling operations and other defects that might lead to problems in service.
- f. In addition to the guidance in Section 5.2.6.3 of C1671, the licensee should specify the maximum permissible thickness deviation of the neutron-absorbing material and the actions to be taken if the thickness is outside the permissible limits.

During the production of neutron-absorbing materials, minor deviations from the specified physical dimensions are expected. The application should discuss these deviations, including variations of the neutron-absorbing material thickness, in a way that is referenced in the certificate of compliance. The applicant should specify the maximum permissible thickness deviation and the actions to be taken if the thickness is outside the permissible limits. This is to ensure adequate performance of the neutron-absorbing materials. In the past, the staff has allowed acceptance testing where a minimum plate thickness is specified, which permitted local depressions, as long as the depressions were no more than 0.5 percent of the area on any given plate and the thickness at their location was not less than 90 percent of the minimum design thickness.

2.2 Package Loading

In addition to the acceptance tests, the certificate of compliance will usually reference the operating procedures, typically in Section 7 of the application. These operating procedures should include the routine determinations required by 10 CFR 71.87 for package loading, preparation for shipment, receipt, unloading and any other determinations deemed necessary in the package application. Note that NUREG/CR-4775, Guide for Preparing Operating Procedures for Shipping Packages," (Ref. 8) may be useful when writing operating procedures for the package. The operating procedures in the application for loading the package should be sufficiently detailed to ensure that all necessary steps for proper loading will be completed, although not necessarily as the step-by-step written procedures that a shipper will follow when loading the package. The detailed written procedures provided by the certificate

holder should be based on, and consistent with, the procedures described in Section 7 of the application. The licensee should ensure that it has and follows the most up-to-date detailed operating procedures issued by the certificate holder.

Before package-loading operations begin, the shipper should perform the following routine determinations, as needed, based on the package type and design:

- a. Inspect the package to ensure that it is in unimpaired physical condition, except for superficial defects;
- b. Ensure that all closure devices, including gaskets, are properly installed and free of defects;
- c. Ensure that any system for containing liquid is adequately sealed and has adequate space or other specified provisions for expansion of the liquid, and, if appropriate, any gas that may be generated due to radiolytic decomposition;
- d. Ensure that any pressure relief device is operable and set in accordance with written procedures; and
- e. Ensure that adequate internal packing material or bracing is available to protect the contents and maintain any required spacing under conditions normally incident to transportation.

To comply with the provisions of the general license, the package should be loaded in accordance with the detailed written procedures provided by the 10 CFR Part 71 certificate holder. The package operations must be consistent with maintaining occupational radiation exposures as low as reasonably achievable, as required by 10 CFR 20.1101(b). Package loading should take place in a controlled area with appropriate surveillance and radiation monitoring by the organization responsible for certification of the package.

In addition to any actions specified in the detailed operating procedures, the shipper should verify the following during package loading:

- a. Proper location of any necessary neutron poison or shielding.
- b. Proper installation of closure device and any required gaskets.
- c. Verify that any internal packing material or bracing used is as described in the operating procedures and the package drawings (if shown).

3.0 Preparation for Transport

After loading the packaging, the shipper should ensure that all actions to prepare the package for transport are completed as specified in the application's operating procedures. The preparations for transport in the operating procedure in Section 7 of the application should be written based on and consistent with the package evaluations in Sections 2 through 6 of the application to ensure that the package is prepared for shipment as designed and evaluated. These preparations for shipment will vary depending on the package type, design, and method of securing it in (or on) the conveyance. Some of the preparations for transport include conducting radiation and contamination surveys, rendering portions of

the package unusable for lifting or tying it down unless evaluated as such, placing the package in or on the conveyance, and securing the package.

Radiation and contamination surveys should be used to ensure that the limits specified in 10 CFR 71.47, "External Radiation Standards for All Packages," and 49 CFR 173.443, "Contamination Control" (Ref. 9), are not exceeded. If appropriate for the package, the shipper should also ensure that accessible surface temperatures will not exceed the limits in 10 CFR 71.43(g).

Any structural part of the package that could be used to lift or tie the package down during transport must be rendered inoperable (i.e., covered or removed), unless those parts have been shown in the application to satisfy the design requirements of 10 CFR 71.45, "Lifting and Tie-Down Standards for All Packages."

Additionally, Type B packages must be leak-tested to show compliance with 10 CFR 71.51 during shipment. The staff has established a method that it finds acceptable for performing leak tests in Regulatory Guide 7.4.

4.0 Receiving and Opening a Package

As required in 10 CFR 20.1906(e) licensees are required to establish, maintain, and retain, written procedures for receipt and opening a package containing radioactive material. The procedures, as a minimum should discuss package receipt, notification of package arrival, package pickup (if the package is not transferred to the consignee at its facility), and monitoring the package to ensure that radiation and contamination levels meet the requirement in 10 CFR Part 71. The licensee should ensure that it has and follows the most up-to-date operating procedures supplied by the certificate holder. These procedures should be based on the operating procedures approved by the NRC for opening and using the package that are references in the certificate of compliance.

Additionally, for first-time receipt of a package, licensees should have discussions with the certificate holder to be aware of the package configuration prior to ordering/receiving radioactive materials to ensure they have the safe means for opening the package and accessing the contents.

4.1 Package Receipt or Notification of their Arrival

In accordance with the requirements in 10 CFR 20.1906, "Procedures for receiving and Opening Packages," licensees who expect to receive radioactive material in excess of a Type A quantities are required to make arrangements to receive a package or notification of its arrival at the carrier's facility. When it is determined that arrangements for receipt or pickup of packages must be made; the arrangements are ordinarily determined by the routing of the expected package, the working hours of the final delivering carrier, and arrangements the consignee has made with the supplier of the radioactive material.

The arrangements that the consignee should make to receive a package or a notification that a package has been received at the carrier's facility depend in part, on when the package is likely to be received at the terminal carrier's facility. The arrangements should provide reasonable assurance that there will be no undue delays in transferring a package containing more than a Type A quantity of radioactive materials from the carrier to the consignee.

4.2 Expeditious Pickup of Packages

In accordance with 10 CFR 20.1906(a)(2), licensees are required to take possession of the package expeditiously. In order to comply with this requirement the pickup of a package containing radioactive material should be accomplished as soon as practicable after receiving notification by the carrier that the package is available. If notice is provided during the normal workday, pickup should be completed the same day, if practicable, within 2 to 3 hours. When notification by the carrier occurs after normal working hours and it is not practicable to pickup or to arrange for pickup of a package from a carrier's facility that same day, pickup should be accomplished as early as possible the following morning.

A distinction can be made between a radioactive material package containing Type A quantity with its smaller potential hazard to individuals due to the smaller quantity and/or the less hazardous nature of the contained radioactive material and a Type B package with its greater potential hazards. If a Type B package is to be delivered, a special effort should be made to take possession of it to the extent that a pickup capability should be provided on weekends, holidays, and other days that are not normal working days. Pickup of a Type A package, with its smaller potential hazard and generally lower external radiation level, can generally be postponed until the next normal workday.

4.3 Monitoring of Packages

The technical aspects of receiving a package vary from package to package and are highly dependent on the packaging design and its contents. However, some items are the same for all packages including: ensuring that appropriate paperwork is available for handling operations; verifying what the contents are and in what form, they are shipped; and ensuring that radiological surveys and safety inspections are made of both the package and the transport vehicle. The general condition of the package and the transport vehicle should be evaluated.

The comprehensive visual survey of the package should ensure that the package was properly assembled and did not sustain any significant damage during shipment. Careful attention should be given to possible damage to components that would affect the unloading of the contents, such as lifting devices, closure devices, or auxiliary equipment (e.g., personnel barriers or sunshields). Specific instruction should be given for any special features of the package that either could be easily damaged or could sustain damage that might not be noted otherwise.

Although the package may arrive undamaged, the condition of the contents should be assessed to ensure that normal transport did not impair their ability to perform their functions after receipt. For example, the quality assurance requirements in 10 CFR Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," (Ref. 10), in particular item VII, Purchase of Material, Equipment and Services, will require that quality assurance programs at the nuclear power plant will have procedures to inspect fresh fuel assemblies arriving at a nuclear power plant to ensure that they have arrived in a condition suitable for use in the reactor.

Labeling and placarding of a package and vehicle should be checked to ensure that they comply with DOT regulations and that the contents and packaging expected was indeed received. Additionally, the inspection should determine whether the tamper indicating device(s) is intact. If this device(s) is not intact, it should be reported to the licensee and shipper. Package tie-downs should also be inspected for proper attachment and wear. Significant damage such as excessive wear or broken, frayed, or cracked connectors should be noted and reported to the shipper.

Direct measurement of the radiation level outside the package after receipt to determine the external radiation levels is required by 10 CFR 20.1906 under specified circumstances and is a prime

indicator of proper performance and assembly of the package. The consignee should perform radiation surveys of the surface by placing the detector as close as is physically possible to the external surface of the package and 1 meter (3.3 feet) from the package with a calibrated instrument that is appropriate for measuring the radiation being emitted from the radioactive material. Since many packages are designed with several parts, these surveys should continue throughout the package disassembly.

If the preliminary survey indicates more than 2 mSv/hr (200 mrem/hr) on the package surface or more than 0.1 mSv/hr (10 mrem/hr) at a distance of 1 meter (3.3 feet) from the package, a more careful measurement of the levels should be performed. Note that radiation levels higher than expected may indicate damage to the package or contents have shifted and ALARA and good radiation safety practices should be used at all times. The package being monitored should be separated from other packages. If the package is in a location where the background level of radiation is reasonably low and relatively constant, it might be preferable to move the other packages away from the package being monitored for receipt. The detailed measurements should be performed on the surface and 1 meter (3.3 ft) from the surface. The radiation levels or a plot of isodose curves and the degree of accuracy of the measurements should be recorded. These results should be provided to the carrier and the NRC as soon as available so that dosage calculations can be made.

Monitoring of a package for external surface contamination normally involves a two-step procedure. First, a wipe test is made of one or more representative sections of the outer surface of the package. The wipe test is made by rubbing a filter paper or other absorbent material over a predetermined area (usually about 300 cm² [46.5 in²]) of the package surface, using moderate finger pressure. Second, the absorbent material is moved to an area where the radiation level is at or near background, and any activity on the absorbent material is measured with appropriately calibrated instruments.

The requirements in 10 CFR 20.1906 stipulate that the licensee shall perform the monitoring not later than 3 hours after the package is received at the licensee's facility if it is received during the licensee's normal working hours, or not later than 3 hours from the beginning of the next working day if it is received after working hours.

Because of the very low probability that any individual package will be found to be contaminated, it is not considered necessary to detain the carrier who delivered the package until a package is monitored, unless the package is damaged or shows evidence of leaking. The name of the delivering carrier should be kept available until the package has been monitored, however, since, in accordance with 10 CFR 20.1906(d), the carrier must be notified in the event the external radiation levels exceed regulatory limits.

4.4 Notification of Excessive Radiation or Contamination Levels

If external radiation levels exceed the limits in 10 CFR 71.47 or the removable radioactive surface contamination exceeds the limits of 10 CFR 71.87(i), the licensee shall immediately notify the delivery carrier and the NRC Operations Center (301-816-5100), by telephone. Because the carrier would take corrective actions in response to such a notification, the presence of high external radiation levels or contamination should be definitely confirmed before notification. Confirmation may be performed by checking the operation of the measuring instrument, reperforming the radiation measurements, rewiping the package surface, counting for a longer time period, or whatever other confirmation seems appropriate for the procedure being used. Note that in the event that one of the criteria in 10 CFR 71.95(a) has been met then a follow-up report is required as discussed below.

5.0 Reports and Records

The regulations in 10 CFR 71.91 require that licensees maintain shipment records for 3 years after the transport of licensed material and that a certificate holder maintain records of each packaging for 3 years beyond the lifetime of the package (permanent removal from service).

5.1 Shipment Records

The regulations in 10 CFR 71.91 require licensees to keep the following records:

- a. Identification of the packaging by model number and serial number, as indicated on the package marking;
- b. Verification that there are no significant defects in the packaging, as shipped;
- c. Volume and identification of any coolant added to the package;
- d. Type and quantity of licensed material in each package and the total quantity in each shipment. Per 49 CFR 172.203 and §173.433, the shipping papers must include the name and form of each radionuclide and its curie content. The shipping papers should also include the mass (in the case of fissile material) in each package; and the quantity of moderation within the contents, such as beryllium, graphite, or hydrogenous moderation (polyethylene, deuterium, or tritium);
- e. The identification of the irradiated fissile material by model number and serial number; the irradiation and decay history to show that its nuclear and thermal characteristics comply with conditions in the certificate of compliance; and any abnormal or unusual condition relevant to radiation safety for each item of irradiated material;
- f. the shipment date;
- g. any special controls exercised for fissile and Type B packages;
- h. the name and address of the transferee;
- i. the address to which the shipment was made; and
- j. the results of the routine determinations required by 10 CFR 71.87 and by the conditions of the package approval process.

5.2 Packaging Records

The regulations in 10 CFR Part 71 require certificate holders to maintain, for a period of 3 years after the life of the packaging, records on the manufacture, maintenance, and inspections performed on the packaging and any other records that could be used to determine the quality of the packaging. Specifically, a certificate holder shall maintain the following records:

- a. Results of the preliminary determinations required by 10 CFR 71.85 (see Regulatory Position 2.0).

- b. Design, fabrication, and assembly records that show that the package was fabricated according to the drawings referenced in its certificate of compliance, including those records that result from the implementation of the certificate holder's quality assurance program, as described in 10 CFR 71.107.
- c. Results of any reviews, inspections, tests, and audits performed on the packaging. Records in this category include tests performed on the packaging, such as leak testing the packaging containment system after the replacement of seals. Inspection, test, and audit records must identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action(s) taken in connection with any deficiencies noted. These records must be retained for 3 years after the life of the packaging to which they apply.
- d. Results of monitoring work performance and packaging materials analyses.
- e. Maintenance, modification, and repair activities made to the packaging.

5.3 Deficiency Reports

The regulations at 10 CFR 71.95(a) require licensees to submit to the NRC a written report describing the following items:

- any significant reduction in the effectiveness of any NRC-approved Type B or Type AF packaging during use,
- the details of any defects with safety significance in any NRC-approved Type B or fissile material packaging after its first use, or
- whenever the conditions of approval or the conditions in the certificate of compliance were not observed in making or completing a shipment.

The licensee should use the items listed in 10 CFR 71.95(c) as an outline for developing the deficiency report that it shall submit to the NRC within 60 days of the event or discovery of the event. If a particular item is not applicable to the licensee's report, it should be included with the notation that it is not applicable, to show that the licensee has considered all these items in developing the report. The licensee should work with the certificate holder in developing the written report to capture accurate and thorough information about the packaging components, safety consequences, and any previous similar events. Because transportation packages may be used among multiple facilities and only infrequently at any one location, a licensee may consider a problem incurred with the package as an isolated event when it may have occurred previously at another facility. This reporting requirement should facilitate the identification of generic packaging problems by gathering operating experience from all users.

Pursuant to 10 CFR 71.95(c), the report should contain, at a minimum:

- a. A brief abstract describing the major occurrences during the event, including all component or system failures that contributed to the event and significant corrective action taken or planned to prevent recurrence.
- b. A clear, specific, narrative description of the event that occurred so that knowledgeable readers conversant with the requirements of 10 CFR Part 71, but not familiar with the

design of the packaging, can understand the complete event. The narrative description must include the following specific information as appropriate for the particular event:

1. Status of components or systems that were inoperable at the start of the event and that contributed to the event;
 2. Dates and approximate times of occurrences;
 3. The cause of each component or system failure or personnel error, if known;
 4. The failure mode, mechanism, and effect of each failed component, if known;
 5. A list of systems or secondary functions that were also affected for failures of components with multiple functions;
 6. The method of discovery of each component or system failure or procedural error;
 7. For each human performance-related root cause, a discussion of the cause(s) and circumstances;
 8. The manufacturer and model number (or other identification) of each component that failed during the event; and
 9. For events occurring during use of a packaging, the quantities and chemical and physical form(s) of the package contents.
- c. An assessment of the safety consequences and implications of the event. This assessment must include the availability of other systems or components that could have performed the same function as the components and systems that failed during the event.
- d. A description of any corrective actions planned as a result of the event, including the means employed to repair any defects, and actions taken to reduce the probability of similar events occurring in the future.
- e. Reference to any previous similar events involving the same packaging that are known to the licensee or certificate holder.
- f. The name and telephone number of a person within the licensee's organization who is knowledgeable about the event and can provide additional information.
- g. The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

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.

Methods or solutions that differ from those described in this regulatory guide may be deemed

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 and certificate holders may continue to use guidance the NRC found acceptable for complying with the identified regulations as long as their current licensing or certification basis remains unchanged. Backfit and issue finality considerations do not apply to licensees and applicants under 10 CFR Part 71.

REFERENCES¹

1. 10 CFR Part 71, "Packaging and Transportation of Radioactive Material," U.S. Nuclear Regulatory Commission, Washington, DC.
2. 10 CFR Part 20, "Standards for Protection Against Radiation," U.S. Nuclear Regulatory Commission, Washington, DC.
3. Regulatory Guide 7.9, "Standard Format and Content of Part 71 Applications for Approval of Packages for Radioactive Material," U.S. Nuclear Regulatory Commission, Washington, DC, March 2005.
4. NUREG/CR-3854, "Fabrication Criteria for Shipping Containers," U.S. Nuclear Regulatory Commission, Washington, DC, March 1985.
5. ASME Boiler and Pressure Vessel Code, Section III, "Rules for Construction of Nuclear Power Plant Components," American Society of Mechanical Engineers, New York, NY.²
6. Regulatory Guide 7.4, "Leakage Tests on Packages for Shipment of Radioactive Materials," U.S. Nuclear Regulatory Commission, Washington, DC.
7. ASTM C1671-2007, "Standard Practice for Qualification and Acceptance of Boron Based Metallic Neutron Absorbers for Nuclear Criticality Control for Dry Cask Storage Systems and Transportation Packaging," American Society for Testing and Materials International, West Conshohocken, PA.³
8. NUREG/CR-4775, Guide for Preparing Operating Procedures for Shipping Packages," U.S. Nuclear Regulatory Commission, Washington, DC, July 1988.
9. 49 CFR Part 173, "Shippers - General Requirements for Shipments and Packagings," U.S. Department of Transportation, Washington, DC.
10. 10 CFR Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," U.S. Nuclear Regulatory Commission, Washington, DC.

1 Publicly available NRC published 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/>. The documents can also be viewed on-line 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.

2 Copies of American Society of Mechanical Engineers (ASME) standards may be purchased from ASME, Three Park Avenue, New York, New York 10016-5990; telephone (800) 843-2763. Purchase information is available through the ASME Web-based store at <http://www.asme.org/Codes/Publications/>.

3 Copies of ASTM International Standards may be purchased from ASTM, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA, 19428-2959; telephone (877) 909-ASTM. Purchase is available through the ASTM website at [ASTM International - Standards Search](#).