

**Spent Fuel Project Office  
Interim Staff Guidance - 20  
Transportation Package Design Changes Authorized Under 10 CFR Part 71  
Without Prior NRC Approval**

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**Issue**

Authority for licensees to transport radioactive material comes from 10 CFR Part 71. Licensees are authorized to transport Type B quantities and fissile materials in NRC-certified packages under the general license in 71.17. Unlike 10 CFR Part 72, Part 71 does not include change authority, that is, there is no specific Part 71 regulation that allows licensees to make changes in the design or operation of an NRC-certified package without prior NRC approval. However, there is a significant degree of flexibility that may be allowed within the constraints of the NRC package approval (Certificate of Compliance).

This ISG is intended to clarify the degree of flexibility allowed in package design changes, including changes in contents and in package operations, without prior NRC approval. One element that contributes to this flexibility is the level of detail that is included in technical information that is submitted by an applicant as part of the package application. This is particularly true of the parts of the application that are incorporated as conditions of the package approval, such as packaging drawings, contents specifications, package operations, and maintenance programs. Certificate holders and shippers need to provide sufficiently detailed information in these parts for NRC staff to perform an adequate technical review; however, the information should not overly restrict flexibility to make changes without prior NRC approval.

**Regulatory Basis**

The application must include a description of the packaging design in sufficient detail to provide an adequate basis for its evaluation. [10 CFR 71.31(a)(1) and 71.33(a)]

The application must include a description of the contents in sufficient detail to provide an adequate basis for evaluation of the packaging design. [10 CFR 71.31(a)(1) and 71.33(b)]

NRC must approve all changes in the conditions of package approval. An application for modification of a previously approved package may be subject to the provisions of 10 CFR 71.13 and 71.31(b). [10 CFR 71.107(c)]

Before each shipment, the licensee must ensure that the package meets the routine-determination requirements of 10 CFR Part 71. [10 CFR 71.87]

The application must identify codes, standards, and provisions of the quality assurance program used for the acceptance testing and maintenance program for the packaging. [10 CFR 71.31 (c) and 71.37(b)]

The licensee must perform any tests that NRC deems appropriate. [10 CFR 71.93(b)]

## Technical Review Guidance

For package approvals under 10 CFR Part 71, the Certificate of Compliance typically identifies the conditions necessary for shipment of radioactive material in packages of that design. Sections of the package application incorporated by specific reference into the Certificate of Compliance are considered binding on Certificate holders and shippers. These sections identify the components and operations important to safety and assure that the package meets the performance requirements in the regulations. There is benefit in allowing Certificate holders and shippers appropriate flexibility in design and operational changes that do not affect the safe performance of the package. Since the Certificate of Compliance specifies the conditions of the approval, changes in design or drawings, contents specifications, and package operations that are incorporated as conditions of the approval should be developed to allow an appropriate degree of flexibility with respect to changes that do not affect safety.

NRC has issued significant guidance on package approvals, under 10 CFR Part 71. Regulatory Guide 7.9, "Standard Format and Content of Part 71 Applications for Approval of Packages for Radioactive Material," provides guidance on format and content of applications for approval of Type B and fissile material transportation packages. NUREG-1609, "Standard Review Plan for Transportation Packages for Radioactive Material," and NUREG-1617, "Standard Review Plan for Transportation Packages for Spent Nuclear Fuel," provide guidance on the procedures that the staff uses to determine that the package meets the regulatory requirements.

For technical review, it is important that the information included in drawings, contents description, package operations, acceptance tests, and maintenance program are consistent with the package evaluation. Level of detail and specificity needed for each of these items is discussed below. In addition, there are two appendixes for this ISG. Appendix A provides the background and regulatory basis for the reviewers of radioactive transportation package applications and amendments. Appendix B provides a table that lists examples of flexibility that may be provided in the Certificate of Compliance for various package types.

### 1. Engineering Drawings

NUREG-1609 includes appendices that describe various package types. For each package type, general guidance is provided on the safety functions of the package. Safety features are described, and specific areas of technical review are identified. Technical review should focus on these features. Components and features that provide a safety function should be clearly identified, with sufficient specificity, on packaging drawings. The degree of specificity should be commensurate with its safety function, and the sensitivity of package performance with the particular feature. For a spent nuclear fuel package, NUREG-1617 provides guidance on components and features that should be identified with sufficient specificity on packaging drawings.

In general, the engineering drawings define the design that is authorized for shipment of radioactive material. The packagings used for shipment must conform in all ways to the engineering drawings that are referenced in the Certificate of Compliance. It is important, therefore, that the drawings capture the safety features that are needed to ensure package performance under normal and accident conditions. The reviewer should ensure that reasonable tolerances for dimensions and weights are specified, because packaging features may be subject to some variability in fabrication. Not only does this assure the safety

performance of each packaging, but it also provides flexibility for reasonable variation in the fabrication of the packagings. Furthermore, it is important for demonstrating compliance and facilitating inspection activities. For example, when tolerances are not specified, any slight deviation in dimensions could cause the package to be out of compliance, even though the deviation may not affect safety. Thus, drawings that are well-prepared and which include appropriate tolerances facilitate the inspection process.

Engineering drawings often include features that may not contribute to safety, but are part of the package design. These features may be important for other reasons (e.g., ease of handling radioactive material within a facility, product protection, or cosmetic reasons). It is important that flexibility be allowed for these non-safety features, to eliminate unnecessarily restricting or regulating non-safety significant design features. However, it is often necessary to show the features, to ensure that the package configuration is authorized. For these cases, a general representation may be noted, or optional configurations may be included in the drawings.

Because of the variety of transportation package types, the safety importance of certain package features also varies. For example, the O-ring seals on a spent fuel cask provide a safety function (containment), but for a fresh fuel package, the O-ring seals only provide weather protection for product cleanliness. The specificity of the sealing system design for these two packages would therefore be significantly different. The reviewer should verify that the drawings for the spent fuel cask show the seal surface and O-ring groove details, including surface finish, groove dimensions within strict tolerances, O-ring size, type, and material. For the fresh fuel package, the drawing may note the presence of a gasket, but its use may be considered optional for safety in transport. Some examples of package features that may be safety related for some designs, but not for other designs, include: paint and coatings; seals, spacers, and dunnage; supplemental radiation shielding; inner containers; outer packagings; or overpacks. For those package features that are not safety related in a design, detailed information need not be shown in the drawings.

NUREG/CR-5502, "Engineering Drawings for 10 CFR Part 71 Package Approvals," contains information useful for the technical review of packaging designs and engineering drawings. NUREG/CR-6407, "Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety," also contains useful information about the safety significance of packaging components and features. These documents may be useful in judging whether the information provided is sufficiently detailed.

## **2. Contents Specification**

Contents that are authorized for transport should be clearly identified in the package application, typically in Section 1, "General Information". Applicants are encouraged to include a contents description suitable for including in a Certificate of Compliance. The contents description should be consistent with the package evaluation. The specificity of the contents description may be different for different package types and the safety significance of the contents. Contents description should include radionuclides present and quantity of radioactivity, fissile materials present, and masses of each fissile nuclide. Some package designs require the radioactive material to be in special form.

For Type B quantities of radioactive material in normal form, the applicant should specify the chemical and physical form of the material. The physical form is important with respect to the

dispersability of the material under normal and accident conditions, to demonstrate that the package provides adequate containment (10 CFR 71.51). The chemical form should be evaluated against significant interactions with packaging materials, including water leakage.

For fissile material, significant detail should be provided consistent with the criticality analysis of the package. For example, detailed listing of fissile nuclides present, uranium enrichment, etc. The chemical form is also important and should be specified and considered in the criticality analysis. Review the information on spacers or other features used for geometry control or confinement. If these features are needed to demonstrate criticality safety, then they must be included in the description of the authorized contents. Internal moderation (e.g., moisture in powder, plastic inserts, or wrap for fuel assemblies) should also be addressed, if it is important for criticality safety. Wrapping of fresh fuel assemblies with plastic is permitted if the top and bottom are free to allow flow of water sufficient to prevent preferential flooding of the fuel region. In general, if credit is taken for certain parameters (e.g., confinement features, uranium enrichment, chemical form, etc.), then those parameters should be specified in the description of the authorized contents. If criticality safety relies on certain components for spacing or confinement of the fissile material, these should be defined in packaging drawings, and should be included in the structural evaluation, to ensure their performance under normal conditions of transport and hypothetical accident conditions.

For spent fuel, NUREG/CR-6716 includes useful information about the fuel parameters that are important for criticality safety in a transport package. Parameters that are normally controlled include: fuel type, lattice size, enrichment, fuel rod pitch, fuel pellet diameter, cladding thickness, and active fuel length. It is not necessary to limit all parameters, if the analysis has shown that they are not important for the package evaluation. For example, if the applicant evaluates the criticality safety of the fuel without taking credit for the clad material being present, the minimum clad thickness may not need to be specified.

### **3. Package Operations**

Section 7 of the package application is "Package Operations", and because the certificate typically references Chapter 7, the applicant should submit a high level description of the essential elements needed to prepare the package for shipment, to ensure that its performance under normal and accident conditions will be as described in the package evaluation. Section 7 should include a clear description of these elements, and should include steps specified in 10 CFR 71.87, "Routine Determinations". The reviewer should verify that the package operations described in the application focuses only on the steps needed to ensure the package performance. Excessive detail and specificity, with respect to package operations, are not needed. Therefore, the applicant should not submit procedures actually used in the field when preparing the package. Instead, Section 7 should allow flexibility with respect to steps that are not specifically related to package preparation. For example, a written procedure may specify which lifting rigging to use for package handling, whereas Section 7 would only address this in a generic way, since the rigging may change at different facilities.

Sequencing of operational steps should be flexible in Section 7, when the performance of activities in different order would not affect the package preparation.

NUREG/CR-4775, "Guide for Preparing Operating Procedures for Shipping Packages," contains information useful for the technical reviewer.



**References**

U.S. Code of Federal Regulations, "Packaging and Transportation of Radioactive Material," Part 71, Chapter I, Title 10, "Energy."

U.S. Nuclear Regulatory Commission, "Standard Format and Content of Part 71 Applications for Approval of Packages for Radioactive Material," Regulatory Guide 7.9, Revision 2, March 2005.

U.S. Nuclear Regulatory Commission, "Standard Review Plan for Transportation Packages for Radioactive Material," NUREG-1609, May 1999.

U.S. Nuclear Regulatory Commission, "Standard Review Plan for Spent Fuel Transportation Packages," NUREG-1617, March 1998.

U.S. Nuclear Regulatory Commission, "Engineering Drawings for 10 CFR Part 71 Package Approvals," NUREG/CR-5502, May 1998.

U.S. Nuclear Regulatory Commission, "Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety," NUREG/CR-6407, February 1996.

U.S. Nuclear Regulatory Commission, "Recommendations on Fuel Parameters for Standard Technical Specifications for Spent Fuel Storage Casks," NUREG/CR-6716, March 2001.

U.S. Nuclear Regulatory Commission, "Guide for Preparing Operating Procedures for Shipping Packages," NUREG/CR-4775, July 1988.

U.S. Nuclear Regulatory Commission, "Fabrication Criteria for Shipping Containers," NUREG/CR-3854, March 1985.

U.S. Nuclear Regulatory Commission, "Welding Criteria for Use in the Fabrication of Radioactive Material Shipping Containers," NUREG/CR-3019, March 1984.

American National Standards Institute, ANSI N14.5, "Leakage Tests on Packages for Shipment," New York.

## **APPENDIX A**

### **Background for ISG-20**

#### **Change Authority in 10 CFR Parts 50 and 72**

U.S. Nuclear Regulatory Commission (NRC) regulations in 10 CFR Part 50 authorize licensees to make certain changes to reactor facilities and operations without prior NRC approval. In 1999, NRC amended its regulations to expand the provisions at 10CFR 72.48 for a similar change authority to certificate holders for spent fuel storage casks. Because some spent fuel storage casks are intended to be used both for storage of spent fuel under 10 CFR Part 72 as well as the eventual transport of fuel, NRC considered the possible benefits of authorizing limited change authority, under 10 CFR Part 71, for certificate holders for dual purpose (storage and transport) cask systems.

#### **Part 71 Proposed Rule**

On April 30, 2002, NRC published a proposed rule for a major revision of 10 CFR Part 71 (Ref. 67 FR 21390). Among other items, the proposed rule included a set of provisions that would allow certificate holders for dual-purpose spent fuel casks, designated as Type B(DP) transportation packages, to make certain changes to the package without prior NRC approval. After evaluating the proposed rule and public comments, NRC determined that implementation of this change would result in new regulatory burdens and costs that could be significant. At the direction of the Commission, NRC solicited stakeholder input on the values and impacts of this change. Based on the staff's evaluation and stakeholder input, the provisions for limited change authority were not adopted (Ref. 70 FR 312).

As a result of this process, staff recognized that the regulatory structure of Part 71 already allows certain changes to the package without prior NRC approval. For transportation packages, NRC approves the package design, and the Certificate of Compliance is the approval document that specifies the design (including packaging and radioactive contents) and operational elements that are necessary for safe transport. In general, changes to the design or operations that are not conditions of the approval do not require prior NRC approval.

#### **General License**

Under the requirements of 10 CFR 71.3, a licensee must have a license to transport radioactive material or to deliver radioactive material to a carrier for transport. This license is separate from, and in addition to, any license needed to possess the radioactive material. Subpart C of Part 71 gives general licenses for this transport. The general license in 10 CFR 71.17 authorizes NRC licensees to ship Type B quantities of radioactive material and fissile material in NRC-approved packages. The general license imposes certain conditions, such as the licensee must comply with the terms and conditions in the approval, typically a Certificate of Compliance. In other words, the Certificate of Compliance (along with the general license provisions) establishes the conditions under which the shipment is authorized.

#### **Package Approval (Certificate of Compliance)**

NRC Certificates of Compliance define the package design that is authorized for transport. As defined in 10 CFR 71.4, package means the packaging, together with its radioactive contents, as presented for transport. Therefore, the package design includes the packaging (hardware) design and the contents (radioactive material). The certificate may also include package

operations that are important to safety, (i.e., the package operations that ensure the package, as presented for transport, will meet the regulatory performance standards.) Packaging acceptance tests (e.g., tests for shielding integrity and leakage tests) and the maintenance program may also be included as conditions of the approval.

In general, therefore, the Certificate references the applicable sections of the package application (safety analysis report) as conditions of the approval. These sections typically include:

- Packaging drawings that define the design and that are included in Chapter 1 of the application.
- Description of the authorized contents derived from Chapter 1 of the application.
- Operations that are needed to prepare a package for transport and operate a package, as given in Chapter 7 of the application.
- Acceptance tests that are performed on each packaging before to its first use, as given in Chapter 8 of the application.
- The maintenance program used to ensure continued performance of the packaging, as given in Chapter 8 of the application.

### **Package Application (Safety Analysis Report)**

In the context of Part 71, the Safety Analysis Report (SAR) is called the package application. The sections identified above are typically incorporated by reference into the package approval. Other information provided in the package application report is not typically considered a condition of the approval. The package application simply provides the information that demonstrates that the design meets the performance standards in the regulations. The package application is typically listed as a "reference" at the end of the certificate, not as a condition. To use a package under the General License in Subpart C of 10 CFR Part 71, the licensee is required to have a copy of the packaging drawings and other documents, referenced in the Certificate, that relate to the use and maintenance of the package, and actions to be taken before shipment. The licensee must follow the terms and conditions in the certificate, i.e., the shipment must conform, in all respects, to the certificate and any documents specifically cited as a condition of the approval. The licensee does not need to have a copy of the complete package application. This is in contrast to casks licensed under 10 CFR Part 72, where a general licensee must have, and is required to review, the SAR, including updates (see, for example, 10 CFR 72.212(b)(3) and 72.248(c)(7)).

### **Changes authorized without prior NRC approval**

In general, prior NRC approval is only needed for changes that affect the conditions in the Certificate of Compliance. Therefore, the key to allowing flexibility is to ensure that drawings and the specific SAR sections that are to be included as conditions of approval include only the information needed for package performance. The Certificate of Compliance normally specifies the following: (1) engineering drawings, which control the packaging design; (2) the authorized contents; (3) the package operations; and (4) acceptance tests and maintenance program that



are included in the package application. Special additional conditions may be explicitly identified in the Certificate of Compliance (i.e., modal restrictions, minimum ambient temperature for transport, and package leakage testing). Other regulatory requirements (e.g., terms and conditions of the general license in 10 CFR 71.17, and the preliminary and routine determinations in 10 CFR 71.85 and 71.87) always apply. The four items identified above are discussed below.

### **Design Drawings**

Each package application must include information about the packaging design. This design information is typically captured in engineering drawings submitted in Chapter 1 of the package application. NUREG/CR-5502, "Engineering Drawings for 10 CFR Part 71 Package Approvals," includes information on the purpose of the drawings submitted with the package application, and describes recommended format and technical content for these drawings. In general, engineering drawings should focus on the safety features of the package and components that are important in the performance of the package and in the package evaluation.

### **Package Contents**

The description of the radioactive contents is included in Chapter 1 of the application. The authorized contents are typically specified in detail in the Certificate of Compliance. The description of the contents should be complete with respect to the chemical and physical form of the material, as well as the radioactive content (radionuclides and quantity) of the material. The content description must be consistent with respect to assumptions made about the contents in the package evaluation (e.g., in the containment, shielding, and criticality evaluations).

### **Package Operations**

Package operations included in Chapter 7 of the package application should focus on those actions needed to ensure the proper preparation of the package for shipment. The actions must ensure that the package, as presented for transport, will perform in the same manner as demonstrated in the package evaluation. NUREG/CR-4775, "Guide for Preparing Operating Procedures for Shipping Packages," includes information that is useful to applicants in the development of Chapter 7. The information in Chapter 7 is not intended to constitute the detailed operating procedures for the package, but is intended to provide the essential elements of the operations that must be incorporated into the detailed, written operating procedures that are required by 10 CFR 71.87(f).

### **Acceptance Tests and Maintenance Program**

The acceptance tests that must be performed for each packaging manufactured from an approved design and the packaging maintenance program are described in Chapter 8 of the application. These sections also focus on the essential elements that ensure the package, as presented for transport, will function as intended and will perform consistent with the package evaluation. Information on acceptance tests is included in NUREG/CR-3854, "Fabrication Criteria for Shipping Containers," and NUREG/CR-3019, "Welding Criteria for Use in the Fabrication of Radioactive Material Shipping Containers."

## **NRC Approved Quality Assurance Program**

As specified in 10 CFR 71.31(a)(3), the package application must include a quality assurance program description, including provisions that are applicable to a particular package design. The quality assurance program should meet the requirements of Subpart H of 10 CFR Part 71. Regulatory Guide 7.10 provides the standard format and content guide for quality assurance programs.

## **References**

U.S. Code of Federal Regulations, "Domestic Licensing of Production and Utilization Facilities," Part 50, Title 10, "Energy."

U.S. Code of Federal Regulations, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater Than Class C Waste," Part 72, Title 10, "Energy."

U.S. Code of Federal Regulations, "Packaging and Transportation of Radioactive Material," Part 71, Title 10, "Energy"

U.S. Nuclear Regulatory Commission, "Engineering Drawings for 10 CFR Part 71 Package Approvals," NUREG/CR-5502, May 1998.

U.S. Nuclear Regulatory Commission, "Guide for Preparing Operating Procedures for Shipping Packages," NUREG/CR-4775, July 1988.

U.S. Nuclear Regulatory Commission, "Fabrication Criteria for Shipping Containers," NUREG/CR-3854, March 1985.

U.S. Nuclear Regulatory Commission, "Welding Criteria for Use in the Fabrication of Radioactive Material Shipping Containers," NUREG/CR-3019, March 1984.

U.S. Nuclear Regulatory Commission, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material," Regulatory Guide 7.10, Revision 2, March 2005.

## APPENDIX B

### Examples of Flexibility Provided in the NRC Certificate of Compliance

The following table includes typical examples of what a reviewer should look for in a package design and operations in a well-prepared package application from the applicant. Examples are provided for the major package types, and represent actual experience with package approvals.

Package Type - Feature	Examples of How Flexibility Can be Provided
Radiography Package - supplemental gamma shielding in drawings	Drawings should show a general arrangement for using supplemental shielding, if needed to meet normal condition dose rate limits. The materials of construction, maximum weight and thickness, and method of attachment should be shown. The specific details are not needed, because the supplemental shielding is intended for the maximum strength source to meet the normal conditions dose rate limit. If the radiation survey does not confirm that the shielding is adequate, the source may not be shipped. The shielding evaluation should show that the package can meet the accident conditions dose rate limit without the supplemental shielding, so its attachment is not critical to the safe performance of the package.
Type B Waste Package - contents specification	The exact isotopic distribution of the contents is often not known for these packages. The contents may be identified in terms of the number of $A_2$ values for containment considerations. For shielding considerations, a representative loading, along with normal conditions dose rates could be used. The radiation analysis should show that a reasonable rearrangement of contents under accident conditions would result in a dose rate less than the accident condition limit.
Unirradiated Fuel Package - component dimensions in drawings	Drawings should include reasonably lenient dimensional tolerances for the outer packaging to allow practical fabrication variability. For example, the outer length of the container may vary without affecting the performance of the package. Dimensions that are important with respect to criticality safety should be strictly limited. For example, the separation distance provided by certain structural features (e.g., clamps, spacers) may be important for criticality, and those features should be identified with close tolerances.
Low Enriched Uranium Oxide Package - outer drum in drawings	Drawings should show the outer drum in a general configuration, without precise details. For example, the drawings should show material of construction, which may be "steel" without a specification, and relatively lenient tolerances on the drum dimensions. The general configuration of the rolling hoops may be shown, without identifying exact dimensions. Material and thicknesses should be shown for components such as the shell, bottom head, lid, closure ring, and bolt. The gasket, which typically does not serve a containment function may be shown as an option or with minimum specificity.

Transuranic Waste Packages - leakage tests described in package operations	Package operations should identify key leakage testing steps, setup configuration, and acceptance criteria. Over-specification of leakage testing equipment (e.g., specifying a leak detector manufacturer) should be avoided. The key parameters for a pre-shipment leakage test, for example, a pressure rise test, may be minimum test duration, maximum pressure drop allowed along with the maximum temperature change allowed. These parameters may be justified by calculation of test sensitivity using guidance in ANSI N14.5.
Low Enriched Uranium Hexafluoride Packages - acceptance tests for foam-filled overpacks	As specified in Department of Transportation regulations, uranium hexafluoride must be packaged within cylinders that conform to ANSI N14.1. For foam-filled overpacks, the acceptance tests for the foam should include reasonable ranges for material density, compressive strength, thermal conductivity, etc. Structural analyses may be used to justify the ranges. Reference to ASTM test standards should be reviewed to ensure that the standard does not overly restrict the testing of foam characteristics.
High Enriched Uranium or Plutonium Package - contents specification	Contents specification may include multiple loadings, each of which is separately evaluated for criticality safety. Such multiple loadings may include ranges of fissile material enrichment, ranges of H/X (hydrogen atoms per atom of fissile material), and minimum CSI. The multiple loadings, including ranges that satisfy criticality safety requirements, may be constructed to allow maximum flexibility for operations.
Type B Special Form Package - O-ring seals in drawings, package operations, and maintenance	O-ring seals for packages containing special form sources may have limited safety significance, because most of the radioactivity is within the special form source. O-rings would retain any contamination that might be within the package introduced during source loading, etc. O-ring seals may be shown in a general configuration, and optional materials may be shown. O-ring replacement schedules may be omitted, provided that the O-ring is inspected and replaced when damaged.
Spent Fuel Package - contents specification	Spent fuel assemblies should be specified by physical characteristics, not by vendor or name. The physical characteristics must be identified that are important to the criticality analyses in the application. The analyses should show that the entire range of physical characteristics is considered. Minimum and maximum values should be specified when convenient (e.g., maximum uranium enrichment, minimum clad thickness). Nominal values may be used if the safety of the package is insensitive to small changes in the parameter specified (e.g., active fuel length). A table of fuel assembly physical parameters that is suitable for inclusion in a Certificate of Compliance should be submitted with an application. There should be a clear nexus between the table of fuel parameters and the criticality safety analysis.