DOE Package Review Guide for Reviewing Radioactive Material Transportation Safety Analysis Reports for Packages

Revision 4

B. Anderson
D. Biswas
L. B. Hagler
E. W. Russell
S. Sitaraman
J. Wen

August 9, 2021

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DOE Package Review Guide
for Reviewing
Safety Analysis Reports for Packages

Revision 4

August 9, 2021

Prepared by
B. L. Anderson, D. Biswas, L. B. Hagler,
E. W. Russell, S. Sitaraman, J. Wen

Lawrence Livermore National Laboratory
7000 East Avenue
Livermore, CA 94550

Prepared for
DOE Packaging Certification Program
Office of Packaging and Transportation
Environmental Management
U.S. Department of Energy
Germantown, Maryland 20874
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This DOE Package Review Guide (PRG) provides guidance for Department of Energy (DOE) review and approval of packages to transport fissile and Type B quantities of radioactive material. It fulfills, in part, the requirements of DOE Order 460.1D for the Headquarters Certifying Official to establish standards and to provide guidance for the preparation of Safety Analysis Reports for Packages (SARP).

This PRG is intended for use by the United States Department of Energy Headquarters Certifying Official and their staff, DOE Secretarial offices, operations/field offices, and applicants for DOE package approval.

This PRG is generally organized at the chapter-level in a format similar to that recommended in United States Nuclear Regulatory Commission Regulatory Guide 7.9. One notable exception is the addition of Chapter 9 Quality Assurance, which is not included as a separate chapter in Regulatory Guide 7.9. Within each chapter, this PRG addresses the technical and regulatory bases for the review, the manner in which the review is accomplished, and findings that are generally applicable for a package that meets the approval standards.
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## ABBREVIATIONS AND ACRONYMS

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<tr>
<td>ANL</td>
<td>Argonne National Laboratory</td>
</tr>
<tr>
<td>ANS</td>
<td>American Nuclear Society</td>
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<tr>
<td>ANSI</td>
<td>American National Standards Institute</td>
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<tr>
<td>ASME</td>
<td>American Society of Mechanical Engineers</td>
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<tr>
<td>AWS</td>
<td>American Welding Society</td>
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<tr>
<td>B&amp;PV</td>
<td>Boiler and Pressure Vessel (ASME Code)</td>
</tr>
<tr>
<td>Bq</td>
<td>Becquerel</td>
</tr>
<tr>
<td>cc</td>
<td>cubic centimeter</td>
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<tr>
<td>CDG</td>
<td>Commercial Grade Dedication</td>
</tr>
<tr>
<td>CFR</td>
<td>Code of Federal Regulations</td>
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<tr>
<td>cg</td>
<td>center of gravity</td>
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<td>CoC</td>
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<td>Containment Vessel</td>
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<td>U.S. Department of Energy</td>
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<td>U.S. Department of Energy Order (used in designation of new-series orders)</td>
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<td>International Atomic Energy Agency</td>
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<td>IEEE</td>
<td>Institute of Electrical and Electronics Engineers</td>
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<tr>
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<td>m</td>
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<tr>
<td>psi</td>
<td>pounds (force) per square inch</td>
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<td>Quality Assurance</td>
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<td>Safety Analysis Report for Package(s)*</td>
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INTRODUCTION

Background
Department of Energy Order 460.1D (i.e., DOE O 460.1D)[I-1] establishes requirements for the proper packaging and transportation of hazardous material by DOE and its contractors.* Unless otherwise authorized or excluded by this order, DOE transportation of fissile and Type B quantities of radioactive material shall be in a package (i.e., packaging with its contents) that is approved by the Headquarters Certifying Official (HCO) under conditions specified in the DOE Certificate of Compliance (CoC).

The authority for DOE to certify packages is established by 49 CFR 173.7(d),[I-2] which states that packages shall be evaluated, approved, and certified against standards equivalent to those specified in 10 CFR 71.[I-3] DOE O 460.1D explicitly states that such packages shall comply with the regulations of 10 CFR 71, and with any other requirements deemed applicable by the Headquarters Certifying Official.

Purpose
This DOE Package Review Guide (PRG) provides guidance for DOE review and approval of packages used to transport fissile and Type B quantities of radioactive material. It fulfills, in part, the requirements of DOE O 460.1D for the Headquarters Certifying Official to establish standards and to provide guidance for the preparation of Safety Analysis Reports for Packages (SARPs).

This PRG is intended for use by the Headquarters Certifying Official and their review staff, DOE Secretarial offices, operations/field offices, and applicants for DOE package approval. The primary objectives of this PRG are to:

- Summarize the regulatory requirements for package approval
- Provide pertinent details of related regulatory guides and consensus standards
- Describe the technical review procedures by which DOE determines that these requirements have been satisfied
- Establish and maintain the quality and uniformity of reviews
- Define the base from which to evaluate proposed changes in scope and requirements of reviews
- Provide the above information to DOE organizations, contractors, other government agencies, and interested members of the general public.

* Similar requirements were previously established by DOE Orders 1540.2, 5480.3, 460.1A, 460.1B, and 460.1C which may still be applicable depending on specific contractual relationships.
This PRG was originally published in September 1987. Revisions 1, 2 and 3 were issued 1988, 1999, and 2008, respectively. Revision 4 is a complete update of Revision 3 and supersedes all previous revisions.

Related Documents
DOE’s authority to certify packages is based on the premise that the DOE evaluation and approval process will provide an assurance of safety equivalent to that required by the United States (US) Nuclear Regulatory Commission (NRC). Such assurance can be provided by:

- **Requiring that DOE package designs meet the regulatory requirements of 10 CFR 71 or their equivalent**
- **Ensuring that the evaluation methods used to demonstrate compliance with these regulations are equivalent to those used by the Nuclear Regulatory Commission.**

Consequently, the evaluation process described in this PRG relies substantially on 10 CFR 71 and the following other NRC documents:

- **NUREG-2216, Standard Review Plan for Transportation Packages for Spent Fuel and Radioactive Material.**
- **Regulatory Guide 7.9, Standard Format and Content of Part 71 Applications for Approval of Packaging for Radioactive Material.**
- **Regulatory Guide 7.10, Establishing Quality Assurance Programs for Packaging Used in Transport of Radioactive Material.**
- **NUREG-3019, Recommended Welding Criteria for Use in the Fabrication of Shipping Containment for Radioactive Materials.**
- **NUREG/CR-3854, Fabrication Criteria for Shipping Containers.**
- **NUREG/BR-0167, Software Quality Assurance Program and Guidelines.**
- **Other regulatory guides such as U.S. Nuclear Regulatory Commission Interim Staff Guidance (ISG) and NUREG reports that provide guidance on criteria for evaluating transportation packages.**

The NRC regulatory and guidance documents can be found on their website: www.nrc.gov. A collection of package certification documents can be found at the DOE Packaging Certification Program website: rampac.energy.gov.


Scope
This PRG is intended to provide a general description of the principles and procedures for evaluating applications for certification of packages for transportation of radioactive material. This PRG does not relieve the applicant from the requirements of DOE O 460.1D or other...
pertinent regulations or imply that SARPs prepared or reviewed in accordance with this guide will necessarily be approved.

This PRG addresses shipment of fissile (i.e., Type AF) or Type B quantities of radioactive material in DOE certified packages under the provision of DOE O 460.1 D and 10 CFR 71. This PRG has a focus on Normal Form radioactive material, however, guidance for Special Form radioactive material is also provided where applicable. The following areas of DOE O 460.1 D and 10 CFR 71 are not currently within the scope of this PRG:

- Shipment of hazardous material other than fissile and Type B quantities of radioactive material
- Shipment of DOE radioactive material in packages approved by Department of Transportation (DOT), NRC, or International Atomic Energy Agency (IAEA)
- Shipment of Type B quantities of plutonium by air
- Qualification and shipment of low specific activity material and surface contaminated objects
- Notifications, violations, and penalties
- Exemptions and exceptions
- All requirements incorporated into DOE O 460.1 D or 10 CFR 71 by reference to other regulations (e.g., DOE, NRC, DOT, or U.S. Postal Service).

**Organization of DOE Package Review Guide**

The main body of this PRG is organized into nine chapters in a format similar to that recommended in Regulatory Guide 7.9 (RG 7.9) for the SARP. One notable exception is the addition of Chapter 9 (Quality Assurance), which is not included as a separate chapter in RG 7.9. Within each chapter, the PRG addresses the technical and regulatory bases for the review, the manner in which the review is accomplished, and general findings applicable to a package that meets the approval standards. Each chapter of the PRG follows the format below.

**Introduction**

The introduction succinctly states the objective of the review for each chapter, provides summary information, and identifies the information required for review of other chapters of the SARP. Chapters of a SARP are interdependent with information flow among chapters. For example, the Containment review depends in part on: (1) the packaging and contents description presented in the General Information chapter; and (2) the condition of the package under the normal and hypothetical accident condition tests in the Structural and Thermal Evaluation chapters. Likewise, the results of the Containment review may result in the need to implement specific Package Operations, Acceptance Tests, or other Quality Assurance procedures. The introduction to each section of this PRG presents a schematic representation of these interfaces. These representations are intended as examples and should not be considered as a complete list of all information to be reviewed. In addition, specific interfaces may vary with the details of a particular package design.
Subsection 1. Areas of Review
This subsection identifies the principal areas that are reviewed to demonstrate that the package design complies with regulatory requirements. In general, the Areas of Review correspond to the major subsections of RG 7.9. In some cases, additional information is provided for clarity and completeness.

Subsection 2. Regulatory Requirements
This subsection summarizes the applicable regulatory requirements of 10 CFR 71. In many instances, the wording from the regulation is shortened, and two or more related requirements are sometimes combined for brevity. These modifications in wording are not intended to change or interpret the regulations. Regulatory requirements are generally listed in the order that they are addressed in the Review Procedures.

Subsection 3. Review Procedures
This subsection provides guidance for performing the review of the Areas of Review identified in Subsection 2 above. These procedures will cover a majority of package designs. However, special situations may require new or modified review procedures.

The review of the statements and representations presented in the SARP will often necessitate confirmatory analyses by the reviewers. The effort and level of detail of such analyses will depend on several factors, including the importance to safety of the issue, the margin between evaluated performance and regulatory requirements, the method and complexity, similarity to other approved packages, and other factors.

Subsection 4. Evaluation Findings
This subsection provides guidance on documenting the findings that the requirements of Subsection 2 are satisfied. An example statement of the major findings of the review is presented in this subsection. The review staff will modify the wording as appropriate to address specific details of the SARP and methods of review. This subsection also identifies additional conditions of approval deemed necessary for regulatory compliance.

Subsection 5. References
This subsection identifies references cited in the section. Revision designations are those in effect at the time of publication of this PRG.

Appendices of DOE Package Review Guide
This PRG contains five appendices:

- Appendix A provides Definitions of common package-related terms, many of which are also defined in 10 CFR 71 and/or 49 CFR Part 173.
- Appendix B contains the Significant Changes and Additional Requirements That Resulted From the 2004 Revision of 10 CFR 71.
Appendix C provides a Summary of Issues Relevant to Materials, Fabrication and Quality Assurance including definitions, which are typically addressed in several SARP chapters.

Appendix D provides recommendations for documenting the Quality Assurance of Software and Analyses.

Appendix E provides guidance on using Transfer Function Method for Evaluation of External Radiation Limits.

Requirements and Guidance
Throughout this PRG, the word shall is intended to imply a requirement imposed by CFR or DOE order. Other conditions generally considered necessary for package approval are specified by the word should. Because these conditions are not specifically imposed by regulation or order, the SARP may, if appropriate, justify that they are not applicable or that other conditions are more pertinent to the proposed package.

Technical Review Report
The technical reviews of SARPs in support of DOE certification are conducted by Lawrence Livermore National Laboratory (LLNL), Argonne National Laboratory (ANL), Savannah River National Laboratory (SRNL), or a combination of these laboratories. The results of these reviews are documented in a Technical Review Report (TRR), which summarizes for each chapter:

- Applicable regulatory requirements
- Methods (e.g., testing, calculations, comparison to similar certified packages, use of standards) by which the SARP demonstrated that these requirements were met
- A description of the technical review of the evaluation presented in the SARP, including confirmatory analysis and other bases for accepting the SARP evaluation
- Summary conclusions of the technical review.

The TRR provides the justification for the technical information included in the Safety Evaluation Report (SER), a report issued by the Headquarters Certifying Official (HCO) to document DOE’s review of the package for compliance with DOE O 460.1 D and 10 CFR 71. The HCO then issues a Certificate of Compliance (CoC) for the use of the package.
Reference


1.0 GENERAL INFORMATION REVIEW

This review verifies that the package has been described in sufficient detail to provide an adequate basis for its evaluation relative to the regulatory requirements in 10 CFR 71.\(^\text{[1-1]}\)

The General Information chapter of the Safety Analysis Report for Package (SARP) is reviewed by all members of the review team. During the review, the team leader (or the team leader’s designee) coordinates input from team members and prepares questions, or requests for additional information from the applicant, as appropriate. At the completion of the review, the individual responsible for questions on the General Information chapter also prepares the corresponding section of the Technical Review Report (TRR).

The results of the General Information review are considered in the review of all other chapters of the SARP. An example of this information flow for this review is shown in Figure 1.1.

Figure 1.1 Example of Information Flow for the General Information Review
1.1 **Areas of Review**

The package description and SARP drawings should be reviewed. The review should include:

1.1.1 **Introduction**
- Purpose of Application
- Summary Information
- Statement of Compliance
- Summary of Evaluation

1.1.2 **Package Description**
- Packaging
- Contents
- Special Requirements for Plutonium
- Operational Features

1.1.3 **Appendices**
- Drawings
- Other Information

1.2 **Regulatory Requirements**

The requirements of 10 CFR 71 applicable to the General Information review include:

- An application for package approval shall be submitted in accordance with §71.0(d)(2), which specifies that the application for package approval must be completed in accordance with Subpart D of 10 CFR 71. [§71.0(d)(2)]

- An application for modification of a previously approved package is subject to the provisions of §71.19 and §71.31(b). All changes in the conditions of package approval shall be approved. [§71.19, §71.31(b), §71.107(c)]

- The application shall include a description of the packaging design in sufficient detail to provide an adequate basis for its evaluation. [§71.31(a)(1), §71.33(a)]

- The application shall include a description of the contents in sufficient detail to provide an adequate basis for evaluation of the packaging design. [§71.31(a)(1), §71.33(b)]

- The application shall reference or describe the quality assurance program applicable to the package. [§71.31(a)(3), §71.37]

- The application shall identify the established codes and standards used for the package design, fabrication, assembly, testing, maintenance, and use. In the absence of such codes, the application shall describe the basis and rationale used to formulate the package quality assurance program. [§71.31(c)]
An application for renewal of a previously approved package shall be submitted no later than 30 days prior to the expiration date of the approval to assure continued use. [§71.38]

The smallest overall dimension of the package shall not be less than 10 cm (4 in.). [§71.43(a)]

The outside of the package shall incorporate a feature that, while intact, would be evidence that the package has not been opened by unauthorized persons. [§71.43(b)]

A package with a transport index greater than 10, a Criticality Safety Index greater than 50, or an accessible external surface temperature greater than 50°C (122°F) shall be transported by exclusive-use shipment. [§71.43(g), §71.47(a), §71.47(b), §71.59(c)]

The maximum activity of radionuclides in a Type A package shall not exceed the $A_1$ or $A_2$ values listed in Appendix A of 10 CFR 71, Table A-1 (depending on the contents being special form or normal form). For a mixture of radionuclides, the provisions of Appendix A of 10 CFR 71, paragraph IV apply, except that for Krypton-85, an effective $A_2$ equal to 10 $A_2$ may be used. [Appendix A, §71.51(b)]

A fissile material packaging design to be transported by air shall meet the requirements of §71.55(f).

A fissile material package shall be assigned a Criticality Safety Index for nuclear criticality control to limit the number of packages in a single shipment. [§71.59, §71.35(b)]

Plutonium in excess of 0.74 TBq (20 Ci) shall be shipped as a solid. [§71.63]

The package shall be conspicuously and durably marked with its model number, serial number, gross weight, and package identification number. [§71.19, §71.85(c)]

1.3 Review Procedures

The following procedures are generally applicable to the review of the General Information chapter of the SARP. These procedures correspond to the Areas of Review listed in Section 1.1 of this PRG.

1.3.1 Introduction

1.3.1.1 Purpose of Application

The application may be for approval of a new package, for modification of an approved package, or for renewal of an existing approval [e.g., Certificate of Compliance (CoC)]. The purpose may be identified in the SARP itself, and/or in an accompanying transmittal letter for the application. Verify that the purpose of the application is clearly stated.

Applications for approval of a new package should be complete and should contain the information identified in Subpart D of 10 CFR 71, Application for Package Approval.

Applications for modification of an approved package should clearly identify the changes being requested. Modifications may include packaging design changes, changes in authorized contents, or changes in the conditions of the approval (including changes in the designation of the package identification number). Package design changes should be clearly identified on revised SARP...
drawings. The application should include a summary assessment of the requested changes and justification that these changes do not affect the ability of the package to meet the requirements of 10 CFR 71. Applications for modifications are subject to the provisions of §71.19 and §71.31(b), as applicable. Changes in the package identification number to designate compliance with revised regulations (e.g., the addition of “-96”) are subject to §71.19(d). A summary of regulatory changes affecting the “-96” designation is provided in Appendix B of this PRG.

1.3.1.2 Summary Information
Confirm that the package type and model number are designated. A new Type B package design should be designated B(U)-96 unless it has a maximum normal operating pressure greater than 700 kPa (100 psi) gauge or a pressure relief device that would allow the release of radioactive material under the tests specified in §71.73 (hypothetical accident conditions). In those cases, the package should be designated B(M)-96.

Confirm that the contents are identified as either ‘Special Form’ or ‘Normal Form.’ Normal Form radioactive material is material that cannot be demonstrated to be Special Form. Special Form radioactive material is: (1) either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule; and (2) the piece or capsule has at least one dimension not less than 5 mm (0.2 in); and (3) it satisfies the requirements of 71.75. This high physical integrity of Special Form material can be a result of the material’s inherent properties, such as it being in a non-dispersible solid form. Most often, however, a material is qualified as Special Form material as a result of it being welded (encapsulated) into an extremely durable metal capsule. For material to be considered as Special Form it shall be formally qualified as such by satisfying the testing requirements in 10 CFR 71.75, including: (1) impact; (2) percussion; (3) bending; (4) heat; and (5) leaching. If applicable, the Special Form qualification report might be presented in an appendix to the General Information chapter or in another chapter of the SARP (e.g., Structural Evaluation).

Confirm that each radionuclide in the contents is identified along with its maximum mass or activity. Confirm that any non-radioactive impurities are also clearly identified with their masses. Ensure that the contents are consistent with the designated package type. The maximum activity of Special Form radioactive material permitted in a Type A package is $A_1$, and the maximum activity of radioactive material (Normal Form) permitted in a Type A package is $A_2$ (See Appendix A, Table A–1 of 10 CFR 71 for a listing of $A_1$ and $A_2$ values for each nuclide). If the content is Special Form and has more than $A_1$ quantity of radioactive material or is Normal Form and has more than $A_2$ of radioactive material, then the material shall be transported in a Type B package.

For a mixture of radionuclides, guidance on the maximum activity allowed in a Type A package, and the determination of effective $A_1$ and $A_2$ values is given in 10 CFR 71 Appendix A and §71.51(b). Packages for transporting fissile radionuclides should also be designated as fissile material packages (i.e., Type AF, Type BF, Type B(U)F, or Type B(M)F) unless the exemptions of §71.15 are applicable.

Ensure that any restrictions regarding the type of conveyance for shipment of the package are designated. Note that special requirements apply to the air shipment of plutonium, e.g., §71.64,
§71.74, and §71.88, and that review of packages for plutonium air shipments is not addressed in detail in this PRG.

For Type B packages, verify that the designated package category is properly justified. Definitions of package categories are summarized in Table 1.1 for Special Form and Normal Form radioactive material. Detailed justification, including calculation of an effective $A_1$ or $A_2$ from the maximum activity of the contents, might be presented in an appendix to the General Information chapter or in another chapter of the SARP (e.g., Containment).

### Table 1.1 Category Designations for Type B Packages

<table>
<thead>
<tr>
<th>Contents Form</th>
<th>Category I</th>
<th>Category II</th>
<th>Category III</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal Form*</td>
<td>Greater than $3,000 A_2$ or greater than $1.11$ PBq (30,000 Ci)</td>
<td>Between $3,000 A_2$ and $30 A_2$, and not greater than $1.11$ PBq (30,000 Ci)</td>
<td>Less than $30 A_2$ and less than $1.11$ PBq (30,000 Ci)</td>
</tr>
<tr>
<td>Special Form*</td>
<td>Greater than $3,000 A_1$ or greater than $1.11$ PBq (30,000 Ci)</td>
<td>Between $3,000 A_1$ and $30 A_1$, and not greater than $1.11$ PBq (30,000 Ci)</td>
<td>Less than $30 A_1$ and less than $1.11$ PBq (30,000 Ci)</td>
</tr>
</tbody>
</table>

* Normal form uses $A_2$ and special form uses $A_1$

The package category will determine which structural design and fabrication code[1-3] or other criteria[1-4, 1-5] are appropriate for components that affect the structural integrity of containment, criticality, or shielding systems. Although the designation of these codes or standards should be indicated on the SARP drawings and applicable fabrication specifications indicated in this chapter (see Section 1.3.3.1), a more detailed discussion and justification may be deferred to the Structural Evaluation chapter of the SARP. Similarly, details of other codes and standards for the package may be presented in the General Information chapter or may be discussed in the applicable chapters of the SARP.

Confirm that the SARP identifies the applicant’s quality assurance (QA) program applicable to the package. Details of QA program requirements and implementation should be presented in the QA chapter of the SARP. Important elements of a quality assurance program for packaging used in the transport of radioactive material are provided in Regulatory Guide 7.10[6] and in DOE’s Quality Assurance Guidance for Packaging of Radioactive and Fissile Materials.[7]

For fissile material packages, confirm that a Criticality Safety Index (CSI), based on nuclear criticality safety, is designated for each content. This index will generally be designated in the CoC as the minimum criticality safety index. Unlike the CSI that is based on criticality safety calculations, the Transport Index (TI) is determined by measured external radiation levels of the package as loaded for shipment and is not specified in the CoC. Ensure that the maximum number of packages that may be shipped in a single conveyance and any restrictions for exclusive-use shipment, if applicable, are consistent with the CSI.

Determine if the shipment of the package is limited to exclusive use because of other regulatory requirements (e.g., external radiation levels or Criticality Safety Index (CSI) value, or package
surface temperatures). Additional information should be included in the Package Operations chapter of the SARP.

1.3.1.3 Statement of Compliance
Confirm that the SARP contains an unequivocal statement that the package complies with 10 CFR 71.

1.3.1.4 Summary of Evaluation
In addition to a statement that the package complies with 10 CFR 71, the General Information chapter of the SARP should include a summary of the package evaluations presented in subsequent SARP chapters, with a specific reference to the chapters in which compliance is demonstrated. The summary information should address:

- Criticality requirements, §71.15, §71.22, §71.23, §71.55, §71.59.
- Specify minimum Criticality Safety Index (CSI) value for the package.
- General requirements for all packages, §71.43.
- Structural requirements for shipments containing more than $10^5 A_2$, §71.61.
- External radiation requirements for all packages, §71.47.
- Requirements for Type B packages, §71.51.
- Special requirements for plutonium packages, §71.63.
- Structural and thermal performance of the package under the tests for normal conditions of transport and hypothetical accident conditions, §71.71 and §71.73, respectively.
- Requirements for operating controls and procedures, Subpart G.
- Requirements for quality assurance, Subpart H, and recommendations for quality level implementation.
- Requirements for the qualification of any special form radioactive material incorporated in the package design, §71.75.

The review of each SARP chapter should confirm that this summary information is consistent with the detailed evaluation and with the requirements of 10 CFR 71.

1.3.2 Package Description
1.3.2.1 Packaging
Review the text description of the packaging. Sketches, figures, Q-items (see Chapter 9 for discussion of a Q-list) or other schematic diagrams shall be provided. Ensure that the description of the packaging presented in the text and figures is consistent with that depicted on the SARP drawings (see Section 1.3.3.1).

Verify that the following information, as applicable, is adequately discussed:
• General packaging description, including overall dimensions, center of gravity, materials and fabrication description, maximum weight, and minimum weight, if appropriate

• Containment features, including a clear identification of the containment boundary

• Shielding features, including personnel barriers and shield inserts

• Criticality control features, including neutron absorbers, moderators, and spacers

• Heat-transfer features, including structural features (e.g. heat dissipating fins), gaps and coolants, that affect transfer and dissipation of heat

• Structural features, including supporting structures, lifting and tie-down devices, and impact limiters.

Proprietary information, including materials, components, and/or fabrication processes, should be clearly identified. Justification for withholding this information from public disclosure should be presented in a format comparable to that specified in 10 CFR 2.390, Public inspections, exemptions, requests for withholding.

Verify that the SARP defines the exact boundary of the containment system. This may include the containment vessel, welds, drain or fill ports, valves, pressure relief devices, seals, test ports, lids, cover plates, and other closure devices. If multiple seals are used for a single closure, the seal defined as part of the containment boundary should be clearly identified. A sketch of the containment system should be provided, and all components should be shown on the SARP drawings in the Chapter 1 Appendices. Additional information regarding the review of the containment boundary and containment requirements are addressed in Chapter 4 of this PRG.

Based on the package description and SARP drawings, confirm that the package meets the requirements of §71.43, including:

• The smallest overall dimension of the package is not less than 10 cm (4 in.)

• The outside of a package shall incorporate a feature, such as a seal, that is not readily breakable and that, while intact, would be evidence that the package has not been opened by unauthorized persons [i.e., Tamper Indicating Device (TID)]

1.3.2.2 Contents
Confirm that the contents are described in the same detail as that intended for the CoC. The description should include, as a minimum, the following information:

• Identification of the contents as ‘special form’ or ‘normal form’ radioactive material

• Identification and maximum quantity (radioactivity or mass) of each radionuclide in the contents

• Identification and maximum quantity of fissile and fissionable isotopes (including enrichment level for uranium contents for nuclear fuel)
Identification and maximum quantity of all light elements, e.g., Aluminum, Argon, Beryllium, Boron, Carbon, Chlorine, Fluorine, Lithium, Magnesium, Neon, Nitrogen, Oxygen, Phosphorous, Silicon, Sodium, and Sulfur

Identification and quantity of all non-radioactive materials

Chemical and physical form of radioactive and non-radioactive materials, including density and moisture content

Location and configuration of contents within the packaging, including secondary containers, wrapping, dunnage, shoring, and other material not defined as part of the packaging

Identification and quantity of materials used as reflectors, neutron absorbers, or moderators

Identification and quantity of any material subject to chemical, galvanic, radiolysis, or other reaction, including the generation of combustible and reactive gases

Maximum Normal Operating Pressure (MNOP)

Maximum weight (including shoring, canisters, secondary containers, etc.) and minimum weight if appropriate

Maximum decay heat.

If the contents include spent nuclear reactor fuel, the following additional information should be specified, as appropriate:

Type of fuel, range of enrichment and density of fissile material prior to irradiation (including specifications of non-uniform enrichment, if applicable). If the reactivity of irradiated fuel is larger than fresh fuel, the isotopic composition of the irradiated fuel should also be presented.

Range of burnups, initial enrichment, cooling time, specific power, and heat load

Fuel assembly specifications, including fuel matrix (e.g., PWR 17 x 17) dimensional data for the fuel pellets, cladding, fuel-cladding gap, rods, guide tubes, and other assembly structures considered in the evaluation

Control assemblies or other contents (e.g., startup sources), spacers, etc. present

Number of assemblies or rods

For damaged fuel, the extent of damage, description of containerization, or any other applicable limits

Other information necessary to evaluate compliance with 10 CFR 71, as applicable.

1.3.2.3 Special Requirements for Plutonium

If the contents include plutonium in excess of 0.74 TBq (20 Ci), verify that the contents are in solid form, [§71.63].
1.3.2.4 Operational Features
Verify that features for the safe operation of the package are described and discussed. A schematic diagram of any special operational feature should be included if applicable. Detailed information on operational features are presented in the Package Operations Chapter 7 of the SARP.

1.3.3 Appendices

1.3.3.1 Drawings
Verify that information on the SARP drawings is sufficiently detailed and consistent with the package description. The appendices need not include a full set of drawings for large, complex packages, nor include detailed construction drawings for packages of any type. A detailed discussion of information to be included on drawings is presented in NUREG/CR-5502.[1-8]

Department of Energy (DOE) orders (e.g., DOE Order 460.1D[1-9] and DOE Order 1540.2[1-10]) authorize transportation of Type B or fissile radioactive material by DOE and DOE contractors in packages approved by the Headquarters Certifying Official under conditions specified in the CoC. The purpose of the SARP drawings is to define the package design, as approved by DOE. Compliance with the SARP drawings is included in the Certificate of Compliance (CoC) as a condition of package approval. Packages that do not conform to the drawings in the SARP are not authorized for use.

Confirm that each drawing has a title block that identifies the preparing organization, drawing number, sheet number, title, date, and signature or initials indicating approval of the drawing. Revised drawings should identify the revision number, date, and description of the change in each revision. Proprietary information, if applicable, should be clearly identified. The drawings should include:

- General arrangement of package, including dimensions
- Design features (for a discussion of Q-items, see Chapter 9) that affect the package evaluation (see Section 1.3.2.1 above)
- Packaging markings, including model number, serial number, gross weight, and package identification number
- Maximum allowable weight of the package
- Maximum allowable weight of the contents and secondary packaging
- Minimum weights, if appropriate.

Information on design features important to safety (Q-items) shall include:

- Identification of the design feature and its components
- Materials of construction, including applicable material specifications
- Codes and consensus standards, or other similar documents for fabrication, assembly, testing, inspection, and acceptance. As appropriate, such information may be included on
a separate fabrication specification that can be referenced as a condition of approval in the CoC. Compliance with this specification should be described in the drawing as notes.

- For state-of-the-art emerging technology manufacturing and fabrication processes, see Appendix C for information on the development of specifications
- Dimensions with appropriate tolerances, including surface treatments and surface finishes
- Operational specifications (e.g., bolt torque, specifications of pressure-relief devices, etc.).

1.3.3.2 Fabrication Specifications
The appendices may also provide supporting information on special fabrication procedures and/or processes (as noted on the drawings with applicable reference to code, consensus standard, or “custom” specifications developed by the applicant). Detailed specifications of standard and custom fabrication methods should be included in the appendices. These specifications should detail material qualifications and special fabrication processes, as required. Based on quality level of the item being fabricated, material qualifications should align with appropriate regulations, codes, and standards. Fabrication specifications should reference all applicable codes and standards. Material testing requirements to determine acceptability of finished products should be included, along with applicable testing forms and data sheets. See Appendix C, Summary of Issues and Terms Relevant to Materials, Fabrication, and Quality Assurance, for more detail.

1.3.3.3 Other Information
Confirm that other appendices include a list of references and a copy of any references not generally available to the reviewer. Included in the appendices may be the determination of the package category (as applicable), details of the contents (including thermal profiles), a comparison between the prototype design and the SARP drawings, and other appropriate supplemental information deemed necessary by the applicant or reviewer (e.g., photographs).

1.4 Evaluation Findings
1.4.1 Findings
The review should ensure that the information presented supports a conclusion that the regulatory requirements in Section 1.2 above are satisfied. Because confirmation of some information presented in the General Information chapter of the SARP depends on a detailed review of subsequent chapters, preparation of the findings for this section may be deferred until the review of later chapters is completed.

The TRR should include a conclusion similar to the following:

Based on review of the statements and representations in the SARP, the Staff concludes that the package design has been adequately described to meet the requirements of 10 CFR 71.
1.4.2 Conditions of Approval
The TRR should clearly identify any conditions of approval that should be included in the CoC. In addition to a summary package description and specifications of authorized contents, the conditions of approval applicable to the General Information chapter of the SARP typically include:

- Type of conveyance
- Restriction to exclusive-use shipment, if applicable
- Drawings that define the package design, and additional fabrication specifications as applicable
- Reference to SARP Chapter 7, Operating Procedures requirements, Chapter 8, Acceptance Testing and Maintenance requirements, and Chapter 9, Quality Assurance requirements to add serial numbers to previously approved packages, as applicable.
1.5 References


2.0 STRUCTURAL REVIEW

This review verifies that the structural performance of the package design has been adequately evaluated for the tests specified under normal conditions of transport and hypothetical accident conditions and that the package design meets the structural requirements of 10 CFR 71 [2-1]. This chapter of the SARP should identify, describe, discuss, and analyze the principal structural design of the packaging, components, and systems important to safety.

The Structural Review is based in part on the descriptions and evaluations presented in the General Information and the Thermal Evaluation chapters of the Safety Analysis Report for Package (SARP). Similarly, results of the Structural review are considered in the review of subsequent chapters of the SARP. An example of this information flow for the Structural Review is shown in Figure 2.1.

Although 10 CFR 71 specifies only a few explicit structural requirements for packages (e.g., lifting and tie-down requirements), the structural performance of the package under normal conditions of transport and hypothetical accident conditions significantly affects its ability to meet the containment, shielding, and subcriticality regulatory requirements. Consequently, the Structural Review focuses on confirming the SARP evaluation of the effects of these tests and on coordinating these effects with the review of the Thermal, Containment, Shielding, and Criticality Evaluation chapters.

2.1 Areas of Review

The structural design of the package should be meticulously reviewed. The Structural review should include the following:

2.1.1 Description of Structural Design
- Structural Design Features Important to Safe Operation of the Package
- Codes and Standards Used for the Packaging Design

2.1.2 Materials of Construction
- Material Specifications and Properties
- Prevention of Chemical, Galvanic, or Other Reactions (e.g. corrosion)
- Effects of Radiation on Materials (e.g. neutron embrittlement of metals; degradation of seals; etc.)

2.1.3 Fabrication, Assembly, and Examination
- Fabrication and Assembly
- Examination
Figure 2.1 Example of Information Flow for the Structural Review
2.1.4 General Considerations for Structural Evaluations
- Evaluation by Test
- Evaluation by Analysis

2.1.5 Structural Evaluation of Lifting and Tie-Down Devices
- Structural Performance of Lifting Devices
- Structural Performance of Tie-Down Devices

2.1.6 Structural Evaluation for Normal Conditions of Transport
- Heat
- Cold
- Reduced External Pressure
- Increased External Pressure
- Vibration
- Water Spray
- Free Drop
- Corner Drop
- Compression
- Penetration
- Structural Requirements for Fissile Material Packages

2.1.7 Structural Evaluation for Hypothetical Accident Conditions
- Free Drop
- Crush (as applicable)
- Puncture
- Thermal
- Immersion–Fissile Material
- Immersion–All Packages

2.1.8 Structural Evaluation for Special Pressure Conditions
- Special Requirement for Packages >10^5 A_2
- Analysis of Pressure Test

2.1.9 Appendices
2.2 Regulatory Requirements

The following regulatory requirements are specifically for Normal Form contents. Section 2.3.6.12 discusses the supplementary requirements for Special Form contents.

Regulatory requirements of 10 CFR 71 applicable to the Structural review are as follows:

- The package shall be described and evaluated to demonstrate that it meets the structural requirements of 10 CFR 71. [§71.31(a)(1), §71.31(a)(2), §71.31(a)(3), §71.31(b), §71.33, §71.35(a)]
- The application shall identify the established codes and standards used for the package design, fabrication, assembly, testing, maintenance, and use. In the absence of such codes, the application shall thoroughly describe the basis and rationale used to formulate the quality assurance program. [§71.31(c)]
- The package shall be made of materials of construction that assure there will be no significant chemical, galvanic, or other reactions, including reactions due to possible inleakage of water, among the packaging components, among package contents, or between the packaging components and the package contents. The effects of radiation on the materials of construction shall be considered. [§71.43(d)]
- The package design shall meet the lifting and tie-down requirements of §71.45.

A fissile material packaging design to be transported by air shall meet the requirements of §71.55(f):

- A Type B package, containing more than $10^5$ A$_2$, shall be designed so that its undamaged containment system can withstand an external water pressure of 2 MPa (290 psi) for a period of not less than one hour without collapse, buckling, or inleakage of water. [§71.61]
- The performance of the package shall be evaluated under the tests specified in §71.71 for normal conditions of transport. [§71.41(a)]
- The package shall be designed, constructed, and prepared for shipment so there would be no loss or dispersal of contents, no significant increase in external surface radiation levels, and no substantial reduction in the effectiveness of the packaging under the tests specified in §71.71 for normal conditions of transport. [§71.43(f), §71.51(a)(1)]
- A package for fissile material shall be so designed and constructed and its contents so limited to meet the structural requirements of §71.55(d)(2) through §71.55(d)(4) under the tests specified in §71.71 for normal conditions of transport.
- The performance of the package shall be evaluated under the tests specified in §71.73 for hypothetical accident conditions. [§71.41(a)]
- The package design shall have adequate structural integrity to meet the internal pressure test requirement specified in §71.85(b).
2.3 Review Procedures

The following procedures are generally applicable to the review of the Structural Evaluation chapter of the SARP. These procedures correspond to the Areas of Review listed in Section 2.1 of this PRG.

2.3.1 Description of Structural Design

2.3.1.1 Structural Design Features Important to Safe Operation of the Package

Review the structural design features presented in the General Information and Structural Evaluation chapters of the SARP. Design features important to the safe operation of the package include:

- Components that provide structural integrity for heat transfer, containment, shielding, and subcriticality design features (e.g., impact limiters, containment vessels, neutron-absorber plates)
- Components that affect, or are affected by, the performance of structural components (e.g., lead shielding, lifting and tie-down devices, closures, and ports)
- Components that provide structural integrity to the contents (e.g., internal supporting structures).

Confirm that the discussion on structural design features includes the locations of these items on the SARP drawings. Information on structural design features should include, as appropriate:

- Location, dimensions, and tolerances
- Materials of construction and their specifications (See Section 2.3.2.1)
- Fabrication methods (See Section 2.3.3.1)
- Weights and centers of gravity of packaging and major subassemblies
- Maximum weight of contents (minimum weight, if appropriate)
- Maximum Normal Operating Pressure (MNOP)
- Description of closure systems
- Description of handling requirements.

Verify that the text and sketches describing the structural design features are consistent with the SARP drawings and the structural evaluations.

2.3.1.2 Codes and Standards Used for the Package Design

Confirm that the SARP identifies established structural design codes and standards applicable to the structural evaluation. Confirm that the codes and standards used to determine material properties, design limits, and methods of combining loads and stresses are identified. Confirm that the codes and standards are appropriate for the intended purpose and are properly applied.
The reviewer should verify that the code or standard:

- Was developed for structures of similar design and material, if not specifically for shipping packages
- Was developed for structures with similar loading conditions
- Was developed for structures that have similar consequences of failure
- Adequately addresses potential failure modes
- Adequately addresses margins of safety.

Several regulatory guides, NUREGs, structural design codes, and consensus standards documents provide guidance for package design. U.S. Nuclear Regulatory Commission (NRC) Regulatory Guide 7.8[2-2] identifies the load combinations to be used in package evaluations, and NRC Regulatory Guide 7.6[2-3] provides design criteria for containment systems. The criteria of Regulatory Guide 7.6 are based on the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel (B&PV) Code,[2-4] Section III, Division 1, Subsection NB. In addition, ASME has published a new code section (Section III, Division 3), which is specifically intended for transportation package containment. Although both Regulatory Guide 7.6 and ASME Section III, Division 3, specifically address the containment systems of spent-fuel (and high-level-waste packages), their guidance may also be applied to the containment systems of other Category I packages. NUREG/CR-4554, Volume 6[2-5] and NUREG/CR-6322[2-6] discuss the buckling evaluation of containment vessels and baskets, respectively. In addition, ANSI N14.6[2-7] and NUREG-0612[2-8] have been used for the design of packaging trunnions.

Other NUREGs provide useful guidance for package design because the code or standard for fabrication should be the same as that for design, operation, and maintenance unless justified otherwise (e.g., NUREG/CR-3854,[2-9] NUREG/CR-3019[2-10]).

Table 2.1 summarizes those sections of the ASME B&PV Code that are generally acceptable for Type B packages, based on the package category designations described in Table 1.1. Because the ASME Code (except for Section III, Division 3) was not developed for transportation packages, various articles may not be applicable and some Code requirements (e.g., pressure relief devices) may not be consistent with 10 CFR 71 requirements. The review should ensure that the SARP clearly identifies the provisions of the Code applicable to materials, fabrication, examination, and testing of the packaging and that excluded provisions are appropriately justified.
### Table 2.1 Sections of ASME B&PV Code Applicable to Type B Packages

<table>
<thead>
<tr>
<th>Component Function</th>
<th>Category I</th>
<th>Category II</th>
<th>Category III</th>
</tr>
</thead>
<tbody>
<tr>
<td>Containment</td>
<td>Section III, Division 1, Subsection NB or Section III, Division 3</td>
<td>Section III, Division 1, Subsection ND*</td>
<td>Section VIII, Division 1**</td>
</tr>
<tr>
<td>Criticality (structural support)</td>
<td>Section III, Division 1, Subsection NG (NF for Buckling)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shielding and Other Safety Features</td>
<td>Section VIII, Division 1 or Section III, Division 1, Subsection NF</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Category I criteria are also acceptable
** Category I and II criteria are also acceptable

### 2.3.2 Materials of Construction

Summary guidance for review of materials and fabrication is presented in Appendix C of this PRG.

#### 2.3.2.1 Material Specifications and Properties

As discussed in Section 1.3.3.1, an appropriate specification should be identified on the SARP drawings for the control of each material. Materials and their properties should be consistent with the design code or standard selected. In the ASME B&PV Code, material specifications are addressed in Section II, Parts A, B, and C.

Review the properties of the materials of construction. Verify that the materials of construction have been examined as required by the design code or selected standard. If no code or standard is available, the SARP should provide adequately documented material properties along with references and as appropriate, justify the quality assurance methods used to ensure that these properties are achieved. Coordinate with the Quality Assurance review as appropriate.

Verify that the material properties are appropriate for the load conditions (e.g., static, cyclic, or dynamic impact loading, hot or cold temperatures, wet or dry conditions, and any combination of them). Material properties (e.g., Young’s modulus, yield strength, etc.) can be dependent on temperature, straining-rate, etc. Confirm that appropriate temperatures at which allowable stress limits are defined are consistent with minimum and maximum service temperatures. Verify that the force-deformation properties for impact limiters are based on appropriate test conditions (e.g., strain rate and temperature). Ensure that materials are thermally stable for long-term exposure at elevated temperatures, as appropriate.

Verify that the materials of structural components have sufficient fracture toughness to preclude brittle fracture under normal conditions of transport and hypothetical accident conditions. Regulatory Guide 7.11[2-11] and Regulatory Guide 7.12[2-12] provide criteria for fracture toughness of ferritic steels. Brittle fracture is usually not a concern for austenitic steels unless fabrication processes increase their susceptibility to embrittlement. If the contents include or produce hydrogen gas, ensure that hydrogen embrittlement has been appropriately addressed.
Additional guidance on materials review is given in the NRC Interim Staff Guidance document on materials evaluation (i.e. spent nuclear fuel).[2-13]

2.3.2.2 **Prevention of Chemical, Galvanic, or Other Reactions**

Review the materials and coatings of the package to verify that they will not produce a significant chemical, galvanic, or other reaction among packaging components, among packaging contents, or between the packaging components and the package contents. The review should consider reactions resulting from inleakage of water, including wet loading of spent fuel or other contents. Evaluate the possible generation of hydrogen and other flammable or corrosive gases. A particular example is given in NRC Information Notice 96-34,[2-14] which discusses hydrogen generation that resulted from the reaction between acidic borated water and a zinc coating applied to the internal surfaces of a spent fuel storage cask.

Galvanic interactions and the formation of eutectics should be considered for metallic components that may come into physical contact with one another. Such interactions could occur with depleted uranium, plutonium, lead, or aluminum in contact with steel.

2.3.2.3 **Effects of Radiation on Materials**

Verify that the effects of radiation on the packaging materials have been appropriately considered. These effects include degradation of seals, sealing materials, coatings, adhesives, and structural materials.

Review of radiolysis, and of the associated production of hydrogen and other gases by radiation is discussed in Sections 3 and 4 of this PRG.

2.3.3 **Fabrication, Assembly, and Examination**

Summary guidance for review of fabrication, assembly, examination, and acceptance criteria is presented in Appendix C of this PRG.

2.3.3.1 **Fabrication and Assembly**

Paragraphs 71.31(c) and 71.37(a) of 10 CFR 71 specify that the application shall provide information on codes, standards, and the quality assurance program for fabrication and assembly. In terms of the ASME B&PV Code, these processes are referred to as fabrication and installation, and are generally addressed in the 2000- and 4000-series articles of Section III, with primary welding and brazing qualification requirements specified in Section IX. In SARP reviews, the term “fabrication” is often used to mean both fabrication and assembly (e.g., welding and brazing). As noted above, guidance on appropriate codes and standards is provided in NUREG/CR-3854[2-9] and NUREG/CR-3019.[2-10]

If fabrication and assembly specifications are prescribed by an appropriate code or standard (e.g., the ASME B&PV Code, American Welding Society [AWS] Structural Welding Codes), the code or standard shall be identified on the SARP drawings. Unless the SARP justifies otherwise, specifications of the same code or standard used for design should also be used for fabrication and assembly. For components for which no code or standard is applicable, the SARP shall completely identify the specifications on which the evaluation depends and thoroughly describe the method of control to assure that these specifications are achieved. This description shall
reference a quality assurance or other appropriate specifications document. Such specifications shall be included on the SARP drawings and separate fabrication specifications as appropriate. Appendix C of this PRG provides guidance on the development of specifications for emerging technology, state-of-the-art fabrication methods, such as additive manufacturing. As noted in Section 1.3.3.1 of this PRG, the SARP drawings are specified as conditions of approval in the Certificate of Compliance (CoC).

Verify that any effects due to assembly pre-loads and/or residual stresses from fabrication have been evaluated. These may be an important initial condition for the NCT structural evaluation.

2.3.3.2 Examination

Although the term “examination” is not specifically mentioned in 10 CFR 71, it is generally considered as part of the fabrication and assembly processes, or simply as part of fabrication. In the ASME B&PV Code, nondestructive examination (NDE) is addressed in the 5000-series articles of Section III, with additional details on nondestructive examination methods specified in Section V, Subsections A and B.

Examination addresses the methods and criteria by which the fabrication is determined to be acceptable. Unless the SARP justifies otherwise, specifications of the same code or standard used for fabrication should also be used for examination. For components for which no fabrication code or standard is applicable, the SARP shall summarize the examination methods and acceptance criteria in the Acceptance Tests and Maintenance Program chapter. As noted in Section 8 of this PRG, acceptance tests are generally included as conditions of approval in the CoC. Examination specifications shall also be provided on the SARP drawings and fabrication specifications as appropriate.

2.3.4 General Considerations for Structural Evaluations

Structural evaluations of the package design may be performed by analysis, test, or a combination of both methods. The evaluations shall demonstrate that the structural performance of the package meets the criteria discussed in Section 2.3.6 below for normal conditions of transport and in Section 2.3.7 for hypothetical accident conditions. Additional conditions for evaluation of the structural design are described in Sections 2.3.5 and 2.3.8. The review of these evaluations should verify that:

- The most unfavorable initial loading and environmental conditions have been addressed. See US NRC Regulatory Guide 7.8[2] for guidance on selection of initial conditions.
- The most unfavorable drop or loading orientations for the entire sequence of tests have been considered. The most unfavorable orientations for one component may not be the most unfavorable for another component.
- The evaluation methods are appropriate for the loading conditions considered and follow accepted practices and precepts.
- The results are interpreted correctly.
2.3.4.1 Evaluation by Test

If the package is evaluated by test, the review shall include the following:

- Verify that the test methods, procedures, equipment, and facilities are adequate. Detailed procedures should be described that conform to the requirements of the quality assurance program (QAP) described in the SARP Chapter 9. Confirm that the methods and instruments are sufficient for describing the structural response or damage. Both interior and exterior damage should be considered. UCRL-ID-121673[2-15] provides guidance for drop testing, including the use of reduced-scale models.

- Review the description of the target surface (e.g., material, mass, dimensions) used for the drop, crush, and puncture tests. Confirm that it represents an essentially unyielding surface. An example of such a surface is described in an International Atomic Energy Agency (IAEA) Guide,[2-16] but the determination that a surface is essentially unyielding depends on package-specific details.

- Review the description of the steel plate (e.g., material, mass, dimensions, orientation) used for the crush test, if applicable. Confirm that it meets the specifications of §71.73(c)(2).

- Review the description of the steel bar (e.g., material, dimensions, orientation, method of mounting) used for the puncture test. Confirm that it is securely attached to an essentially unyielding surface, has sufficient length to cause maximum damage to the package, and meets the other specifications of §71.73(c)(3).

- Verify that the test specimen has been fabricated using the same materials, methods, and quality assurance as specified in the package design. Any differences should be identified, and the effects evaluated in the SARP. The test specimen should include all components and design features (e.g., gap between containment and internals) that are expected to have significant effects on the test results. Substitutes for the contents and other simulated components should have the same weight, structural properties, and interaction with the packaging as the actual contents and components. If applicable, verify that the scale-model specimen is properly scaled, fabricated, and instrumented. Confirm that the SARP thoroughly explains the scaling rationale and justifies that size effects are not significant (e.g., material properties are not affected by size).

- Verify that the tests consider the orientations for which the most unfavorable damage is expected, and that the selection is justified. The SARP should address drops that (1) produce the highest g-loads on package components and (2) challenge the most vulnerable orientations and components of the package (e.g., bolts, closure rings, seals, valves, and ports). The first group of drops includes those with the package center of gravity (cg) located directly above the center of the impact area, such as end drops, side drops, and cg-over-corner drops. It also includes slap-downs, in which the cg is not directly over the impact area, as slap-down drops of a long package can produce a high g-load in the second impact. Drops in the second group will depend on the vulnerable package components and their failure modes. Components vulnerable to impact loads should generally be protected by special design features such as recessed construction, protective cover plates, and impact limiters. Ensure that the evaluation of most
unfavorable damage considers the thermal (fire) test and water immersion test (if applicable), which follow the drop, crush (if applicable), and puncture tests.

- Verify that the test addresses movement or damage of the contents as appropriate. For example, movement or damage of fuel rods or assemblies may impact the criticality evaluation.

- Verify that all test results are reported, evaluated and their implications interpreted. The test report shall include all significant interior and exterior damage of the test article and shall be documented as a QA record as described in Chapter 9. Unexpected or unexplainable test results indicating possible testing problems or non-reproducible specimen behavior shall be discussed and evaluated. If the package tested was not identical in all respects to the package design described in the SARP, the differences shall be identified, and a justification provided of why the differences will not affect the test results.

- Likewise, verify that the interpretation of the test results addresses differences between test conditions and regulatory conditions. For example, ambient temperature and decay heat may result in package temperatures and stresses during transportation that differ from those of the tested specimen.

- Review the videos and photos of the tests as appropriate.

- Verify that the test results are reliable and repeatable. Test results shall convincing show that any package fabricated in accordance with the approved design will meet regulatory requirements.

- Review the criteria for evaluating pass/fail for the test conditions. Compare the test results with these criteria. If acceptance tests are performed after the structural testing, the acceptance tests should be performed according to appropriate codes and standards.

- Verify that the testing demonstrates an adequate margin-of-safety.

2.3.4.2 Evaluation by Analysis

If the package is evaluated by analysis, the review should include the following:

- Verify that the SARP clearly describes the software, analysis methods, models, and results, including all assumptions and input data. (See RG 7.6 for guidance on design criteria for analysis.)

- Verify that the models and material properties are appropriate for the load combinations considered. Ensure that the material properties and the material models for non-linear behavior (e.g., elastic, plastic) are consistent with the analysis methods and loading conditions. The SARP should justify the strain rate at which the properties were determined. Confirm that the analysis considers true stress-strain or engineering stress-strain, as applicable.

- Verify that the applied boundary conditions in the analysis model are appropriate. For free-drop impact analyses, impact loads for package components are usually derived from the dynamic analyses of the package and used in a quasi-static stress analysis of the component. Confirm that a dynamic amplification factor has been appropriately applied.
to account for vibration and other dynamic effects. A summary of quasi-static and dynamic analysis methods for impact analysis is provided in NUREG/CR-3966.[2-17]

- Verify that the analysis evaluates the most unfavorable orientations, and that the selection is justified. Ensure that the evaluation of most unfavorable damage considers the entire sequence of tests.
- Verify that the analysis evaluates the effect of the test conditions on the contents as appropriate. (See Section 2.3.4.1.)
- Verify that the computer codes, if applicable, are properly used, benchmarked, and maintained under an appropriate quality assurance program. Verify that the computer codes and models (e.g., finite element analysis code) are adequate to produce results of sufficient accuracy and fidelity. At least one representative input and output file (or key section of the file) should generally be included in the SARP. Appendix D of this PRG provides guidance on the recommended documentation to establish the pedigree of the software and analysis methods used.
- Verify that the response of the package to loads, in terms of stress and strain to components and structural members, is shown and that the structural stability of individual members, as applicable, is evaluated.
- Verify that the results are correctly interpreted and demonstrate adequate margin of safety. The maximum stresses or strains should be compared to corresponding design-code allowable criteria.

2.3.5 Structural Evaluation of Lifting and Tie-Down Devices

2.3.5.1 Structural Performance of Lifting Devices
Review the design and evaluation of lifting devices that are a structural part of the package, their connection to the package body, and the package body in the local area around the lifting devices. Verify that the evaluation demonstrates these devices comply with the requirements of §71.45(a), including failure under excessive load.

2.3.5.2 Structural Performance of Tie-Down Devices
Review the design and evaluation of tie-down devices that are a structural part of the package, their connection to the package body, and the package body in the local area around the tie-down devices. Verify that the evaluation demonstrates that these devices comply with the requirements of §71.45(b), including failure under excessive load.

2.3.5.3 Evaluation of Lifting and Tie-Down Devices
Details of the hand calculations or computer evaluations of the lifting and tie-down devices should be included in a Chapter 2 appendix.

2.3.6 Structural Evaluation for Normal Conditions of Transport
The evaluation of the package under the normal conditions of transport is based on the effects of the tests and conditions specified in §71.71. These tests serve as an important initial condition for the follow-on Hypothetical Accident Condition tests. These tests shall not result in a significant decrease in package effectiveness. For example, these tests should result in:
• No significant decrease in the effectiveness of packaging components that provide heat transfer or insulation. Coordinate with the Thermal review.

• No significant decrease in the effectiveness of packaging components that provide containment, including no loss or dispersal of contents or release of radioactive material exceeding the requirements of §71.51(a)(1), as applicable. Coordinate with the Containment review.

• No significant decrease in the effectiveness of packaging components that provide shielding, including no increase in radiation levels exceeding the requirements of §71.47 or §71.51(a)(1). Coordinate with the Shielding review.

• No significant decrease in the effectiveness of packaging components that provide criticality control, including no change exceeding the requirements of §71.55(d). (See Section 2.3.6.11.) Coordinate with the Criticality review.

• No change to the contents that significantly affects heat transfer, containment, shielding, or criticality.

• No change to the packaging or contents that affects their performance under the tests for hypothetical accident conditions discussed in the next section.

The ambient air temperature before and after the tests shall remain constant at that value between -29°C (-20°F) and +38°C (100°F) which is most unfavorable for the feature under consideration. The initial internal pressure in the containment vessel shall be considered to be the Maximum Normal Operating Pressure (MNOP) unless a lower internal pressure consistent with the selected ambient temperature is less favorable.

2.3.6.1 Heat
Verify that the evaluation for the heat condition is adequate. Confirm that the maximum temperatures used for this evaluation are consistent with the Thermal Evaluation chapter of the SARP. The evaluations should consider the maximum normal operating pressure in combination with the maximum internal heat load and any residual fabrication stresses.

Verify that any differential thermal expansions and possible geometric interferences have been considered.

Verify that the stresses are within the limits for normal condition loads.

2.3.6.2 Cold
Verify that the evaluation for the cold condition is adequate. Confirm that the temperatures used for this evaluation are consistent with the Thermal Evaluation chapter of the SARP. The evaluations should consider the minimum internal pressure with the minimum internal heat load and any residual fabrication stresses. The minimum decay heat should be zero unless the SARP provides a minimum heat load as a condition of package approval.

Verify that differential thermal expansions which could result in possible geometric interferences have been considered. Confirm that possible freezing of liquids and brittle fracture of materials have been considered.
Verify that the stresses are within the limits for normal condition loads.

2.3.6.3 Reduced External Pressure
Ensure that the SARP adequately evaluates the package design for the effects of reduced external pressure equal to 25 kPa (3.5 psi) absolute. Verify that the SARP considers the greatest possible pressure difference between the inside and outside of the package as well as between the inside and outside of the containment system.

2.3.6.4 Increased External Pressure
Determine that the SARP adequately evaluates the package design for the effects of increased external pressure equal to 140 kPa (20 psi) absolute. Verify that the SARP considers this loading condition in combination with minimum internal pressure. Confirm that the SARP considers the greatest possible pressure difference between the inside and outside of the package as well as between the inside and outside of the containment system. Ensure that the SARP has considered the possibility of buckling (see NUREG/CR-4554, Vol. 6).[2-5]

2.3.6.5 Vibration
Determine that the SARP adequately evaluates the package design for the effects of vibration incident to transport. A fatigue analysis should be provided for highly stressed systems and systems exhibiting significant vibration response (e.g., spent nuclear fuel baskets). The combined stresses due to vibration, temperature changes, and pressure loads should be considered. If closure bolts are reused, verify that the bolt preload is included in the fatigue evaluation. NUREG/CR-6007[2-18] provides guidance on bolt evaluation. Verify that a resonant vibration condition, which can cause rapid fatigue damage, is not present in any packaging component. The effect on package internals should be considered. Additional guidance for vibration evaluation is provided in NUREG/CR-2146[2-19] and NUREG/CR-0128.[2-20]

2.3.6.6 Water Spray
Review the package design for the effects of the water spray test. Verify that this test has no significant effect on material properties.

2.3.6.7 Free Drop
Review the package design for the effects of the free drop test.

Review the evaluation of the closure lid bolt design for the combined effects of free drop impact force, internal pressures, thermal stress, O-ring compression force, and bolt preload. Bolt evaluation methods are presented in NUREG/CR-6007.[2-18]

Review the evaluation of other package components, such as port covers, port cover plates, and shield enclosures, for the combined effects of package drop impact force, internal pressures, and thermal stress.

2.3.6.8 Corner Drop
Review the package design for the effects of the corner drop test, if applicable.
2.3.6.9 Compression
Review the package design for the effects of the compression test, if applicable.

2.3.6.10 Penetration
Review the evaluation of the package for the penetration test. Verify that the SARP considers the most vulnerable package location.

2.3.6.11 Structural Requirements for Fissile Material Packages
The SARP should demonstrate that there will be no reduction in effectiveness of the packaging, including:

- The geometric form of the contents is not substantially altered
- The containment system precludes inleakage of water, unless such inleakage has been assumed in the criticality analysis of arrays under normal conditions of transport as specified in §71.59(a)(1)
- The total effective packaging volume on which nuclear criticality safety is assessed is not reduced by more than 5%
- The effective spacing between fissile contents and the outer surface of the packaging is not reduced by more than 5%
- No occurrence of an aperture in the outer surface of the packaging is large enough to permit the entry of a 10-cm (4-in.) cube.

Coordinate with the Criticality review as appropriate.

2.3.6.12 Structural Requirements for Special Form Contents
If “special form” content is specified in the SARP verify that it satisfies all following:

- It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule,
- The piece or capsule has at least one dimension not less than 5 mm (0.2 in), and
- Satisfies the test requirements of §71.75.

2.3.7 Structural Evaluation for Hypothetical Accident Conditions
The evaluation under hypothetical accident conditions shall be based on sequential application of the tests specified in §71.73, in the order indicated, to determine their cumulative effect on a package. The evaluation of the ability of a package to withstand any one test shall consider the damage resulting from the preceding tests. In addition, as stated in Section 2.3.6, the tests under normal conditions of transport shall not affect the package’s ability to withstand the hypothetical accident condition tests.

Verify that the SARP has properly determined the effects of the hypothetical accident condition tests on both the packaging and its contents. The most unfavorable effects of these tests should
be identified for evaluation in the Thermal, Containment, Shielding, and Criticality Evaluation chapters of the SARP. Ensure that the SARP has addressed the effects of the tests on the:

- Components required for heat transfer or insulation
- Components of the containment system (plastic deformation of the containment closure region is generally unacceptable)
- Shielding components
- Components required for subcriticality
- Displacement, deformation, and geometry of the contents.

Coordinate with the Thermal, Containment, Shielding, and Criticality reviews as appropriate.

With respect to the initial conditions for the tests (except for the water immersion tests), the ambient air temperature before and after the tests shall remain constant at that value between -29°C (-20°F) and +38°C (100°F) which is most unfavorable for the feature under consideration. The initial internal pressure within the containment system shall be the maximum normal operating pressure unless a lower internal pressure consistent with the selected ambient temperature is less favorable.

2.3.7.1 **Free Drop**
Review the evaluation of the free drop test. Verify that structural evaluation has addressed the most unfavorable drop orientation, including cg-over-corner, oblique orientation with secondary impact (slap down), side drop, and drop onto the closure systems. Determination of the most unfavorable orientation shall consider the entire sequence of tests, and the most unfavorable orientation might not be the same for all components. If a feature such as a tie-down component is a structural part of the package, it should be addressed in the evaluation.

For a package with lead shielding, the effects of lead slump should be evaluated. The lead slump determined should be consistent with that used in the shielding evaluation. Lead slump is discussed in NUREG/CR-4554, Volume 3.[2-21]

2.3.7.2 **Crush**
Review the evaluation of the package for the dynamic crush test, if applicable. Verify that the choice of the most unfavorable orientation has been justified.

2.3.7.3 **Puncture**
Review the evaluation of the package for the puncture test. Verify that the most unfavorable orientation has been identified and justified. Any damage resulting from the free drop and crush tests shall be included in the evaluation. Ensure that punctures at oblique angles, near a support, at a valve, and at a penetration or protrusion have been considered, as appropriate. Ensure that any possible prying action on package closure regions has been evaluated. Confirm that the puncture test does not result in peripheral damage that could jeopardize the package during the subsequent thermal and water-immersion tests (e.g., loss of package lid which could result in melting of seals in fire).
Although analytical methods are available for predicting puncture, empirical formulas derived from puncture test results of laminated panels are usually used for design of packages. The Nelm’s formula, developed specifically for package design, provides the minimum thickness needed for preventing the puncture of the steel surface layer of a typical steel-lead-steel laminated cask wall. A description of methods for puncture evaluation is provided in NUREG/CR-4554, Volume 7.[2-22] Additional considerations for puncture testing are identified in NRC Bulletin 97-02.[2-23]

2.3.7.4 Thermal
Coordinate with the Thermal review to verify that the structural design is evaluated for the effects of a fully engulfing fire, as specified in §71.73(c)(4). Any damage resulting from the free drop, crush, and puncture conditions shall be incorporated into the initial condition of the package for the fire test. Determination of the maximum pressure in the package during or after the test should consider the temperatures resulting from the fire and any increase in gas inventory caused by combustion or decomposition processes. Verify that the maximum thermal stresses, which can occur either during or after the fire, are properly evaluated and are consistent with the Thermal Evaluation chapter of the SARP.

2.3.7.5 Immersion—Fissile Material
If the contents include fissile material subject to the requirements of §71.55, and if water inleakage has not been assumed for the criticality analysis, review the evaluation of the test of a damaged specimen immersed under a head of water of at least 0.9 m (3 ft.) in the attitude for which maximum leakage is expected.

2.3.7.6 Immersion—All Packages
Review the evaluation of a separate, undamaged specimen subjected to water pressure equivalent to immersion under a head of water of at least 15 m (50 ft.). For test purposes, an external pressure of 150 kPa (21.7 psi) gauge is considered to meet these conditions.

2.3.8 Structural Evaluation of Special Pressure Conditions
2.3.8.1 Special Requirement for Type B Packages Containing More Than $10^5 A_2$
Verify that Type B packages containing more than $10^5 A_2$ with an activity greater than $10^5 A_2$ are appropriately evaluated to demonstrate that their containment system can withstand an external water pressure of 2 MPa (290 psi) for a period of at least one hour without collapse, buckling, or inleakage of water. This pressure should be applied directly to the containment system, and no structural support from other package components should be considered.[2-24] Ensure that the stresses in the vicinity of the closure regions do not result in permanent deformation.

2.3.8.2 Analysis of Pressure Test
As required by §71.85(b), prior to first use of each packaging with a maximum normal operating pressure exceeding 35 kPa (5 psi) gauge, the containment system shall be pressure tested at 150% of its maximum normal operating pressure. A similar test (125% of the design pressure) is prescribed by Section III of the B&PV Code. If such tests are applicable, confirm that analysis in the SARP demonstrates that they can be performed safely.
2.3.9 Appendices
Confirm that the appendices include a description of test facilities, test conditions, test results, list of references, and copies of applicable references if not generally available to the reviewer. Also, a description of all structural analyses included in the body of chapter, including computer code descriptions, input and output files, analyses results, and other appropriate supplemental information (e.g. derivations of formulae used in the structural evaluation if no reference is provided). For recommendations on the documentation of the QA of analyses, software pedigree, and models, see Appendix D of this PRG. The appendices should also include specifications of materials and manufacturing methods for items that are significant with respect to safety but are not produced to generally recognized standards (See Appendix C of this PRG for recommendations on the development of specifications).

2.4 Evaluation Findings
2.4.1 Findings
The review should ensure that the information presented supports a conclusion that the regulatory requirements in Section 2.2 above are satisfied.

The Technical Review Report (TRR) should include a conclusion similar to the following:

Based on review of the statements and representations in the SARP, the staff concludes that the structural design has been adequately described and evaluated and that the package design meets the structural requirements of 10 CFR 71.

2.4.2 Conditions of Approval
The TRR should clearly identify any conditions of approval that should be included in the Certificate of Compliance (CoC). In addition to specifications of authorized contents and information specified on the SARP drawings, conditions of approval typically applicable to the Structural Evaluation chapter of the SARP include:

- Maximum weight of the package (if not indicated on drawings), minimum weight, if applicable.
- Maximum weight of the contents, including shoring, packing materials, and other components not defined as part of the packaging (if not indicated on drawings), minimum weight, if applicable.
2.5 References


3.0 THERMAL REVIEW

The Thermal Review verifies that the thermal performance of the package design has been demonstrated to satisfy the thermal requirements in 10 CFR 71,[3-1] and has been adequately evaluated by tests and/or analyses when subject to normal conditions of transport (NCT) and hypothetical accident conditions (HAC).

The Thermal review is mainly based on information in the Thermal Evaluation chapter in addition to the descriptions and evaluations presented in the General Information and Structural Evaluation chapters of the Safety Analysis Review for Package (SARP). Similarly, the results of the Thermal Evaluation, such as temperature, pressure, material properties, thermal deformation are relevant to the Structural and Containment Evaluations as well as the reviews of subsequent chapters of the SARP. An example of information flow for the Thermal review is shown in Figure 3.1.

Although 10 CFR 71 specifies only a few explicit thermal requirements for packages (e.g., maximum allowable surface temperature, and thermal performance of the package under NCT and HAC), the combined structural/thermal performance of the package should be evaluated to confirm that the package performance under NCT and HAC has an adequate safety margin to meet the regulatory requirements related to containment, shielding, and subcriticality. Consequently, the review of the Thermal Evaluation focuses on confirming the SARP evaluation of the effects of the thermal tests and/or analyses, and on coordinating the results of the Thermal Evaluation with the Structural Evaluation, Containment Evaluation, Shielding Evaluation, and Criticality Evaluation.

3.1 Areas of Review

The description and evaluation of the package thermal design should be reviewed. The Thermal review should include the following:

3.1.1 Description of Thermal Design

- Design Features and Dimensions
- Maximum Decay Heat of Contents, and Contents configuration
- Codes and Standards for package design, fabrication, assembly, testing, maintenance, and use
- Summary Tables of Component Temperatures
- Summary Table of Maximum Pressures
- Maximum Normal Operating Pressure

3.1.2 Material Properties, Thermal Limits, and Component Specifications

- Material Properties, including temperature-dependent behavior
- Material Temperature Limits associated with Codes and Standards, and/or specifications
- Component Specifications
3.1.3 General Considerations for Thermal Evaluations

- Evaluation by Tests
- Evaluation by Analyses

![Diagram of Thermal Review]

Figure 3.1 Example of Information Flow for the Thermal Review
3.1.4 Thermal Evaluation under Normal Conditions of Transport
- Initial Conditions
- Effects of Test Conditions
- Assumptions Used for Testing and Analyzing
- Identify Convection and Radiation Formulas Used for Modeling
- Maximum and Minimum Temperatures
- Maximum Normal Operating Pressure
- Maximum Thermal Stresses and Thermal Deformation

3.1.5 Thermal Evaluation under Hypothetical Accident Conditions
- Initial Conditions
- Effects of Thermal Test Conditions
- Assumptions Used for Testing and Analyzing
- Identify Convection and Radiation Formulas Used for Modeling
- Maximum Temperatures and Pressures
- Maximum Thermal Stresses

3.1.6 Thermal Evaluation of Maximum Accessible Surface Temperature
- Decay Heat and boundary conditions

3.1.7 Appendices
- Description of Test Facilities and Equipment
- Test Results
- Applicable Supporting Documents or Specifications
- Details of Analyses
- Pedigree of Thermal Analyses Models and Software, including software quality assurance plans, as applicable

3.2 Regulatory Requirements
Regulatory requirements of 10 CFR 71 applicable to the thermal evaluation are as follows:

- The package (packaging and associated contents) design shall be described and evaluated to demonstrate that it satisfies the thermal requirements of 10 CFR 71. [§ 71.33, § 71.35]
- The application shall identify the established codes and standards used for the package design, fabrication, assembly, testing, maintenance, and use. In the absence of such codes, the application shall describe the basis and rationale used to formulate the quality assurance program. [§ 71.31(c)]
• The package shall be made of materials of construction that assure there will be no significant chemical, galvanic, or other reactions, including reactions due to possible inleakage of water, among the packaging components, among package contents, or between the packaging components and the package. The effects of radiation on the materials of construction shall be considered. [§71.43(d)]

• The package shall be designed, constructed, and prepared for transport so that in still air at 38°C (100°F) and in the shade, the accessible surface temperature does not exceed 50°C (122°F) in a nonexclusive-use shipment or 85°C (185°F) in an exclusive-use shipment. [§71.43(g)]

• The package design shall not rely on filters or mechanical cooling systems to meet Type B containment requirements. [§71.51(c)]

• A fissile material packaging design to be transported by air shall meet the 60 minutes fire HAC requirements of §71.55(f)(iv).

• The performance of the package shall be evaluated under the heat and cold tests specified in §71.71(c) for normal conditions of transport of Type B packages. [§71.41(a)]

• The package shall be designed, constructed, and prepared for shipment, so there would be no loss or dispersal of contents, no significant increase in external surface radiation levels, and no substantial reduction in the effectiveness of the packaging under the tests specified in §71.71 for normal conditions of transport. [§71.43(f), §71.51(a)(1)]

• The performance of the package shall be evaluated under the tests specified in §71.71 for normal conditions of transport and §71.73 for hypothetical accident conditions. [§71.41(a)]

• Maximum normal operating pressure developed in the containment system in a period of 1 year under the heat condition specified in §71.71(c)(1) shall be evaluated

3.3 Review Procedures
The following procedures are generally applicable to the review of the Thermal Evaluation chapter of the SARP. These procedures correspond to the Areas of Review listed in Section 3.1 of this PRG.

3.3.1 Description of Thermal Design
3.3.1.1 Design Features
Review the thermal design features presented in the General Information and Thermal Evaluation chapters of the SARP, including:

• Structural and physical means for the transfer of heat (e.g., size of solid transfer mediums, type of fill gas, internal supporting structures, contact condition between components and surface conditions of the packaging components, coolant receptacles, type and volume of coolants, cooling fins if coolant system is equipped)

• Insulating features, including gaps, and insulating materials

• Configuration and distribution of the contents within packaging
- Maximum decay heat
- Maximum pressure of sealed sources, if applicable

Information on thermal design features should include location, dimensions, tolerances, materials, and other data as appropriate.

Confirm that the text and sketches describing the thermal design features are consistent with the SARP drawings.

3.3.1.2 Decay Heat of Contents
Verify that the maximum decay heat is consistent with that described in the General Information chapter of the SARP, with the radioactivity of the contents, and with the source terms used in the Shielding Evaluation chapter. Coordinate as appropriate with the Shielding review. If there is more than one contents, the content that has the maximum decay heat or one that has most unfavorable thermal load should be considered.

3.3.1.3 Codes and Standards
Verify that any codes or standards applicable to the thermal design of the package are identified and appropriate, including those for material specifications from manufacturers. If materials used do not have specifications in applicable consensus codes and standards, applicant-developed specifications should be included in an appendix. Ensure that such codes and standards are consistent with those specified in the General Information and Structural Evaluation chapters of the SARP. Make sure if these codes or standards specify temperature limits for component’s materials.

3.3.1.4 Summary Tables of Temperatures
Review the tables that summarize the maximum temperatures of all major components affecting structural integrity, thermal performance, containment, shielding, and criticality. As a minimum, these tables should include:

- The maximum temperatures of components under normal conditions of transport under the insolation (Sun)
- The maximum temperatures of components under hypothetical accident conditions, and post-fire cool down period
- The maximum temperatures of accessible surfaces under normal conditions of transport in shade.

Confirm that these temperatures are consistent with those of the General Information, Structural Evaluation, and Containment chapters.

The initial component temperatures for cold tests will be -40°C (-40°F) (See Section 3.3.2.2 for details).
3.3.1.5 Summary Table of Maximum Pressures

Verify that a summary table includes the Maximum Normal Operating Pressure (MNOP) and the maximum pressure in the containment system(s) during hypothetical fire accident and cool-down events. Determine if other confined volumes of the package, other than containment, are subject to maximum pressure limitations (e.g., outer shell, neutron shielding system, contents) in the NCT and HAC conditions and if such limitations exist they should be included in the table as appropriate. Confirm that these pressures are consistent with those in the General Information, Structural Evaluation, and Containment chapters.

3.3.2 Material Properties, Temperature Limits, and Component Specifications

3.3.2.1 Material Properties

Verify that material thermal properties as a function of temperature are specified for components that affect heat transfer between packaging components such as gaps, and between the package and the environment, pressures developed in the package, and thermal stresses. The temperature range for which the materials properties of the packaging components are specified should be consistent with the NCT and HAC conditions. If a property is treated as temperature independent, ensure that its value is conservative compared with a temperature-dependent specification. Note that a material thermal property value that produces a conservative result under NCT may not necessarily give a conservative result under HAC. Generally, material properties should be referenced from primary reference sources. If the applicant determines thermal properties experimentally, the experiments shall be conducted under a 10 CFR 71, Subpart H quality assurance program, or a quality assurance program approved by the Design Authority.

Material properties of a package (packaging and contents) for the thermal evaluation includes density, thermal conductivity, specific heat, surface emissivity, and absorptivity. For radiation heat transfer, confirm that the absorptivities and emissivities are appropriate for the packaging surface conditions, geometries, and type of material for both NCT and HAC. If the SARP justifies an absorptivity less than unity for insolation on external packaging surfaces, ensure that controls and procedures are in place to maintain these surface conditions during service life. Coordinate with the Package Operations review as applicable. For convection heat transfer, confirm that the package orientation and the correlations used in the analysis are appropriate for the intended package applications.

Material properties that may affect the thermal pressures or thermal stresses of a package include: the coefficient of thermal expansion, modulus of elasticity, Poisson’s ratio, gas masses, water content, and free volumes. Verify that the material properties used in the thermal analyses are consistent with those in the Structural Evaluation chapter.

If materials are expected to have any chemical or physical changes (e.g., phase change, decomposition, dehydration, or combustion) under NCT and/or HAC, verify that the temperature thresholds and temperature dependencies (over the range of operating temperatures) are presented along with corresponding material thermal property changes (e.g., conductivity, specific heat, density, and glass transition temperature).
3.3.2.2 Temperature Limits

Confirm that the maximum allowable temperatures are specified for each package component, as appropriate. If applicable, ensure that the SARP distinguishes between long-term and short-term temperature limits.

For spent fuel, the SARP should provide the allowable fuel/cladding temperatures. This supporting information should include: the type of fuel/cladding materials, cooling time, irradiation conditions, storage/transport environment (including the package fill gas), temperature history of the fuel since removal from the reactor and intended post-transport storage or disposition. Additionally, the materials and temperature limits for components, such as spent fuel baskets and criticality control features should be provided. Temperature limits should address the issues of creep, creep rupture, diffusion controlled cavity growth, eutectic melting, and other conditions as appropriate.

The minimum temperature of all packaging components will generally be that of the ambient environment, and the minimum allowable temperatures should not be below -40°C (-40°F) and in shade §71.71(c)(2) and -29°C (-20°F) for the initial thermal conditions as in NCT §71.71 and HAC §71.73.

Ensure that the maximum and minimum temperatures listed in the summary tables are within the allowable component and material temperature limits.

3.3.2.3 Component Specifications

Ensure that thermal and pressure information and manufacture specifications are provided for commercial components (e.g., pressure relief valves, fusible plugs, valves, seals), as appropriate. Confirm the thermal and pressure limits are not exceeded. Verify that specification limits (e.g., rupture pressure) are included on the SARP drawings.

3.3.3 General Considerations for Thermal Evaluations

Thermal evaluations of the package design can be performed by analysis, test, or a combination of both methods. The evaluations should demonstrate that the thermal performance of the package meets the criteria discussed in Section 3.3.4 for normal conditions of transport and Section 3.3.5 for hypothetical accident conditions. The review of these evaluations should verify that:

- The most unfavorable combinations of initial thermal and structure conditions are given in NRC Regulatory Guide 7.8. Note that the thermal evaluations should consider an undamaged package for NCT and a damaged package after the HAC tests §71.73, as appropriate. Coordinate with the Structural review to identify post-HAC package condition.
- The most unfavorable orientations have been considered. The most unfavorable orientation for one component may not be the most unfavorable orientation for another component.
- All regulatory test requirements have been included in the evaluation.
- Assumptions are appropriate and reasonable for the thermal evaluations.
• The evaluation methods are appropriate for the thermal conditions considered and follow accepted practices.
• The time interval after the fire test is adequate to assure that maximum component temperatures have been determined.
• The results are interpreted correctly.
• The thermal evaluations appropriately address pass/fail criteria governed by the regulatory requirements and the sufficient safety margins for component temperatures, pressures, and thermal stresses. Verify that these discussions include the effects of uncertainties in thermal properties, geometry, shape, dimensions, and surface conditions. The discussion should also include the uncertainty in numerical modeling, analytical methods, test conditions, and diagnostic equipment, as appropriate.

3.3.3.1 Evaluation by Test
If the package is evaluated by test, the review should include the following:

• Personnel conducting tests, test equipment, and/or test procedures, shall be qualified as per the quality assurance program implemented by the applicant’s design authority.
• Verify that the test facility and instrumentation are adequately described and that the test methods and equipment are sufficiently accurate for determining the thermal performance of the package. Also verify whether the equipment has to be calibrated before and after the test and consider if there are differences between the conditions of the test and calibration. Section 3.3.7.1 below provides more detailed information about the test facility.
• Verify that the test procedures, test conditions, and test results are adequately documented. Section 3.3.7.2 provides a list of details on test documentation.
• Verify that the test specimen has been fabricated using the materials, methods, and quality control specified for the package design (see SARP drawings). Any differences should be identified, and the effects evaluated in the SARP. The test specimen should include all components that could affect the test results. Substitutes for the contents or other simulated components should have similar weight, thermal properties, and equivalent interaction with other packaging components as the actual contents or components. Thermal testing of reduced-scale packages should generally be avoided. If scale models are used, the SARP should justify that the evaluation is applicable to the actual package design.
• Verify that decay heat of the contents is properly addressed in the tests as well as included in post-test analysis.
• Verify that all test results are reviewed and evaluated, and their implications correctly interpreted. Unexpected or unexplainable test results indicating possible testing problems or non-reproducible thermal performance should be described and evaluated.
• If a furnace is used, verify that the description of the furnace includes the volume and emissivity of the furnace interior as well as the method of measuring the interior...
temperature. The oxygen concentration in a furnace should be consistent with that of a hydrocarbon fire.

- Verify that the interpretation of the test results addresses and evaluates the differences between test conditions and regulatory conditions. Such test results should be extended to the regulatory conditions by detailed analysis.
- Verify that the effect of the content decay heat is included in the tests. If the content decay heat is simulated in the tests, the temperature distribution of a simulated content should be compared and evaluated relative to the actual content.
- Review the video and photographs of the tests as appropriate.
- Verify that the test results are reliable and accurate, and the methodology is repeatable. Test results should convincingly show that any package fabricated in accordance with the approved design will meet regulatory requirements.
- Review the criteria for evaluating pass/fail for the test conditions. Compare the test results with these criteria. If acceptance tests are performed after the thermal testing, the acceptance tests should be performed according to appropriate codes and standards.

Additional guidance on thermal testing of packages is provided in *A Guide for Thermal Testing Transport Packages for Radioactive Material—Hypothetical Accident Conditions*.[3-2] Additional guidance for conducting the test using a furnace can be found in *Fire and Furnace Testing of Transportation Packages for Radioactive Materials: Facilities and Measurements*[3-3], and *Thermal Testing of Type B Packages in Furnaces per ASTM Standard Practice E 2230*[3-4].

### 3.3.3.2 Evaluation by Analysis

If the package is evaluated by analyses, the review should include the following:

- Verify that the SARP clearly describes the analysis methods and models, and that they are appropriate for the thermal conditions considered.
- Verify that the analysis methods, models, and software have been qualified in accordance with a risk-based program as described in the SARP Chapter 9 Quality Assurance (see Appendix D of this PRG for more details).
- Verify that the initial and boundary conditions are appropriate.
- Verify that all assumptions, including those in modeling heat sources and heat transfer paths, heat transfer modes, resistance at thermal contacts, and emissivity values between gaps are clearly stated and justified.
- Verify that appropriate equations and/or correlations are used for conductive, convective, and radiative heat transfer between the package and the environment. Verify that the coefficients derived from the equations and/or correlations are appropriate.
- Verify that appropriate thermal properties for the package materials are correctly incorporated into the analysis.
- Verify that the computer codes, if applicable, are properly used, benchmarked, and maintained under an appropriate quality assurance program. At least one representative
input and output file (or key section of the file) should generally be included in the SARP Chapter 3 appendices.

- Verify that the results are correctly interpreted and demonstrate adequate margin of safety based on uncertainties and assumptions of the analyses.
- Review that the criteria for pass/fail acceptance criteria are appropriate for the thermal analyses. Evaluate these results against the criteria. The maximum temperatures should be less than the allowable values from design or manufacturer specifications.

### 3.3.4 Thermal Evaluation under Normal Conditions of Transport

The package shall be evaluated for the effects of the tests in §71.71 on the thermal performance of the package.

#### 3.3.4.1 Initial Conditions

The initial ambient temperature for the tests under normal conditions of transport shall be between -29°C (-20°F) and 38°C (100°F), whichever is most unfavorable for the feature(s) under consideration. The initial pressure in the containment system shall be considered to be the Maximum Normal Operating Pressure (MNOP) unless a lower internal pressure consistent with the ambient temperature is more unfavorable. Note that the determination of MNOP shall assume that the package is subjected to the insolation specified in §71.71(c)(1).

For cold ambient temperature as specified in §71.71(c)(2), the effects of low temperature on the package shall be considered at -40°C (-40°F) in still air and shade (no insolation).

#### 3.3.4.2 Effects of Normal Condition Tests (NCT)

Confirm that the thermal evaluation demonstrates that the tests for NCT do not result in significant reduction in package effectiveness, including:

- Significant degradation of the heat-transfer capability (e.g., creation of new gaps between components) or significant degradation of insulating capability.
- Changes in material properties (e.g., expansion, contraction, thermal stresses, gas generation, and chemical, galvanic, or other reactions) that significantly affect the structural performance of the package. Coordinate with the Structural review.
- Changes in the packaging or contents that significantly affect containment, shielding, or criticality (e.g., thermal decomposition or phase changes of materials). Coordinate with the Containment, Shielding, and Criticality review as appropriate.

#### 3.3.4.3 Maximum and Minimum Temperatures

Verify that the maximum and minimum temperatures of package components under NCT are properly evaluated and are consistent with those presented in the summary tables discussed in Section 3.3.1.4 above.

#### 3.3.4.4 Maximum Normal Operating Pressure (MNOP)

Verify that the Maximum Normal Operating Pressure (MNOP) is properly evaluated and is consistent with the summary table in Section 3.3.1.5. MNOP is the maximum gauge pressure that
would develop in the containment system in a period of one year under the heat condition specified in §71.71(c)(1), in the absence of venting, external cooling by an ancillary system, or operational controls. The evaluation should include the effects of local distributed temperatures and total gas inventory within the containment system. Ensure that the evaluation considers all possible sources of gases within any confined volume, such as:

- Package back-fill gas
- Saturated vapor, including water vapor from the contents or packaging
- Helium from the radioactive decay of the contents
- Fill gas and fission product gas from spent fuel rods, including a justification for the leakage assumed (see guidance in NUREG/CR-6487, *Containment Analysis for Type B Packages Used to Transport Various Contents* [3-5])
- Hydrogen or other gases resulting from thermal or radiolytic decomposition of materials (e.g., water, plastics), or other reactions, as appropriate.

Ensure that the determination of the Maximum Normal Operation Pressure (MNOP) including any generation of flammable gases. Confirm that the SARP demonstrates that any combustible gases generated in the package during a period of one-year do not constitute a safety issue. Gas generation, including flammable gas generation, can occur due to radiolysis, thermal degradation, as well as chemical reactions. Confirm that these evaluations do not include credit for getters, catalysts, or other recombination devices. However, credit may be taken for diffusion and leakage to evaluate the combustible gas release rate versus the combustible gas generation rate.

Ensure that for contents other than Transuranic (TRU) waste, inerting is not used to limit the concentration of flammable gasses. However, if inerting is proposed, at a minimum ensure that the applicant has:

- Demonstrated the inerting process will prevent the development of flammable gas mixtures in any confined area of the package throughout the entire shipment period
- Provide a detailed evaluation or analysis to demonstrate that there are no flammable gas mixtures (considering the worst case concentration of hydrogen or any other flammable gas, and oxygen) during shipment
- Provide a detailed configuration of all passages to ensure that the inerting gas could be introduced effectively (e.g., injection path, port orientation) to the innermost packaging or other confined areas within the containment system of the package
- Demonstrate that the inerting gas either effectively occupies the containment cavity or is in uniform concentration throughout the cavity
- Discuss how the concentrations of combustible gases would be quantitatively analyzed, and
- Provide detailed information on the different steps of the inerting process in the Package Operations section of the SARP

Guidance in NUREG-2216\textsuperscript{[3-6]} stipulate that combustible gas concentrations should not exceed 5% (by volume), or lower if warranted by the type of flammable gas, in any confined region of the package under Normal Conditions of Transport or Hypothetical Accident Conditions. Combustible gases in radioactive material transportation packages are further restricted in the NRC Information Notice 84-72\textsuperscript{[3-7]} *Clarification of Condition for Waste Shipments Subject to Hydrogen gas Generation*, where flammable gas concentrations are limited to 5% by volume in any confined region of a package over a period that is *twice* the shipping period. Although the NRC Information Notice 84-72 addresses waste shipments, the combustible gas limit has generally been applied to Type AF, and Type B packages regardless of the content. Since the Maximum Normal Operating Pressure (MNOP) is determined for a period of 1-year for Type B packages, and the periodic leakage test is required within one-year of shipment, the shipping period is typically taken as one-year and therefore, according to NRC Information Notice 84-72, the flammable gas limit is usually taken as no more than 5% combustible gases over a period of two-years.

Ensure that Chapter 3 of the SARP includes a calculation that shows the time it takes to reach 5% by volume combustible gas in any confined volume for each of the contents listed in Chapter 1 [or by another method of demonstration acceptable to the DOE Package Certification Program (PCP)]. Coordinate with the reviewers for Chapters 4 and 7 to ensure that these chapters include the shipment period limit if the total combustible gas inventory within any confined volume exceeds 5% by volume in less than two-years. For contents with shipping period limits, ensure that the SARP is clear when the shipping period begins, which is typically when the package containment boundary is sealed, and not when the package is offered for shipment. Consequently, the shipping period includes the time after the package containment boundary has been sealed when the package may be in storage pending shipment.

Additional guidance on issues concerning combustible-gas generation can be found in NUREG/CR-6673\textsuperscript{[3-8]}, *Hydrogen Generation in TRU Waste Transportation Packages*. Reviews of combustible gas generation issues should be coordinated with the Structural, Containment, Operations, Acceptance Tests and Maintenance, and Shielding reviews, as appropriate. If other confined volumes of the package, other than containment, are subject to pressure build up (e.g., secondary containment, outer shell, neutron shielding system, contents), confirm that pressures in these volumes are appropriately evaluated and within safety limits.

Ensure that these pressures presented in Thermal chapter are consistent with those in the General Information, Structural Evaluation, and Containment chapters.

### 3.3.4.5 Maximum Thermal Stresses

Ensure that the thermal stresses caused by differential thermal expansion are evaluated in Chapter 2, Structural Evaluation, and that the results are consistent with the inputs provided by the Thermal Evaluation. Ensure that thermal stresses caused by thermal gradients, even in individual components, are evaluated in Chapter 2 and are consistent with the results of the thermal review, as appropriate. The evaluation should include the maximum thermal stresses as well as cyclic thermal stresses during the service life of the package.
3.3.5 Thermal Evaluation under Hypothetical Accident Conditions

The thermal performance of the package shall be evaluated under the hypothetical fire tests described in §71.73.

3.3.5.1 Initial Conditions

Prior to the 30-minute fire test, the package shall be evaluated for the effects of the drop, crush (if applicable), and puncture tests. Ensure that the initial physical condition of the package design in the thermal HAC evaluations is based on sequential application of the tests. Note that the most unfavorable condition for the fire test is not necessarily the most overall structural damage of the package. Coordinate with the Structural review.

Verify that initial conditions of ambient temperature and internal pressure in the containment system are consistent with the requirements of §71.73(b). Although 10 CFR 71 does not specifically address insolation required for the fire test, supplemental information published with the 1996 rule stated that insolation may be neglected prior to and during the 30-min fire test but should be considered in subsequent package cool-down evaluation after the fire. Neglecting insolation prior to the fire will result in an initial temperature in the containment system that is inconsistent with the condition evaluating the maximum normal operating pressure and may result in peak temperatures during the fire that are less than those under normal conditions of transport with insolation. Although solar insolation is not specifically mentioned as part of the package initial conditions prior to the Hypothetical Accident Conditions (HAC) fire test, the requirement that the package be at the Maximum Normal Operating Pressure (MNOP) prior to the fire test implies that solar insolation, as well as the other heat conditions in §71.71(c)(1), shall be required as initial conditions for the HAC fire test (unless a lower pressure and/or temperature would be more unfavorable). Ensure that the initial conditions of the package prior to the fire test, including ambient temperature, insolation, internal pressure, and decay heat, have been justified as being most unfavorable.

3.3.5.2 Effects of Thermal Tests

Verify that the package design is evaluated for the effects of a fully engulfing fire, as specified in §71.73(c)(4). Ensure the fire test has an average emissivity coefficient of at least 0.9, with an average flame temperature of at least 800°C (1475°F) for a period of 30 minutes.

Confirm that during the cool-down period after the fire:

- No artificial cooling is applied to the package
- The package is subjected to full insolation
- An adequate supply of oxygen is maintained
- All combustion is allowed to proceed until it terminates naturally.

Additional guidance on thermal evaluation of packages under hypothetical accident condition are provided in UCRL-ID-110445[3-2].
3.3.5.3 Maximum Temperatures and Pressures
Verify that the SARP appropriately evaluates the transient peak temperatures of the package components as a function of time. The maximum temperatures in the components may occur following cessation of the fire, with the delay time increasing with the distance inward from the package surface. Verify also that the SARP determines the maximum temperatures of the package components post-fire. Ensure that temperatures under HAC are described and analyzed for differences between regulatory conditions and test conditions, if applicable. Confirm that these temperatures do not exceed their maximum allowable values. For example, verify that lead shielding does not reach melting temperature (see Section 5.3.3.2).

Confirm that the evaluation of the maximum pressure in the containment system uses MNOP as an initial condition (Section 3.3.4.4). Verify that possible increases in gas inventory resulting from the hypothetical accident condition tests (e.g., from thermal combustion, decomposition, release of fill/fission product gases of spent fuel rods) have been accounted for in the maximum pressure determination.

Ensure that the SARP demonstrates that accumulated hydrogen gas comprise no more than 5% by volume of the total gas inventory within any confined volume, especially in the containment vessel during HAC, or otherwise addresses concerns for deflagration and/or detonation of hydrogen and other flammable gases.

If the package has any confined volumes other than the containment vessel (e.g., secondary containment, outer shell, neutron shielding system, or contents), confirm that their pressures are properly determined.

Ensure that these pressures are consistent with those in the General Information, Structural Evaluation, and Containment chapters.

3.3.5.4 Maximum Thermal Stresses
Verify that the SARP evaluates the thermal stresses for HAC. The maximum interference between components with different coefficients of thermal expansion in a package during HAC usually occurs during the post-fire cool-down. Ensure that the maximum thermal stresses are consistent with those in the Structural Evaluation section of the SARP.

3.3.6 Thermal Evaluation of Maximum Accessible Surface Temperature
Confirm that the maximum temperature of the accessible package surface is less than 50°C (122°F) for a nonexclusive-use shipment or 85°C (185°F) for an exclusive-use shipment when the package is in still air at 38°C (100°F) and in the shade as §71.43(g). For packages with a significant heat load, coordinate with the Package Operations review to ensure that the accessible package surface will not exceed the temperature limits at any time during transportation §71.87(k).

3.3.7 Appendices
The appendices should include information on test facilities, test conditions, and test results, a list of references, and copies of any applicable references not generally available to the reviewer. The appendices should also include computer code descriptions, input and output files, details of
Thermal Evaluation on included in the body of Chapter 3, and other appropriate supplemental information (see Appendix D for details related to the quality assurance of analyses, software and modeling).

3.3.7.1 Description of Thermal Test Facilities and Equipment
Confirm that the descriptions of a test facility include:

- Type of facility (e.g., fire, furnace).
- Method of heating the package (e.g., pool fire, gas burners, electrical heaters).
- Volume and emissivity of the furnace interior.
- Types, locations, calibration curves, and measurement uncertainties of all sensors used to measure the fire heat fluxes, fire temperatures, air moisture and test package component temperatures and pressures.
- The post-fire environment for a time period adequate to attain the maximum component temperatures.
- Methods for ensuring an adequate supply and circulation of oxygen for initiating and maintaining the combustion of any burnable package component throughout the fire and post-fire periods until natural termination.

3.3.7.2 Thermal Test Results
Verify that appropriate test reports are included in the appendices. These reports should include:

- Test plan and procedures.
- Test package description and condition.
- Test initial and boundary conditions.
- Test chronologies (planned and actual).
- Photographs of the package components, including any structural or thermal damage, before and after the tests.
- Test measurements, including documentation of test package physical changes and temperature and heat-flux histories, as appropriate.
- Test results corrected to regulatory conditions.
- Methods used to obtain these corrected results.

Confirm that all sensors that measure heat fluxes and temperatures are appropriately positioned and have proper operating ranges for the test conditions. Verify that possible perturbations caused by the presence of these sensors (e.g., by disturbing local convective and radiative heat-transfer) are appropriately considered.

For a pool-fire facility, verify that the fire dimensions and test package relative location conform to the specification in §71.73(c)(4):
- The fire width should extend horizontally between one and three meters beyond any external surface of the package.
- The package should be positioned one meter above the surface of the fuel source.

Since the method of supporting the package in the test facility may locally perturb fire conditions adjoining the test package, verify that such an effect has been appropriately incorporated into the thermal evaluation.

3.3.7.3 Applicable Supporting Documents or Specifications
Verify that appropriate selections from reference documents are included in these appendices. These may include a variety of items such as thermal specifications of O-rings and other components, documentation of the thermal properties, computer input and output files, and other appropriate information.

3.3.7.4 Details of Analyses
Verify that the SARP has detailed calculations supporting the thermal evaluation, including all references and derivations.

3.4 Evaluation Findings
3.4.1 Findings
The reviewer should ensure that the information presented supports a conclusion that the regulatory requirements in Section 3.2 above are satisfied.

The Technical Review Report (TRR) should include a conclusion similar to the following:

Based on review of the statements and representations in the SARP, the staff concludes that the thermal design has been adequately described and evaluated, and that the thermal performance of the package meets the thermal requirements of 10 CFR 71.

3.4.2 Conditions of Approval
The TRR should clearly identify any conditions of approval that should be included in the Certificate of Compliance (CoC). In addition to specifications of authorized contents and information specified on the SARP drawings, other conditions of approval that may be applicable to the Thermal Evaluation chapter of the SARP include:

- Decay heat limits.
- Requirement for exclusive-use shipment due to package surface temperatures.
- Maximum duration of shipment (e.g., to limit hydrogen production).
3.5 References


4.0 CONTAINMENT REVIEW

This review verifies that the package design satisfies the containment requirements of 10 CFR 71[4-1] under normal conditions of transport and hypothetical accident conditions.

The Containment review is based in part on the descriptions and evaluations presented in the General Information, Structural Evaluation, and Thermal Evaluation chapters of the Safety Analysis Report for Package (SARP). Similarly, results of the Containment Review are considered in the review of the Package Operations, Acceptance Tests and Maintenance Program, and Quality Assurance chapters. An example of the information flow for the Containment Review is shown in Figure 4.1.

![Figure 4.1 Example of Information Flow for the Containment Review](image-url)
4.1 Areas of Review
The description and evaluation of the containment design should be reviewed. The Containment review should include the following:

4.1.1 Description of the Containment Design
- General Considerations for Containment Evaluations
  — Type AF Packages
  — Type B Packages
  — Combustible-Gas Generation
- Design Features
- Codes and Standards
- Special Requirements for Plutonium
- Special Requirements for Spent Fuel

4.1.2 Containment under Normal Conditions of Transport
- Containment Design Criteria
- Demonstration of Compliance with Containment Design Criteria

4.1.3 Containment under Hypothetical Accident Conditions
- Containment Design Criteria
- Demonstration of Compliance with Containment Design Criteria

4.1.4 Leakage Rate Tests for Type B Packages

4.1.5 Appendices

4.2 Regulatory Requirements
Regulatory requirements of 10 CFR 71 applicable to the Containment review are as follows:

- The package design shall be described and evaluated to demonstrate that it meets the containment requirements of 10 CFR 71. [§71.31(a)(1), §71.31(a)(2), §71.33, §71.35(a)]
- The application shall identify the established codes and standards used for the package design, fabrication, assembly, testing, maintenance, and use. In the absence of such codes, the application shall describe the basis and rationale used to formulate the quality assurance program. [§71.31(c)]
- The package shall include a containment system securely closed by a positive fastening device that cannot be opened unintentionally or by pressure that may arise within the package. [§71.43(c)]
- The package shall be made of materials and constructed to assure that there will be no significant chemical, galvanic, or other reactions, including reactions due to possible inleakage of water, among the packaging components, among package contents, or
between the packaging components and the contents. The effects of radiation on the materials of construction shall be considered. [§71.43(d)]

- Any valve or similar device on the package shall be protected against unauthorized operation and, except for a pressure relief valve, shall be provided with an enclosure to retain any leakage. [§71.43(e)]

- The package shall be designed, constructed, and prepared for shipment to ensure no loss or dispersal of radioactive contents under the tests specified in §71.71 (“Normal conditions of transport”) there would be no loss or dispersal of radioactive contents. [§71.43(f)]

- The package may not incorporate a feature intended to allow continuous venting during transport. [§71.43(h)]

- A Type B package shall meet the containment requirements of §71.51(a)(1) [i.e., \(10^{-6} \text{A}_2\)/hour, for normal form contents] under the tests specified in §71.71 for Normal Conditions of Transport.

- A Type B package shall meet the containment requirements of §71.51(a)(2) [i.e., \(\text{A}_2\) in one-week, for normal form contents] under the tests specified in §71.73 for Hypothetical Accident Conditions.

- The maximum activity of radionuclides in a Type A package shall not exceed the limits of 10 CFR 71, Appendix A, Table A-1. For a mixture of radionuclides, the provisions of Appendix A, paragraph IV apply, except that for krypton-85, where an effective \(\text{A}_2\) equal to 10\(\text{A}_2\) may be used. [Appendix A, §71.51(b)]

- Compliance with the permitted activity release limits for Type B packages may not rely on filters or on a mechanical cooling system. [§71.51(c)]

- For packages that contain radioactive contents with activity greater than \(10^5 \text{A}_2\), the requirements of §71.61 shall be met. [§71.51(d)]

- A Type B package containing more than \(10^5 \text{A}_2\) shall be designed so that its undamaged containment system can withstand an external water pressure of 2 MPa (290 psi) for a period of not less than 1 hour without collapse, buckling, or inleakage of water. [§71.61]

- A package containing plutonium in excess of 0.74 TBq (20 Ci) shall have the contents in solid form for shipment. [§71.63]

### 4.3 Review Procedures

The following procedures are generally applicable to the review of the Containment chapter of the SARP. These procedures correspond to the Areas of Review listed in Section 4.1 of this PRG. The guidance contained herein is consistent and supplementary to the containment-related guidance in U.S. Nuclear Regulatory Commission’s NUREG-2217, Standard Review Plan for Transportation Packages for Spent Fuel and Radioactive Material.[4-2]
4.3.1 Description of the Containment Design

4.3.1.1 General Considerations for Containment Evaluations

4.3.1.1.1 Fissile Type A Packages

Verify that the contents do not exceed a Type A quantity of radioactive material as specified by Appendix A to 10 CFR 71. Note that the only Type A packages subject to 10 CFR 71 are fissile material packages (i.e., Type AF packages), §71.22(a). For mixtures of nuclides, use the approach in 10 CFR 71, Appendix A, Section IV to show that the mixture is less than a Type A quantity. Verify that the calculation showing less than a Type A quantity for a mixture of nuclide is included in an Appendix to Chapter 4.

For Type A packages, no loss or dispersal of radioactive material is permitted under normal conditions of transport, as specified in §71.43(f), and as specified in 49 CFR 173.24(b)(1). Although 10 CFR 71 does not provide quantitative release limits for containment under hypothetical accident conditions for Type A packages (as it does for Type B packages), the containment (sometimes referred to as confinement for Type A packages) shall be adequate to ensure subcriticality. Coordinate with the Criticality review as appropriate.

4.3.1.1.2 Type B Packages

For more than a Type A quantity of material, Type B packages are used. Type B packages shall satisfy the quantitative release rates of §71.51(a)(1) and (a)(2). As is noted in the NRC Regulatory Guide 7.4,[4-3]the guidance contained in American National Standards Institute (ANSI) N14.5,[4-4]Radioactive Materials - Leakage Tests on Packages for Shipment, provides an acceptable method to determine the maximum permissible volumetric leakage rates based on the allowed regulatory release rates under both normal conditions of transport and hypothetical accident conditions (i.e., LN and LA, respectively). These two volumetric leakage rates should be converted to air leakage rates under reference conditions in accordance with the guidance in ANSI N14.5. The smaller of LN and LA (when converted to reference conditions) is defined as the reference air leakage rate, LR.

In general, the normal condition leakage rate is the most restrictive. Hence, LN, when converted to reference conditions, is generally equal to LR. This situation is assumed in the discussion of containment criteria in Sections 4.3.2 and 4.3.3 below. In the very rare case in which LR is determined by LA, the reviewer should refer to ANSI N14.5 to ensure the containment criteria are properly evaluated. Note that this situation can occur only if the releasable source term under hypothetical accident conditions is approximately three orders-of-magnitude greater than the releasable source term under normal conditions of transport.

The maximum permissible release rate (and leakage rate) for a package that contains different radionuclides is based on an effective A2 for the mixture, which shall be determined according to the provisions of §71.51(b).

Representative analyses for determining simplified containment criteria are provided in NUREG/CR-6487[4-5], Containment Analysis for Type B Packages Used to Transport Various Contents, for Type B packages that contain powders, liquids, irradiated fuel rods, gases, or solids. If the SARP uses a method shown in these sample analyses, ensure that the assumptions used in the sample are applicable to the package under consideration. General guidance for
Predicting the Pressure Driven Flow of Gasses Through Micro-Capillaries and Micro-Orifices can be found in NUREG/CR-5403.[4-6] Guidance on containment analyses for aluminum-based spent fuel is provided by WSRC-TR-98-00317.[4-7]

4.3.1.1.3 Combustible-Gas Generation
The following guidance on combustible gas generation is also given in Section 3.3.4.4 Maximum Normal Operating Pressure (MNOP).

Ensure that the determination of the Maximum Normal Operation Pressure (MNOP) including any generation of flammable gases. Confirm that the SARP demonstrates that any combustible gases generated in the package during a period of one year do not constitute a safety issue. Gas generation, including flammable gas generation, can occur due to radiolysis, thermal degradation, as well as chemical reactions. Confirm that these evaluations do not include credit for getters, catalysts, or other recombination devices. However, credit may be taken for diffusion and leakage to evaluate the combustible gas release rate versus the combustible gas generation rate.

Ensure that for contents other than Transuranic (TRU) waste, inerting is not used to limit the concentration of flammable gasses. However, if inerting is proposed, at a minimum ensure that the applicant has:

- Demonstrated the inerting process will prevent the development of flammable gas mixtures in any confined area of the package throughout the entire shipment period
- Provide a detailed evaluation or analysis to demonstrate that there are no flammable gas mixtures (considering the worst case concentration of hydrogen or any other flammable gas, and oxygen) during shipment
- Provide a detailed configuration of all passages to ensure that the inerting gas could be introduced effectively (e.g., injection path, port orientation) to the innermost packaging or other confined areas within the containment system of the package
- Demonstrate that the inerting gas either effectively occupies the containment cavity or is in uniform concentration throughout the cavity
- Discuss how the concentrations of combustible gases are quantitatively analyzed, and
- Provide detailed information on the different steps of the inerting process in the Package Operations section of the SARP

Guidance in NUREG-2216[4-2] stipulate that combustible gas concentrations should not exceed 5% (by volume), or lower if warranted by the type of flammable gas, in any confined region of the package under Normal Conditions of Transport or Hypothetical Accident Conditions. Combustible gases in radioactive material transportation packages are further restricted in the NRC Information Notice 84-72,[4-8] Clarification of Condition for Waste Shipments Subject to Hydrogen gas Generation, where flammable gas concentrations are limited to 5% by volume in any confined region of a package over a period that is twice the shipping period. Although the
NRC Information Notice 84-72 addresses waste shipments, the combustible gas limit has generally been applied to Type AF, and Type B packages regardless of the content. Since the Maximum Normal Operating Pressure (MNOP) is determined for a period of 1-year for Type B packages, and the periodic leakage test is required within one-year of shipment, the shipping period is typically taken as one-year and therefore, according to NRC Information Notice 84-72, the flammable gas limit is usually taken as no more than 5% combustible gases over a period of two-years.

Coordinate with the reviewer of Chapter 3 to ensure that Chapter 3 of the SARP includes a calculation that shows the time it takes to reach 5% by volume combustible gas in any confined volume for each of the contents listed in Chapter 1 [or by another method of demonstration acceptable to the DOE Package Certification Program (PCP)] and that this time period is noted in Chapter 4. Coordinate with the reviewers for Chapters 3 and 7 to ensure that these chapters include the shipment period limit if the total combustible gas inventory within any confined volume exceeds 5% by volume in less than two-years. For contents with shipping period limits, ensure that the SARP is clear when the shipping period begins, which is typically when the package containment boundary is sealed, and not when the package is offered for shipment. Consequently, the shipping period includes the time after the package containment boundary has been sealed when the package may be in storage pending shipment.

Additional guidance on issues concerning combustible-gas generation can be found in NUREG/CR-6673[4-9], Hydrogen Generation in TRU Waste Transportation Packages, and NUREG/CR-6487[4-5], Containment Analysis for Type B Packages Used to Transport Various Contents. Reviews of combustible gas generation issues should be coordinated with the Structural, Thermal, and Shielding reviews, as appropriate.

4.3.1.2 Design Features
Review the containment design features presented in the General Information and Containment chapters of the SARP. Design features important to containment include:

- Containment vessel(s)
- Welds
- Seals
- Valves
- Pressure relief devices
- Lids, cover plates, and similar closure devices
- Bolts and bolt torque
- Special containment features for plutonium
- Special containment features for spent fuel.

Information on containment design features should include, as appropriate:

- Location, dimensions, and tolerances
- Materials of construction, and sealing surface finishes
- Maximum and minimum allowable temperatures of components, including seals
- Maximum and minimum temperatures of components under the tests for normal conditions of transport and hypothetical accident conditions
- Maximum normal operating pressure and maximum pressure in the containment system under hypothetical accident conditions.

The SARP should include a figure or sketch that defines the exact boundary of the containment system, and confinement system as applicable. Confirm that all containment boundary penetrations and their method of closure are adequately described. Verify that the containment system (including the confinement boundary for Type A packages) is securely closed by a positive fastening device that cannot be opened unintentionally or opened by a pressure that may arise within the package. Coordinate with the Structural and Thermal reviews as appropriate. If penetrations are closed with two seals (e.g., to enable leakage testing), verify which seal is defined as the containment boundary. Ensure that all components of the containment system are shown on the SARP drawings.

Verify that the seal material is appropriate for the package. Ensure that the seal will undergo no galvanic, chemical, or other reaction with the packaging or its contents, will not degrade due to irradiation, and will not be permeable to radioactive gases in the contents. Confirm that the seal grooves are properly sized. Coordinate with the Structural review as appropriate to verify that the specified bolt torque will provide proper seal compression. Cover plates and lids should be recessed or otherwise protected.

Confirm that all containment closure systems can be leakage tested as appropriate. If vent/drain ports or similar penetrations utilize quick-disconnect valves that are not part of the containment boundary, ensure that such valves do not preclude leakage testing of the containment.

Review the maximum and minimum temperatures of all containment system components, including seals, under normal conditions of transport and hypothetical accident conditions. Confirm that the allowable temperature range for each component is not exceeded. Compliance with the containment requirements for Type B packages may not rely on filters or a mechanical cooling system. Coordinate with the Thermal review as appropriate.

Performance specifications for components such as valves and pressure relief devices should be identified, and no device may allow continuous venting. Ensure that the maximum pressure under normal conditions of transport or hypothetical accident conditions does not exceed the specification of pressure relief devices, as appropriate. Coordinate with the Thermal review as appropriate.

Any valve or similar device on the package shall be protected against unauthorized operation and, except for a pressure relief valve, shall be provided with an enclosure to retain any leakage. (Note: The requirement to provide an enclosure to retain leakage is not intended to require a second containment boundary for Type B packages.)
Confirm that the information regarding the containment system is consistent with that presented in the General Information, Structural Evaluation, and Thermal Evaluation chapters of the SARP.

4.3.1.3 Codes and Standards
Verify that codes or standards applicable to the containment design of the package are identified and appropriate, including those for material specifications and fabrication/examination. The codes and standards used shall reflect the risk-based assessment of components of the Q-list of Chapter 9, Quality Assurance. Confirm that the fabrication/examination criteria adapted in the SARP comply with the level of safety defined in U.S. NRC Regulatory Guide 7.11,[4-10] Table 1 (for Category I, II, or III contents) and also the recommendation given in NUREG/CR-3854[4-11] for applicable fabrication/examination requirements. Ensure that such codes and standards are consistent with those specified in the SARP drawings of the General Information chapter, and the Structural and Thermal Evaluation chapters of the SARP. Determine if these codes or standards specify temperature limits for materials.

Evaluation of release rates and performance of leakage testing should be in accordance with ANSI N14.5.[4-4]

4.3.1.4 Special Requirements for Plutonium
Prior to the rule changes in October 2004, Special Requirements for plutonium shipments were mandated by the regulations. Specifically, if the contents include more than 0.74 TBq (20 Ci) of plutonium, the reviewer would have had to verify that the plutonium was in solid form, and that double containment was provided as specified in §71.63(b) at that time. In addition, the reviewer would have had to verify that each containment system could separately meet the requirements of §71.51(a)(1) for normal conditions of transport and §71.51(a)(2) for hypothetical accident conditions. Both containment systems would have to be reviewed in the same manner. Although this information is no longer current, it is included here for completeness because (1) the use of double containment systems for plutonium is not prohibited by the regulations, (2) there are still a relatively large number of double-containment plutonium packages in service, and (3) it is expected that these double-containment plutonium packages will be in service for another decade or longer.

Since the double-containment requirement for plutonium was eliminated with the rule change in October 2004, the reviewer need only verify that, if the contents include more than 0.74 TBq (20 Ci) of plutonium, the plutonium shall be in solid form as specified in §71.63.

4.3.1.5 Special Requirements for Spent Fuel
Special containment requirements for spent fuel depend on the condition of the fuel:

- As per the guidance in ISG-1, Classifying the Condition of Spent Nuclear Fuel for Interim Storage and Transportation Based on Function,[4-12] damaged fuel or suspect damaged fuel should be canned in a separate inner canister for handling and criticality control. Appropriate material specifications and the design/fabrication criteria for the inner container should be specified, and any credit for the canning in the containment
evaluation should be justified. If a screen-type container is used, an appropriate mesh size should be justified. Review the design of the inner container, as applicable.

- Spent fuel debris, particles, loose pellets, or fragmented rods/assemblies are not considered to be fuel elements and require a separate (inner) canister for criticality control purposes. Coordinate with the Criticality review as appropriate.

The determination of undamaged fuel should be based, at a minimum, on a review of records to verify that the fuel is undamaged, followed by a visual examination for any obvious damage prior to loading. For fuel in which reactor records are not available, the level of proof should be evaluated on a case-by-case basis. Coordinate with the Package Operations review as appropriate.

### 4.3.2 Containment under Normal Conditions of Transport

#### 4.3.2.1 Containment Design Criteria

Confirm that the radionuclides and physical form of the contents evaluated in the Containment chapter are consistent with those presented in the General Information chapter of the SARP. Ensure that the radionuclides include daughter products as appropriate.

Verify that the SARP identifies the constituents that comprise the releasable source term, which could include radioactive solids, radioactive liquids, radioactive gases, aerosols, and/or spent fuel. If less than 100% of the contents are considered releasable, evaluate the justification for the lower fraction.

Based on the releasable source term, ensure that the maximum permissible release rate and the maximum permissible leakage rate \( L_N \) are calculated in accordance with ANSI N14.5.\(^{[4-4]}\)

Verify that the maximum normal operating pressure and maximum temperature under normal conditions of transport are consistent with those determined in the Thermal Evaluation chapter of the SARP. Using this pressure and temperature, ensure that the maximum permissible leakage rate \( L_N \) is converted to reference cubic centimeters per second (i.e., \( \text{ref·cm}^3/\text{s} \)) in accordance with ANSI N14.5.

Note: If the applicant has elected to adopt the ANSI N14.5 definition of leaktight, i.e., \( \leq 1 \times 10^{-7} \text{ref·cm}^3/\text{s} \), for their containment criterion for normal conditions of transport, then the applicant need not supply any calculations to further justify the criteria.

#### 4.3.2.2 Demonstration of Compliance with Containment Design Criteria

Confirm that the SARP demonstrates that the package meets the containment requirements of §71.51(a)(1) under normal conditions of transport.

If compliance is demonstrated by test:

- Confirm that prior to the test, the leakage rate of the test specimen (when converted to reference conditions) is demonstrated to be less than or equal to \( L_R \), as defined in ANSI N14.5.
• Coordinate with the Structural and Thermal reviews to ensure that a full-scale specimen has been properly tested under the requirements of §71.71. While scale-model testing may yield valuable information for the designer, it is not a reliable, or an acceptable, method for quantifying the leakage rate of a full-scale specimen.

• Verify that the leakage rate of the specimen that has been subjected to the tests of §71.71 does not exceed the maximum allowable leakage rate for normal conditions of transport. To ensure a comparison using consistent units, the leakage rate after the test should generally be converted to reference conditions and then compared with \( L_R \).

If compliance is demonstrated by analysis:

• Confirm that the allowable leakage rate for the fabrication, periodic, and maintenance leakage rate tests is less than or equal to \( L_R \).

• Verify that the structural evaluation shows that the containment system closure region (e.g., bolts, seal, or flange) does not undergo plastic deformation under the tests of §71.71. Coordinate with the Structural review.

### 4.3.3 Containment under Hypothetical Accident Conditions

The review procedures for containment under hypothetical accident conditions are similar to those under normal conditions of transport. Differences relevant to hypothetical accident conditions are noted below.

#### 4.3.3.1 Containment Design Criteria

The releasable source term, maximum permissible release rate, and maximum permissible leakage rate should be based on package conditions and the 10 CFR 71 containment requirements under hypothetical accident conditions. Verify that the temperatures, pressure, and physical conditions of the package (including the contents) are consistent with those determined in the Structural Evaluation and Thermal Evaluation chapters of the SARP. Using this pressure and temperature of the contents under hypothetical accident conditions, ensure that the maximum permissible leakage rate \( L_A \) is converted to reference cubic centimeters per second (ref·cc\(^3\)/s, or \( \text{ref·cm}^3\)/s) in accordance with ANSI N14.5.

Note: If the applicant has elected to adopt the ANSI N14.5 definition of leaktight, i.e., \( \leq 1 \times 10^{-7} \text{ref·cm}^3\)/s, for their containment criterion for hypothetical accident conditions, the applicant need not supply any calculations to further justify their position.

#### 4.3.3.2 Demonstration of Compliance with Containment Design Criteria

Ensure that the SARP demonstrates that the package satisfies the containment requirements of §71.51(a)(2) under hypothetical accident conditions. Demonstration is similar to that discussed in Section 4.3.2.2, except that the package should be subjected to the tests of §71.73 and the maximum allowable leakage rate at reference conditions shall be less than \( L_A \) converted to reference conditions.
4.3.4 Leakage Rate Tests for Type B Packages

Using the reference air leakage rate, confirm that the maximum allowable leakage rates for the following tests are determined in accordance with ANSI N14.5:

- Fabrication leakage rate test
- Periodic leakage rate test
- Maintenance leakage rate test
- Pre-shipment leakage rate test.

The fabrication, periodic, and maintenance leakage rate tests should be addressed in the Acceptance Tests and Maintenance Program review (see Chapter 8 of this PRG). The pre-shipment leakage rate test for assembly verification should be addressed in the Package Operations review (see Chapter 7 of this PRG). Coordinate with those reviews as appropriate.

4.3.5 Appendices

Confirm that the appendices include a list of references, copies of applicable references if not generally available to the reviewer, test results, and supporting Quality Assurance information to establish the pedigree of analyses, models, and software used. Any other additional supplemental information to support the analyses and testing should be included, such as test plans, procedures, content calculations/descriptions, as appropriate.

4.4 Evaluation Findings

4.4.1 Findings

The reviewer should ensure that the information presented supports a conclusion that the regulatory requirements in Section 4.2 above are satisfied.

The Technical Review Report (TRR) should include a conclusion similar to the following:

Based on review of the statements and representations in the SARP, the staff concludes that the containment design has been adequately described and evaluated and that the package design meets the containment requirements of 10 CFR 71.

4.4.2 Conditions of Approval

The TRR should clearly identify any conditions of approval that should be included in the Certificate of Compliance. In addition to specifications of authorized contents and information specified on the SARP drawings, other conditions of approval that may be applicable to Containment chapter of the SARP include:

- Requirement to place damaged fuel in a canister
- Maximum duration of shipment (e.g., to limit hydrogen production)
- Other conditions as appropriate.
4.5 Reference


5.0 SHIELDING REVIEW

This review verifies that the package design meets the external radiation requirements of 10 CFR 71[5-1] under normal conditions of transport and hypothetical accident conditions.

The Shielding review is based in part on the descriptions and evaluations presented in the General Information, Structural Evaluation, and Thermal Evaluation chapters of the Safety Analysis Report for Package (SARP). Results of the Shielding review are considered in the review of Package Operations, the Acceptance Tests and Maintenance Program, and the Quality Assurance Program. An example of the information flow for the Shielding review is shown in Figure 5.1.

![Diagram of Shielding Review Information Flow]

**Figure 5.1 Example of Information Flow for the Shielding Review**
5.1 **Areas of Review**
The description and evaluation of the shielding design should be reviewed. The Shielding review should include the following:

5.1.1 **Description of Shielding Design**
- Design Features
- Codes and Standards
- Summary Table of Maximum Radiation Levels

5.1.2 **Radiation Source**
- Gamma Source
- Neutron Source

5.1.3 **Shielding Model**
- Configuration of Source and Shielding
- Material Properties

5.1.4 **Shielding Evaluation**
- Methods
- Input and Output Data
- Flux-to-Dose-Rate Conversion
- External Radiation Levels

5.1.5 **Appendices**

5.2 **Regulatory Requirements**
Regulatory requirements of 10 CFR 71 applicable to the Shielding review are as follows:

- The package design shall be described and evaluated to demonstrate that it meets the shielding requirements of 10 CFR 71. [§71.31(a)(1), §71.31(a)(2), §71.31(a)(3), §71.31(b), §71.33, §71.35(a)]

- The application shall identify the established codes and standards used for the package design, fabrication, assembly, testing, maintenance, and use. In the absence of such codes, the application shall describe the basis and rationale used to formulate the quality assurance program. [§71.31(c)]

- Under the tests specified in §71.71 for normal conditions of transport, the external radiation levels shall meet the requirements of §71.47(a) for nonexclusive-use or §71.47(b) for exclusive-use shipments. [§71.47]
- The package shall be designed, constructed, and prepared for shipment so that the external radiation levels will not significantly increase under the tests specified in §71.71 for normal conditions of transport. [§71.43(f), §71.51(a)(1)]
- Under the tests specified in §71.73 for hypothetical accident conditions, the external radiation level shall not exceed 10 mSv/h (1 rem/h) at one meter from the surface of a Type B package. [§71.51(a)(2)]

5.3 Review Procedures
The following procedures are generally applicable to the review of the Shielding Evaluation chapter of the SARP. These procedures correspond to the Areas of Review listed in Section 5.1 of this PRG.

5.3.1 Description of Shielding Design
5.3.1.1 Design Features
Review the shielding design features presented in the General Information and Shielding Evaluation chapters of the SARP. Design features important to shielding include:

- Location, dimensions, tolerances, and densities of material for neutron or gamma shielding features of the packaging. This includes extra shielding-related components that are required only for certain contents intended for shipment in the package.
- Structural components that maintain the integrity of the shielding
- Structural components that maintain the contents in a fixed position within the package
- Heat transfer and insulating features that maintain allowable temperatures of the shielding
- Dimensions of the transport vehicle that are considered in the shielding evaluation, if applicable (for example, as required in the case of an exclusive use shipment).

Confirm that the text and sketches describing the shielding design features, are consistent with the SARP drawings and the analysis models used in the shielding evaluation.

5.3.1.2 Codes and Standards
Verify that any codes or standards applicable to the shielding design of the package are identified and appropriate, including those for material specifications and fabrication. Ensure that such codes and standards are consistent with those specified in the General Information, Structural, and Thermal Evaluation chapters of the SARP. Determine if these codes or standards specify temperature limits for materials used in the shielding design.

Flux-to-dose-rate conversion factors should be consistent with American National Standards Institute (ANSI)/ANS6.1.1-1977,[5-2] as discussed below in Section 5.3.4.3.
5.3.1.3 **Summary Table of Maximum Radiation Levels**

Review the summary table of maximum radiation levels. Ensure that the maximum levels are presented for both normal conditions of transport and hypothetical accident conditions at the appropriate locations for nonexclusive or exclusive use (or both), as applicable.

Table 5.1 below is an example of the information that should be presented for nonexclusive use. A similar table should be presented for exclusive use shipment as appropriate.

Verify that the radiation levels are within the regulatory limits, as indicated in Table 5.2 below, and are consistent with those presented in Section 5.4 of the SARP, and any appendices that contain additional shielding analyses.

---

**Table 5.1 Example for Summary Table of External Radiation Levels (Nonexclusive Use)**

<table>
<thead>
<tr>
<th>Normal Conditions of Transport</th>
<th>Package Surface</th>
<th>1 Meter from Package Surface</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Radiation</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Top</td>
<td>Side</td>
</tr>
<tr>
<td>Gamma</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neutron</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10 CFR 71.47(a) Limit</td>
<td>2 (200)</td>
<td>2 (200)</td>
</tr>
</tbody>
</table>

* Transport index, defined as a number equal to the dose rate in mSv/h multiplied by 100 (equivalent to mrem/h) at 1 m from the package surface rounded up to the first decimal place, may not exceed 10 for nonexclusive-use shipment.

---

**Hypothetical Accident Conditions**

<table>
<thead>
<tr>
<th>Hypothetical Accident Conditions</th>
<th>1 Meter from Package Surface</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Radiation</td>
</tr>
<tr>
<td></td>
<td>Top</td>
</tr>
<tr>
<td></td>
<td>Gamma</td>
</tr>
<tr>
<td></td>
<td>Neutron</td>
</tr>
<tr>
<td></td>
<td>Total</td>
</tr>
<tr>
<td>10 CFR 71.51(a)(2) Limit²</td>
<td>10 (1000)</td>
</tr>
</tbody>
</table>

² Applicable to Type B packages only (10 CFR Part 71.51)
Table 5.2 Package and Vehicle Radiation Level Limits

<table>
<thead>
<tr>
<th>Transport Vehicle Use:</th>
<th>Nonexclusive</th>
<th>Exclusive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transport Vehicle Type:</td>
<td>Open or closed</td>
<td>Open (flat-bed)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Package (or Freight Container) Limits, mSv/h (mrem/h):</th>
<th>Nonexclusive</th>
<th>Exclusive</th>
</tr>
</thead>
<tbody>
<tr>
<td>External surface</td>
<td>2 (200)</td>
<td>10 (1000)&lt;sup&gt;c&lt;/sup&gt;</td>
</tr>
<tr>
<td>1 m from external surface</td>
<td>0.1 (10)&lt;sup&gt;d&lt;/sup&gt;</td>
<td>No limit</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Roadway or Railway Vehicle (or Freight Container) Limits, mSv/h (mrem/h):</th>
<th>Nonexclusive</th>
<th>Exclusive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any point on the outer surface</td>
<td>N/A</td>
<td>2 (200)</td>
</tr>
<tr>
<td>Vertical planes projected from outer edges</td>
<td>N/A</td>
<td>2 (200)</td>
</tr>
<tr>
<td>Top of . . .</td>
<td>N/A</td>
<td>load: 2 (200)</td>
</tr>
<tr>
<td>2 m from . . .</td>
<td>N/A</td>
<td>vertical planes: 0.1 (10)</td>
</tr>
<tr>
<td>Underside</td>
<td>N/A&lt;sup&gt;e&lt;/sup&gt;</td>
<td>2 (200)</td>
</tr>
<tr>
<td>Occupied position</td>
<td>N/A&lt;sup&gt;e&lt;/sup&gt;</td>
<td>0.02 (2)&lt;sup&gt;f&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

---

<sup>a</sup> The limits in this table are applicable under normal conditions of transport. For Type B packages, the external radiation levels at one meter from the package surface may not exceed 10 mSv/h (1 rem/h) under hypothetical accident conditions for both exclusive and non-exclusive use. The limits in this table do not apply to excepted packages—see 49 CFR 173.421-426.

<sup>b</sup> Securely attached (to vehicle), access-limiting enclosure; package personnel barriers are considered as enclosures. (see 49 CFR 173.403 for definition of enclosure)

<sup>c</sup> Package secured within the closed vehicle so that its position remains fixed during transportation; no loading or unloading operations between beginning and end of transportation. **All three conditions shall be met; otherwise limit is 2 mSv/h (200 mrem/h).**

<sup>d</sup> Transport index (see footnote in Table 5.1 for definition) shall not exceed 10 for nonexclusive-use shipment.

<sup>e</sup> No dose limit is specified, but separation distances apply to packages with Radioactive Yellow-II (max 0.5 mSv/h on any exterior surface) or Radioactive Yellow-III (max 2 mSv/h on any exterior surface) labels—see 49 CFR 177.842(b).

<sup>f</sup> Does not apply to private carriers if exposed personnel under their control wear dosimetry devices in conformance with 10 CFR 20.1502.

### 5.3.2 Radiation Source

General guidelines applicable to the source definition in the SARP that need to be reviewed:

- Confirm that the contents, both radioactive and non-radioactive materials such as light elements that produce neutrons via the ($\alpha$, $n$) reaction with actinides, used in the shielding
evaluation, are consistent with those specified in the General Information chapter of the SARP.

- If the package is designed for multiple types of contents, ensure that the contents producing the highest external dose rate at each location are clearly identified and evaluated.

- Verify that any assumptions made in selecting bounding contents from a point of view of generating neutrons or photons are clearly explained and justified. Ensure that any reference materials used in making these assumptions are clearly stated or provided if not accessible to the reviewer.

- Ensure that the mass (or activity in the case of radioactive materials) of all contents that contribute to the source term, including non-radioactive contents like light elements, are provided.

- Ensure that the practice of selecting the maximum source term in each group from the set of decay times that have been included in the calculation and using this composite spectrum as the bounding source is valid in producing the maximum levels of external radiation. Ensure that this approach does not bias the source towards less important energy groups at the expense of important energy groups that would result in a skewed spectral shape of the source.

- If the contents include spent fuel, verify that the fuel types (e.g., BWR 10 x 10, PWR 17 x 17, CANDU 37, etc.) and the range of burnup, initial enrichment, and cooling times of the contents have been presented.

  - It is important that the specific fuel rod/guide tube matrix in the fuel assembly (e.g., PWR 17 x 17) be specified since the cross sections used to generate source terms, in addition to enrichment, burnup, and cooling time, are also dependent, for example, on the fuel pin/guide tube matrix (PWR) or fuel rod/water hole matrix (BWR) in the assemblies.

5.3.2.1 Gamma Source

Guidelines to review the method used to determine the gamma source term:

- Ensure that the source contribution from radioactive daughter products is included if it produces higher dose rates than the fresh contents, by decaying the contents long enough to capture the most conservative spectrum.

  - For example, in instances such as the decay of Pu236/U232, the source term can take several years to reach maximum levels, while in other cases such as Am243 the peak can happen in less than a month when the daughter Np239 reaches secular equilibrium with its parent.

- Ensure that the spectrum selected is appropriate such that it captures the important gamma lines from the content and the content is decayed long enough to reach a
maximum intensity of these gamma lines. Such cases may produce higher dose rates even if the total source at these decay times may be smaller (see Section 5.3.4 for more details).

- As an example, the decay of Pu236/U232 produces the important line from Tl208 several generations down the chain.

- Ensure that isotopes like Pu236 and U232 that are present in parts per million quantities are included in the source term as they have a major impact on the gamma dose rates.

- Verify that for radioisotope sources like Co60 (1.17 and 1.33 MeV) where both the intense gamma lines are always emitted, this aspect of the source is considered while estimating external radiation levels. (see Section 5.3.4 for more details).

- Verify that the production of secondary gammas [e.g., from (n,γ) reactions in shielding material or bremsstrahlung from beta decay] is either calculated as part of the shielding evaluation (see Section 5.3.4) or otherwise appropriately included in the source term.

If the contents include spent fuel, verify that the gamma source terms are determined for both the spent fuel and activated hardware.

- If the package is intended to transport other hardware such as control assemblies, top and bottom nozzles, grid spacers, shrouds etc., ensure that the source terms from these components are also included as appropriate.

- Note whether the source terms are specified per fuel rod, per assembly, per total assemblies, or per metric ton, and ensure that the total source is correctly used in the shielding evaluation.

- In the case of spent fuel where the source term is not calculated at the peak burnup, ensure that all applicable peaking factors are applied to ensure conservatism.
  
  - The spent fuel gamma source term typically increases linearly with burnup. The main source of gammas in spent fuel after a cooling time of about 5 years is Cs-137, with a fission yield that is approximately the same for fissions from both U-235 and Pu-239. Co-60 is the main source due to activation of other hardware, such as nozzles or spacers.

In summary, confirm that the source term is presented as a listing of gammas per second, as a function of energy and that the appropriate spectral structure was used to capture important gamma lines that may be present in the contents.

5.3.2.2 Neutron Source
Guidelines to review the method used to determine the neutron source term:

- Verify that the method considers, as appropriate, neutrons from both spontaneous fission and from (α,n) reactions.
- Ensure that the calculation of the source term from \((\alpha, n)\) reactions are generated using the specific light element under consideration since codes can default to oxygen because typically nuclear fuel is in the form of an oxide.

- If the SARP assumes that either of these source contributions is negligible, ensure that an appropriate justification is provided.
  - An example of a lack of the \((\alpha, n)\) source would be the absence of light elements in the presence of actinides.

- Verify that the production of neutrons from subcritical multiplication is either calculated as part of the shielding evaluation (see Section 5.3.4) or otherwise appropriately included in the source term. Typically, subcritical multiplication is accounted for during the radiation transport calculations.

- Confirm that the results of the source term calculation are presented as a listing of neutrons per second as a function of energy. The number of energy groups should be detailed enough to ensure that the important energy groups are sampled adequately in the radiation transport calculations.
  - The average energy of a fission neutron is 2 MeV while the average energy of an \((\alpha, n)\) neutron is at the low end 0.5 MeV (Am-Li)- up to 5 MeV (Am-Be), thus depending on the combination of the actinide and the associated light element.
  - It is also important to note that low energy neutrons, while not being major direct contributors to the dose rate, are very important in producing high energy neutrons via subcritical multiplication in fissionable material that would in turn lead to enhanced dose rates.

General guidelines specific to spent fuel neutron source term:

- Ensure that the SARP specifies a minimum initial enrichment for the fuel, as appropriate.
  - It is important to note that the neutron source term for shielding evaluations can increase significantly with decreasing initial enrichment (for constant burnup and cooling time) due to the buildup of plutonium (mainly Pu238 and Pu240) and curium (Cm242 up to a cooling time of 2 years and Cm244) isotopes that are the main source of neutrons in spent fuel.

- In addition to increasing with decreasing enrichment, the source terms are a strong function of the burnup (e.g., neutron source terms in light water reactors are strong power functions of the burnup with an exponent of between 3 and 5). In the case of spent fuel where the source term is not calculated at the peak burnup, ensure that all applicable factors as provided in the example below have been accounted for in determining the source term.
The source term, $S(\bar{B})$, that has been determined based on a fuel assembly with the maximum average burnup, need not necessarily be bounding due to the axial variation of the burnup within the assembly (particularly in the case of boiling water reactors). The actual maximum burnup, $S_{\text{max}}(B)$, can be calculated by applying a factor, $r$, that is derived using the following equation, where $H$ is the height of the fuel and $f(B(z))$ is the functional relationship between the source and burnup at different axial locations, $z$. By applying the factor, $r$, to $S(\bar{B})$, the correct $S_{\text{max}}(B)$, can be determined.

$$r = \frac{S_{\text{max}}(B)}{S(B)} = \frac{1}{H} \int_{0}^{H} f(B(z)) dz$$

- Verify if any radial peaking factors also need to be applied to obtain the maximum burnup.
- Verify if the maximum burnup value that has already incorporated these conservatisms is specified in the SARP, it can be directly used to calculate the source term.

- Verify that the cross sections used to calculate the source terms are applicable for the burnup indicated since some cross-section libraries are not valid for higher burnups.
- Ensure that the appropriate cooling time is used to derive a conservative source term. Neutron source for given burnup and enrichment decreases as a function of cooling time.

In summary, the initial enrichment, cooling time, and burnup levels are three basic properties of spent fuel and variations of these within the spent fuel can have an impact on the neutron source term. Therefore, ensure that combinations of these have been examined to determine the bounding neutron source term and spectrum for each content in the package.

The practice of specifying a maximum burnup along with a minimum enrichment (either a single pair or a series of burnup/enrichment limits) and a minimum cooling time is typically used to establish a practical upper bound for the source strengths.

### 5.3.3 Shielding Model

Review the Structural and Thermal Evaluation chapters of the SARP to determine the effects that the tests for normal conditions of transport and hypothetical accident conditions have on the packaging and its contents.

Verify that the models used in the shielding calculation are consistent with these effects and with the SARP drawings. Coordinate with the Structural and Thermal reviews as appropriate.

#### 5.3.3.1 Configuration of Source and Shielding

Verify the dimensions of the source and packaging used in the shielding models and ensure that tolerances have been appropriately considered.
• It should be noted that polyethylene wraps or metal casing around a fissile source could enhance subcritical multiplication and hence should be included in the shielding model. If such materials are present, ensure that sensitivity studies have been performed to determine the effect on the external radiation levels with and without these materials.

• If contents can be positioned at varying locations within containment and/or can have varying physical properties, ensure that the location and physical properties (densities, shapes, compositions etc.) of the package contents used in the evaluation are those resulting in the maximum external radiation levels. The source configuration that maximizes the radiation level on the side of the package might not be the same source configuration that maximizes the radiation level on the top or bottom. As examples, sources can be modeled with different shapes or could be distributed in the payload cavity etc. Thus, ensure that a combinations of source configuration and location have been examined to obtain the most bounding value(s) of external radiation.

• Ensure that any changes in configuration (e.g., displacement of source or shielding, reduction in shielding) resulting under normal conditions of transport or hypothetical accident conditions have been included, as appropriate.

• It is possible that in the interest of conservatism, the neutron and gamma source models used may be different, e.g., a spherical source model for neutrons versus a distributed source model for gammas. Ensure whether this approach is acceptable and does result in bounding dose rates for both type of sources.

• Ensure that appropriate tolerances in developing the calculational model have been applied, for example reducing the thickness of the CV wall with the tolerances provided in the SARP drawings.

In the case of spent fuel:

• Confirm that the spent-fuel region and activated-hardware regions (e.g., top/bottom end-pieces, spacers, and plenum) are properly located in the model.

• Ensure that fuel baskets that are used for shipping spent fuel are modeled noting that different baskets may be used for different types of fuel that are to be shipped.

• Ensure that the composition of source materials used in the calculations is appropriate and leads to conservative estimates of the external dose rates.
  - To ensure conservatism, it is recommended that the appropriate mix of fissile materials (U and Pu) based on the most conservative combination of initial enrichment, cooling time and burnup be used without including fission products to maximize subcritical multiplication.
  - Modern calculational software and hardware enable the geometric configuration of the fuel pin matrix to be modeled accurately. Ensure that there is justification
for the selection of the source locations within the assembly, either a pin-by-pin model or one that is uniformly selected in the active source region.

- If neutron absorbers are present in the fuel basket (e.g., borated aluminum), ensure that the material density of the absorber is appropriate and whether the practice of reducing the absorber density by 25% as is done in the criticality safety analysis, produces a more conservative estimate of external dose rate.

For exclusive-use shipments in which the analysis is based on the radiation levels of §71.47(b):

- Confirm that dimensions of the transport vehicle and package location are included as appropriate. These dimensions or vehicle type (open or closed), as well as positioning of the packages (including the use of an enclosure in an open vehicle), shall be limiting conditions in the Certificate of Compliance (CoC) if used in the evaluation. For some packages, the use of radiation levels at distances from the package surface instead of the vehicle surface may be sufficient to demonstrate compliance without the need to specify vehicle dimensions. Please refer to Table 5.2 of this document.

- Verify that the dose point locations in the shielding model include all locations prescribed in §71.47(a) or §71.47(b), and §71.51(a)(2) as appropriate (see Table 5.2 of this document). Ensure that these points are chosen to identify the location of the maximum radiation levels. Confirm that voids, streaming paths, and irregular geometries are included in the model or otherwise treated in an adequate manner.

- For exclusive-use shipments, ensure that the determination of the radiation levels on the bottom surface of the vehicle, at 2 m from the vehicle, and in normally occupied positions account for the contribution from ground scatter, as appropriate.

In general, the shielding model and evaluation need to address radiation levels from only one package and show that the requirements of §71.47 are satisfied. Based on external radiation levels measured prior to shipment, multiple packages may be combined in conveyance in accordance with 49 CFR 177.842 (nonexclusive use), 49 CFR 173.441 (exclusive use), and other applicable Department of Transportation (DOT) regulations. (Combining packages with fissile material shall also address criticality-safety restrictions, as discussed in Chapter 6 of this PRG.)

5.3.3.2 Material Properties
Verify the appropriate material properties (e.g., mass densities and atom densities) are used in the shielding models of the packaging, contents, and conveyance (if applicable). For uncommon materials, especially foams, plastics, and other hydrocarbons, the source of data addressing the chemical composition and mass density should be referenced.

- Verify that the material specifications are consistent with those in the SARP drawings. Any deviations from these specifications should be clearly justified, e.g., for added conservatism etc.

- Confirm that shielding properties will not degrade significantly during the service life of the packaging (e.g., degradation of foam or dehydration of hydrogenous materials). Any
uncommon materials present, e.g., special materials used in spent fuel casks for dose rate mitigation, should be described and pertinent reference material provided as part of the review.

- Ensure that any changes resulting under normal conditions of transport or hypothetical accident conditions have been included, as appropriate. Loss of external shielding, such as a material used for neutron attenuation in spent-fuel packages or lead slump, may be acceptable if it produces no other deleterious effects on the package and if the external radiation levels remain within allowable limits.

- If the shielding model considers a homogenous source region rather than a detailed heterogeneous model of the contents, ensure that such an approach is justified, and verify that the homogenized mass densities are correct. Atom densities should also be confirmed if used as input to shielding calculations.

- If reduced densities are used for fissile material contents to decrease self-shielding for the sake of conservatism, ensure that the correct contribution to the sub-critical multiplication of neutrons is properly accounted for unless it has already been accounted for in the source term.
  - For example, smearing the neutron source into the CV cavity may dilute the effect of subcritical multiplication, or on the contrary, a spherical source may provide sufficient self-shielding resulting in less conservative dose rates.
  - Ensure the density of source model is input correctly in the calculational model.
  - It is common practice to define the contents materials in the radiation transport calculation such that subcritical multiplication is maximized by including only a subset of the actual makeup of the contents. This may not be the case in some spent fuel that is self-moderating such as TRIGA reactor fuel that uses uranium zirconium hydride fuel. In such cases the hydrogen should be included with the fissile material to maximize subcritical multiplication.

### 5.3.4 Shielding Evaluation

The review of the shielding evaluation presented in the SARP should consider that §71.87(j) requires actual external radiation levels to be measured prior to shipment in order to verify that the limits of §71.47 are not exceeded. Other factors that should be considered in determining the level of effort for the shielding review include the expected magnitude of the radiation levels, the margin between calculations and regulatory limits, similarity with previously reviewed packages, thoroughness of the review of source terms and other input data, and bounding assumptions in the analysis.

#### 5.3.4.1 Methods

Except in very rare instances compliance with the regulatory external radiation levels should be demonstrated by detailed calculations presented in the SARP. These can be stochastic (e.g., Monte Carlo codes like MCNP) or deterministic calculations (e.g., DORT/TORT or TWOTRAN/THREETRAN 2D/3D discrete ordinates).
Ensure that the methods used for the shielding evaluation are appropriate. Well-known computer programs should be referenced. Other codes or methods should be described in the SARP, and appropriate supplemental information should be provided. Verify that the number of dimensions of the code is appropriate for the package geometry, for example using a full 3-D code for complex geometries or those with streaming paths.

If a simpler model is used, such as for a 2-D deterministic method, ensure that it is adequate to demonstrate compliance with the regulatory limits. Ensure that the fine mesh structure used is sufficient to properly capture the geometry of the package, e.g., a R-Z model in cylindrical geometry.

Confirm that the cross-section library used by the code is applicable for the shielding calculations. Ensure that the code accounts for subcritical multiplication and secondary gamma production unless these conditions have been otherwise appropriately considered (e.g., in the source-term specification). If multi-group cross sections are used instead of continuous energy cross sections (typically used in deterministic methods), verify that the group structure used is adequate to capture effect of the spectral shape of the source.

Verify that the analysis methods, models, and software have been qualified in accordance with a risk-based program as described in the SARP Chapter 9, Quality Assurance (see Appendix D of this PRG for more details).

Recently a methodology was proposed to potentially reduce the number of calculations to demonstrate compliance with regulatory external radiation limits for isotopes that form the contents of packages. The method relies on using dose rate transfer functions that have been derived based on a unit mass of a content isotope coupled with source spectra based on a unit mass and scaling the results up to masses that would meet regulatory external radiation limits. This method is not suitable for the purposes of demonstrating compliance when mass (or curie) limits are to be established due to issues related to subcritical multiplication and self-shielding. The issues related to this method are discussed in more detail in Appendix E of this document.

Fully non-calculational means of demonstrating regulatory compliance of external radiation limits have also been presented in applications for shipping radioactive material in packages. The applications contained no shielding related calculations and instead stated that compliance would be demonstrated by measuring the dose rates prior to shipment. The USNRC issued a Regulatory Issue Summary (RIS) in 2013 clarifying its position on this approach. The RIS specifically states that the staff typically will not accept pre-shipment measurements as an appropriate §71.35(a) evaluation method for determining compliance with NCT dose rates in §71.47. The guidance explains that a package that relies completely on pre-shipment dose measurements to determine if a package meets its regulatory dose rate limits may not address the possibility of contents shifting or settling during transport, which could potentially result in an increase in package radiation levels. In addition, measurement procedures, instrument accuracy, efficiency, and calibration can vary widely. Calculating the estimated dose rates provides reasonable assurance against natural uncertainties associated with measurements,
especially for packages with small margins to the limit. Only in extremely rare cases where a bounding configuration for shielding analysis is unobtainable, this approach may be acceptable provided it meets a list of criteria listed in the RIS. In summary, this is not a method that is recommended by the USNRC to demonstrate compliance with regulatory exposure limits for packages and any exceptions are allowed only under very rare circumstances.

5.3.4.2 Input and Output Data
Verify that key input data for the shielding calculations are identified. These data will depend on the type of code (e.g., deterministic or Monte Carlo), as well as the code itself. The SARP should also include representative input files used in the analyses. Verify, as appropriate, that the information from the shielding models is properly input into the code.

At least one representative output file (or key sections of the file) should generally be included in the SARP. Ensure that proper convergence is achieved and that the calculated radiation levels in the output files agree with those reported in the text.

5.3.4.3 Flux-to-Dose-Rate Conversion
Ensure that the evaluation properly converts the gamma and neutron fluxes to dose rates. This conversion should generally use ANSI/ANS 6.1.1-1977 flux-to-dose rate conversion factors as recommended by the NRC, although other conversions may be used for point-kernel gamma calculations.

Verify the accuracy of the flux-to-dose rate conversion factors, which should be tabulated as a function of the energy group structure used in the shielding calculation.

5.3.4.4 External Radiation Levels
- Confirm that the external radiation levels under normal conditions of transport and hypothetical accident conditions agree with the summary tables 5.1 and 5.2 discussed in Section 5.3.1.3 and that they meet the limits in §71.47(a) or §71.47(b), and §71.51(a)(2), as applicable.

- Verify that the analysis shows that the locations selected are those of maximum dose rates. To determine maximum dose rates, radiation levels may be averaged over the cross-sectional area of a probe of reasonable size.\[^{5-5}\]

  - For packages with streaming paths or voids, averaging should not be used to reduce the radiation levels resulting from such features. Averaging is also not acceptable for assessing cracks, pinholes, uncontrollable voids, or other defects as required by §71.85(a).

- If stochastic methods are used, verify that the results have converged and are not biased due to the use of variance reduction techniques.

- Verify that the correct source strength is applied to the dose rate values.
For example, in stochastic methods, the typical calculation will calculate dose rates on a per source particle basis. The correct total source strength (particles/s) needs to be applied to this in order to obtain the final result.

- Verify that in cases where more than one gamma line is emitted virtually 100% of the time, for example the 1.17 and 1.33 MeV lines from Co-60, this aspect is correctly treated in the calculations.
  - For example, in a stochastic calculation this can be achieved by doubling the weight of the source particle or, alternately by post multiplying the calculated dose rates by 2.

- Ensure that the external radiation levels are reasonable and that their variations with location are consistent with the geometry and shielding characteristics of the package.
  - Confirm that the differences in the dose rates at various locations as well as under NCT and HAC make physical sense. Examine the results for large variations where they are not expected.

- Verify that the radiation levels presented in the shielding evaluation section are consistent with those in the summary table 5.2 reviewed in Section 5.3.1.3 above.

- Confirm that the evaluation addresses damage to the shielding under normal conditions of transport and hypothetical accident conditions.

- Verify that any damage under normal conditions of transport [§71.71] does not result in a significant increase in the external dose rates, as required by §71.43(f) and §71.51(a)(1). Any increase should be explained and justified as not significant. Since the regulations present this increase as significant without quantifying it, a good practice would be to limit this increase to 20%, which is consistent with the limit stipulated in the IAEA Specific Safety Requirements document, SSR-6, Section VI 624(b)[5-6]

Confirm that the appendices include a list of references, copies of applicable references if not generally available to the reviewer, justification of assumptions or analytical procedures, computer code descriptions, input and output files, flux-to-dose-rate conversion factors, and other appropriate supplemental information such as photographs and results of any tests performed on shielding features in the packaging.

### 5.4 Evaluation Findings

#### 5.4.1 Findings

The review should ensure that the information presented supports a conclusion that the regulatory requirements in Section 5.2 above are satisfied.

The Technical Review Report (TRR) should include a conclusion similar to the following:
Based on review of the statements and representations in the SARP, the staff concludes that the shielding design has been adequately described and evaluated and that the package meets the external radiation requirements of 10 CFR 71.

5.4.2 Conditions of Approval

The TRR should clearly identify any conditions of approval that should be included in the CoC. In addition to specifications of authorized contents and information specified on the SARP drawings, other conditions of approval applicable to the Shielding Evaluation chapter of the SARP may include:

- Restriction for exclusive-use shipment
- Limitations on vehicle dimensions or package position/orientation for exclusive-use shipments
- Requirement for personnel in normally occupied positions of the vehicle to wear dosimetry devices in accordance with 10 CFR 20.1502.

5.5 References


6.0 CRITICALITY REVIEW

This review verifies that the package design meets the criticality safety requirements of 10 CFR 71[6-1] under normal conditions of transport and hypothetical accident conditions.

The Criticality review is based in part on the descriptions and evaluations presented in the General Information, Structural Evaluation, and Thermal Evaluation chapters of the Safety Analysis Report for Package (SARP). Similarly, the results of the Criticality review are considered in the review of the Package Operations, the Acceptance Tests and Maintenance Program, and Quality Assurance. An example of this information flow for the Criticality review is shown in Figure 6.1.

![Diagram of Information Flow for Criticality Review]

Figure 6.1 Example of Information Flow for the Criticality Review
6.1 **Areas of Review**
The description and evaluation of the criticality design should be reviewed. The criticality review should include the following:

6.1.1 **Description of Criticality Design**
- Design Features
- Summary Table of Criticality Evaluation
- Criticality Safety Index (CSI)

6.1.2 **Fissile Material and Other Contents**

6.1.3 **General Considerations for Criticality Evaluation**
- Model Configuration
- Material Properties
- Computer Codes and Cross-Section Libraries
- Demonstration of Maximum Reactivity

6.1.4 **Single Package Evaluation**
- Configuration
- Results

6.1.5 **Evaluation of Undamaged-Package Arrays (Normal Conditions of Transport)**
- Configuration
- Results

6.1.6 **Evaluation of Damaged-Package Arrays (Hypothetical Accident Conditions)**
- Configuration
- Results

6.1.7 **Fissionable Material Packages for Air Transport**

6.1.8 **Benchmark Evaluations**
- Applicability of Benchmark Experiments
- Bias Determination

6.1.9 **Appendices**
6.2 Regulatory Requirements
Regulatory requirements of 10 CFR 71 applicable to the Criticality review of fissile material packages are as follows:

- The package design shall be described and evaluated to demonstrate that it meets the criticality requirements of 10 CFR 71. [§71.31(a)(1), §71.31(a)(2), §71.33, §71.35(a)]
- The application shall identify the established codes and standards used for the package design, fabrication, assembly, testing, maintenance, and use. In the absence of such codes, the application shall describe the basis and rationale used to formulate the quality assurance program. [§71.31(c)]
- A single package shall be subcritical under the conditions of §71.55(b), §71.55(d), and §71.55(e).
- A fissile material package design to be transported by air shall meet the requirements of §71.55(f).
- An array of undamaged packages shall be subcritical under the conditions of §71.59(a)(1).
- An array of damaged packages shall be subcritical under the conditions of §71.59(a)(2).
- A fissile material package shall be assigned a criticality safety index for nuclear criticality control to limit the number of packages in a single shipment. [§71.59(b), §71.59(c), §71.35(b)]
- The package shall be designed, constructed, and prepared for shipment so that there will be no significant reduction in the effectiveness of the packaging under the tests specified in §71.71 for normal conditions of transport. [§71.43(f), §71.51(a)(1), §71.55(d)(4)]
- Unknown properties of fissile material shall be assumed to be those that will credibly result in the highest neutron multiplication. [§71.83]

6.3 Review Procedures
The following procedures are generally applicable to the review of the Criticality Evaluation chapter of the SARP. These procedures correspond to the Areas of Review listed in Section 6.1 of this PRG.

6.3.1 Description of Criticality Design
6.3.1.1 Design Features
Review the General Information chapter of the SARP and any additional description of the criticality design presented in the Criticality Evaluation chapter. Design features important for criticality include:

- Dimensions and tolerances of the containment system for fissile material.
- Dimensions, material composition including properties and fabrication methods, and tolerances of structural components including spacers that maintain the fissile material or neutron absorber in a fixed position within the package or in a fixed position relative to
each other. Possible degradation of material properties during the package service life should be included.

- Locations, dimensions, and densities (concentration) of neutron absorbing materials and moderating materials, including neutron absorbers, and shielding.
- Dimensions and tolerances of floodable voids and flux traps (see Appendix A) within the package.
- Dimensions and tolerances of the overall package that affect the physical separation of the fissile material contents in package arrays.

Confirm that the text and sketches describing the criticality design features are consistent with the SARP drawings and the computational models used in the criticality evaluation.

6.3.1.2 Summary Table of Criticality Evaluation

Review the summary table of the criticality evaluation, which should address the following cases, as described in Sections 6.3.4 through 6.3.6:

- A single package, under the conditions of §71.55(b), §71.55(d), and §71.55(e)
- An array of undamaged packages, under the conditions of §71.59(a)(1)
- An array of damaged packages, under the conditions of §71.59(a)(2)

The results in the summary table should be consistent with the calculated CSI and demonstrate compliance with subcriticality requirements of applicable sections of 10 CFR 71. Verify that the summary table shows that the maximum multiplication factor for each case, including all uncertainties and the bias from benchmark calculations, does not exceed 0.95. (The administrative margin should be 0.05.) The table should include the number of packages evaluated and a brief description of the conditions of the package and array, as applicable. Because of the requirements of §71.43(f), the condition of an undamaged package should be that of a package subjected to the tests for normal conditions of transport.

Table 6.1 illustrates an example table summarizing calculations performed with a Monte Carlo code. The terminology for the bias and bias uncertainties in Table 6.1 is consistent with that in NUREG/CR-5661 [6-2] and NUREG/CR-6361 [6-3]. Because variations in the details of bias determination have been used over the years, the reviewer should ensure that the approach is adequately described as outlined in the ANSI/ANS 8.24 standard. (See Section 6.3.8 of this PRG).

Review of the Criticality Safety Index (CSI) for nuclear criticality control, as listed in the summary table, is discussed in Section 6.3.1.3 below.
### Table 6.1.a Example of Summary Table for Criticality Evaluations

<table>
<thead>
<tr>
<th>Type of Evaluation / Package Condition</th>
<th>Number of Packages*</th>
<th>$k + 2\sigma$ (Package or Array)</th>
<th>Bias ($\beta$)</th>
<th>Uncertainty in Bias ($\Delta\beta$)</th>
<th>$k + 2\sigma - \beta + \Delta\beta$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single Package (Description of package condition)</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Undamaged Array (Description of package condition, array configuration)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Damaged Array (Description of package condition, array configuration)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Criticality Safety Index for Nuclear Criticality Control = _______.

† Positive biases are not subtracted.
### Table 6.1.b Example of Summary Table for Criticality Evaluations

| Package calculated to be subcritical under conditions for maximum reactivity (for flooded condition) | Max. $k_{\text{eff}} = 0.\text{xyz}, \sigma = 0.\text{xyz}$, (case no. xyz) |
|---|
| Most reactive configuration |  |
| Moderation for most reactive configuration | Package flooded/partially flooded |
| Reflection for most reactive configuration | 30 cm water around the package |

**Single Package Results**

#### Array Results

| NCT Array | Max. $k_{\text{eff}} = 0.\text{xyz}, \sigma = 0.\text{xyz}$, (case no. xyz) |
|---|
| Number of packages | Integer, Infinite |
| Most reactive fissile content |  |
| Moderation for most reactive configuration, including interstitial moderation, is any |  |
| Reflection surrounding array | 30-cm water around the package array for finite array |
|  | *Not applicable for infinite array* |

| HAC Array | Max. $k_{\text{eff}} = 0.\text{xyz}, \sigma = 0.\text{xyz}$, (case no. xyz) |
|---|
| Number of packages | Integer, Infinite |
| Most reactive fissile content |  |
| Moderation to credible extent, including interstitial moderation, if any |  |
| Reflection surrounding array | 30 cm water around the package array for finite array |
|  | *Not applicable for infinite array* |

**The upper subcritical limit ($k_{\text{safe}}$) considers all biases and bias uncertainties, and a 5% minimum subcritical (administrative) margin. The $k_{\text{safe}}$ is 0.\text{xyz}.
6.3.1.3 Criticality Safety Index for Nuclear Criticality Control

Based on the number of packages demonstrated to be subcritical in the array analyses reviewed in Sections 6.3.5 and 6.3.6, verify that the SARP has determined the appropriate value of N and has calculated the CSI in accordance with §71.59. The appropriate N should be the smaller value that assures subcriticality for both 5N packages under normal conditions of transport and 2N packages under hypothetical accident conditions. The CSI shall be obtained by dividing the number 50 by the smaller of the two values derived for N in e such that CSI = 50 / N.

Note that due to round-off and differences between exclusive and nonexclusive use, N is not necessarily the number of packages that can be included in a shipment. A higher value of CSI signifies a more reactive (higher k\text{eff}) package.

Ensure that the criticality safety index is consistent with that reported in the summary table of Section 6.3.1.2 above and in the General Information chapter of the SARP. This criticality safety index is always specified in the CoC as the package criticality safety index.

The consignment shall be handled and stowed such that the total sum of CSIs in any group does not exceed 50 (for shipments on a non-exclusive use conveyance) or 100 (for shipments on an exclusive use conveyance) [§71.22(b)(3)], and such that each group is handled and stowed so that the groups are separated from each other by at least 6 m (20 ft). The intervening space between groups may be occupied by other cargo [49 CFR §176.704].

The criticality safety index (CSI) is a dimensionless number (rounded up to the first decimal place) assigned to a package containing fissile material and is used to provide control over the accumulation of packages during transportation. It is placed on the label of a fissile material package.

The regulations do not require the criticality safety evaluation to establish the minimum CSI or the maximum value of N. Consequently, the array evaluation may consider an N value appropriate for the maximum number of packages that are planned to be shipped in a consignment. Such an approach may help significantly reduce the possible arrangements to be considered and reduce not only the analysis effort but also the review effort necessary to confirm adequate subcriticality. Packages with different CSI values may be mixed in a shipment unless prohibited by exclusive use shipment requirements.

6.3.2 Fissile Material and Other Contents

Ensure that the specifications for the contents used in the criticality evaluation are consistent with those in the General Information chapter of the SARP. Specifications relevant to the criticality evaluation include fissile material mass, dimensions, enrichment or isotopic composition, physical and chemical form, density, moisture, and other characteristics depending on the specific contents. In addition, non-fissile materials, used as moderators, absorbers and impurities shall be specified. Any differences in the content specifications from those in the General Information chapter should be clearly identified and justified.

6.3.2.1 General

Specifications relevant to the criticality evaluation include fissile material mass, dimensions, enrichment or isotopic composition, physical and chemical form, density, moisture, and other
characteristics depending on the specific contents. In addition, non-fissile materials, used as moderators, absorbers and impurities shall be specified.

Since a partially filled container may allow more physical space for moderators (e.g., water), the most reactive case is not necessarily that with the maximum allowable contents.

If the package is designed for multiple types of contents, the SARP may include a separate criticality evaluation and propose different criticality controls for each contents type. Any assumptions that certain contents need not be evaluated because they are less reactive than those evaluated should be properly justified. Nuclear criticality safety calculations for each contents type should be documented in the SARP Chapter 6 or in the Chapter 6 appendices, including computer code and analysis, model verification and validations and benchmarks (see Sections 6.3.3 and 6.3.8 for further details).

6.3.2.2 Reactor Fresh or Spent Fuel

Additional details for reactor fuel assemblies and rods should include:

- Type of fuel assemblies or rods and vendor/model, as appropriate
- Dimensions/tolerances of fuel (including annular pellets), cladding, fuel-cladding gap, pitch, and rod length
- Number of rods per assembly, and locations and dimensions of guide tubes and burnable absorbers (see Section 6.3.3.2)
- Materials and densities
- Active fuel length
- Enrichment (variation by rod if applicable) before irradiation (see below)
- Chemical and physical form
- Mass of initial heavy metal per assembly or rod
- Number of fuel assemblies or individual rods per package
- Other information affecting the criticality evaluation, as applicable. For example, burnup information (if burnup credit is considered for the criticality evaluation)
- Fuel rods that have been removed from an assembly should be replaced with dummy rods that displace an equal amount of water unless the criticality analysis considers the additional moderation resulting from their absence. The requirement for dummy rods, if applicable, should be specified as a condition of approval in the CoC.

6.3.2.3 Nuclear Fuel Burnup Credit

The process of accounting for the loss of reactivity of the fuel due to irradiation, that is, taking credit in criticality analyses for the reduction in reactivity of the fuel due to burnup, is referred to as burnup credit.\textsuperscript{[6-4, 6-5]}

To date, burnup credit (to account for depletion of fissile material or increase in fission product absorber due to irradiation) has been accepted only on a very limited basis,\textsuperscript{[6-5]} which is generally
Criticality Review

The NRC did, however, issue a guidance document for burnup credit applications for transportation casks. The burnup credit license includes use of credit for actinides and fission products. The NRC has issued a revised the guidance document, Interim Staff Guidance (ISG-8, Revision 3) in 2012,[6-6] where the limits for the licensing basis are modified as follows:

- Allow for the addition of 20 actinides and fission products in the determination of burnup credit
- Extend credit to 60 gigawatt-days per metric ton uranium (GWD/MTU) assembly average burnup from the current limit of 50 GWD/MTU. The cooled out-of-reactor time period ranges from 1 and 40 years.

Approximately 75% of the reactivity reductions obtained using the new guidance are due to crediting actinide buildup and the remaining 25% to fission products.

The subject of burnup credit is complex and is continuously evolving. A detailed treatment of all aspects of the subject is beyond the scope of this guide. Several reference documents are listed in the reference section for details related to code validation, licensing basis models, and loading curves for burnup credit evaluations.[6-7, 6-8]

6.3.3 General Considerations for Criticality Evaluations

The considerations discussed below are applicable to the review of criticality evaluations of a single package and arrays of packages under normal conditions of transport and hypothetical accident conditions. General guidance for preparing criticality evaluations of transportation packages is provided in NUREG/CR-5661.[6-2]

6.3.3.1 Model Configuration

Three types of calculational models may be considered: contents models, single package model, and NCT array models and HAC array models. The contents models should include all geometric and material regions that are within the defined containment vessel. Sketches of the analytical models should be included.

Additional calculational models may be needed to describe the range of contents or the various array configurations or damage configurations that should be analyzed. An exact model of the package may not be necessary; a bounding model that can be justified as such may be adequate. Sensitivity studies should be performed and documented if there are any concerns with respect to supporting simplifications and bounding model assumptions.

The calculational models should explicitly include the physical features important to criticality safety and should be consistent with the package configurations following the tests prescribed in §71.71 and §71.73. Any differences (e.g., in dimensions, material, geometry) between the
calculational models and the actual package configurations should be identified and justify that the models are conservative. Differences between the models for NCT and HAC should be clearly identified and explained.

For each calculational model, if the simplified sketches are provided by limiting the dimensional features, multiple sketches are needed, with each sketch building on the previous one. If two- or three-dimensional figures of the model generated by the calculational software used for some or all of the sketches, the dimensions need to be clearly verified on the figure or in a table that accompanies the figure. The SARP drawings should identify the materials used in all regions of the model. Any differences between the model and the actual package configuration should be identified and justified.

Examine the Structural and Thermal Evaluation chapters of the SARP to determine the effects of the normal conditions of transport and hypothetical accident conditions on the packaging and its contents. Verify that the models, used in the criticality evaluation, are consistent with these effects and with the SARP drawings. Differences should be identified and justified. Within the specified tolerance range, dimensions should be selected to result in the highest reactivity. Coordinate with the Structural and Thermal reviews as appropriate.

The criticality section of the SARP should address dimensional tolerances of the packaging, including components containing neutron absorbers. When developing the calculational models, tolerances that tend to add conservatism (i.e., produce higher $k_{eff}$ values) should be included.

Subtracting the minus tolerance from the nominal wall thickness of the overpack should be conservative for array calculations and have no significant effect on the single-package calculation.

Review the configuration and dimensions of the contents and packaging used in the criticality models. For some types of packagings and contents (e.g., powders), the contents can be positioned at various locations with different densities. The relative location and physical properties of the contents within the packaging should be justified as those that result in the maximum reactivity. Dimensional tolerances, e.g., for cavity sizes and neutron absorber thickness, should be considered in the manner which maximizes reactivity.

Ensure that the SARP considers deviations from nominal design configurations in the manner that maximizes reactivity. Examples of such deviations include:

- Dimensional tolerances, e.g., for cavity sizes and neutron absorber thickness
- Off-centered positioning of contents within the containment vessel or spent-fuel basket
- Off-centered positioning of basket or containment vessel within the package
- Preferential flooding of regions within the package
- Fully-load versus Partial-loaded configurations
- Contents under NCT and HAC conditions.
Determine if the SARP includes any specifications regarding the condition of the contents. If the contents permit damaged fuel, the maximum extent of damage should be specified and addressed in the criticality analyses, as appropriate. Additional information on canning of damaged fuel is discussed in Section 4.3.1.5 of this PRG.

The contents of some packages (e.g., fuel assemblies) may be in the form of a finite lattice. With current computational capability, homogenization of the fissile region should generally be avoided. If a homogenized configuration is used, the SARP should demonstrate its appropriateness (e.g., by comparing $k_{\text{eff}}$ of heterogeneous and homogeneous models and by consistently evaluating benchmark experiments).

Verify that the SARP considers deviations from nominal design configurations. For example, the fuel assemblies might not always be centered in each basket compartment, and the basket might not be exactly centered in the package. In addition to a fully flooded package, the SARP should address preferential flooding as appropriate. This includes flooding of the fuel-cladding gap and other regions (e.g., flux traps) for which water density might not be uniform in a flooded package. A single contents model that will encompass different loading configurations should be considered only if the justification is clear and straightforward. Packages that transport isotopic waste containing fissile material should ensure that the limiting concentration and/or mix of fissile material is used in the safety analysis.

Due to the difficulty with assuring homogeneity of neutron absorbers for all package conditions, the NRC has historically only allowed 75% of the minimum neutron absorber content specified in the package design drawings to be "credited" in the safety analyses.

In short, the description of the contents, packaging, containment vessel, and the effects due to appropriate testing should be used to formulate the package models needed for the analysis of criticality safety to demonstrate regulatory compliance with the 10 CFR Part 71 requirements.

6.3.3.2 Material Properties
Verify that the appropriate mass densities and atom densities are provided for materials used in the models of the packaging and contents. Material in each region, the density of the material, the constituents of the material, the weight percent and atom density of each constituent should be identified. The source of all density values should be reported and should be from design specifications or standard references when possible. Compositional differences and variation should be discussed and justified. Material properties should be consistent with the condition of the package under the tests of §71.71 and §71.73, and any differences between normal conditions of transport and hypothetical accident conditions should be addressed.

Ensure that materials relevant to the criticality design (e.g., neutron absorbers, foams, plastics, and other hydrocarbons) are properly specified and the data sources referenced. Verify that materials will not degrade during the service life of the packaging. No more than 75% of the specified minimum neutron absorber concentration (or equivalent density of the absorber material) in packaging components or in unirradiated contents should generally be considered in the criticality evaluation. A percentage of neutron absorber material greater than 75% may be considered in the analysis only if comprehensive acceptance tests have been done to verify the presence of the absorber and its uniformity.
No credit should be taken for burnable absorbers in irradiated contents (e.g., spent fuel, except some form of Gd credit in some cases in BWR fuel assemblies, and burnup credit [actinide and fission products] in some PWR assemblies). Unknown properties of fissile material shall be assumed to be those that will credibly result in the highest neutron multiplication, §71.83.

Review materials to identify any criticality properties that could degrade during the service life of the packaging. Such information should also be discussed in more detail in the Acceptance Tests and Maintenance Program or Operating Procedures sections of the SARP.

6.3.3.3 Computer Codes and Cross-Section Libraries
Verify that any codes or standards applicable to the criticality design of the package are identified and appropriate, including those for material specifications and fabrication. Ensure that such codes and standards are consistent with those specified in the General Information, Structural, and Thermal Evaluation chapters of the SARP. Determine if these codes or standards specify temperature limits for materials.

If codes, standards, or similar documents that provide subcritical limits are used in the criticality evaluation, ensure that the conditions specified in those documents are applicable to a package or array of packages under normal conditions of transport and hypothetical accident conditions.

Confirm that an appropriate computer code (or other acceptable method) is used for the criticality evaluation. Well-known codes should be clearly referenced. Other codes or methods should be described in the SARP, and appropriate supplemental information should be provided.

Ensure that the criticality evaluations use an appropriate cross-section library. If multi-group cross sections are used, confirm that the neutron spectrum of the package has been appropriately considered and that the cross sections are properly processed to account for resonance absorption and self-shielding. Additional information regarding cross-sections is provided in ORNL/M-5003[6-9] and NUREG/CR-6686.[6-10]

Confirm that the computer code has been properly used in the criticality evaluation. Key input data for the criticality calculations should be identified. Depending on the code used, these data include number of neutrons per generation, number of generations, convergence criteria, mesh selection, etc. The SARP should include at least one representative input file for a single package, undamaged array, and damaged array evaluation. Verify, as appropriate, that the information from the criticality model, material properties, and cross-sections is properly input into the code.

An output file (or key sections) should generally be included in the SARP for each representative input file. Ensure that the calculations have properly converged and that the calculated multiplication factors from the output files agree with those reported in the evaluation. Verify that the analysis methods, models, and software have been qualified in accordance with a risk-based quality assurance program, as described in Chapter 9 (see Appendix D of this PRG for more details).

The review should generally include a detailed confirmatory analysis of the criticality calculations reported in the SARP. As a minimum, perform an independent calculation of the
most reactive case, as well as sensitivity analyses to confirm that the most reactive case has been correctly identified. To the extent practical, use an independent model of the package and a different code and cross-section set from that of the SARP evaluation.

6.3.3.4 Demonstration of Maximum Reactivity
Verify that the analyses evaluate the most reactive configuration of each case listed in Section 6.3.1.2 (single package, array of undamaged packages, and array of damaged packages). Assumptions and approximations should be clearly identified and justified.

Ensure that the analysis determines the optimum combination of internal moderation (within the package) and interspersed moderation (between packages), as applicable. Interspersed moderation between packages from mist, rain, snow, foam, flooding, etc., should not be considered for package array. Confirm that preferential flooding of different regions within the package, including the fuel-cladding gap, is considered as appropriate. Consider varying degrees of moderation by water and packaging materials. All credible combinations of moderator density and spacing variation that may cause a higher $k_{\text{eff}}$ value should be considered and a discussion should be provided in the SARP demonstrating that the maximum $k_{\text{eff}}$ value has been determined.

Care should be taken so that the most reactive array configuration has been considered. An array arrangement that minimizes the surface-to-volume ratio typically decreases leakage and would tend to maximize $k_{\text{eff}}$. This requirement typically means trying to arrange the array such that the array is as close to a cuboid as possible. However, the improved neutron interaction between packages that can often be realized by arranging packages in a triangular pitch complicates the number of possible arrangements that may need consideration. As noted in Section 6.3.2, the maximum allowable fissile material is not necessarily the most reactive contents, because partial fissile loading may permit introduction of additional moderator.

Additional guidance on determining the most reactive configurations is presented in NUREG/CR-5661 and in Sections 6.3.4 to 6.3.6 below.

6.3.4 Single Package Evaluation

6.3.4.1 Configuration
Ensure that the criticality evaluation analyzes a single package under the most reactive condition of §71.55(d) (normal conditions of transport) and §71.55(e) (hypothetical accident conditions), with water moderation as required by §71.55(b). The evaluations should consider:

- Fissile material in its most reactive credible configuration consistent with the condition of the package and the chemical and physical form of the contents.
- Water moderation to the most reactive credible extent, including water inleakage to the containment system.
- Evaluate variations of flooding of packaging outside containment.
- Ensure fissionable content is still optimally moderated.
• Full water reflection (30 cm) on all sides of the package, including close reflection of the containment system or reflection by the package materials, whichever is more reactive.

• Implicit in §71.55(b) is that the single package shall be evaluated with containment flooding, even if it is considered leak tight, unless the special exemption in §71.55(e) is invoked.

• If necessary, create a simplified single damaged model with most reactive combinations of contents, containment systems.

• If package uses neutron absorbers, Chapter 6 should specifically address post-testing condition of absorbers and potential reduction in neutron absorber effectiveness, if any.

Verify that the package also meets the specifications of §§71.55(d)(2) through 71.55(d)(4) under normal conditions of transport. Coordinate with the Structural review.

6.3.4.2 Results
Confirm that most reactive single-package conditions are evaluated and that the results are consistent with the information presented in the summary table discussed in Section 6.3.1.3. If the package is shown to be subcritical by reference to a standard such as ANSI/ANS 8.1 [6-11] in lieu of calculations, verify that the standard is applicable to the package conditions.

6.3.5 Evaluation of Undamaged-Package Arrays (Normal Conditions of Transport)

6.3.5.1 Configuration
Ensure that the criticality evaluation analyzes an array of 5N undamaged packages. N cannot be less than 0.5. The evaluation should consider:

• The most reactive configuration of the array (e.g., pitch, package orientation, and shape of the array) with nothing between the packages (no interstitial moderators).

• The most reactive credible configuration of the packaging and its contents under normal conditions of transport. If the evaluation of the water spray test has demonstrated that water would not leak into the package, water inleakage need not be assumed.

• Full water reflection (30 cm) on all sides of a finite array.

• Look at various array arrangements, depending on the shape of the package. For example, for cylindrical packages, evaluate square pitched and hexagonally close packed arrays.

• Look at varying the numbers of rows, columns, and layers to maximize $k_{eff}$.

• In general, a roughly cubic shaped array should be optimal.

6.3.5.2 Results
Confirm that the most reactive array conditions are evaluated and that the results of the analysis are consistent with the information presented in the summary table discussed in Section 6.3.1.3.
6.3.6 Evaluation of Damaged-Package Arrays (Hypothetical Accident Conditions)

6.3.6.1 Configuration

Ensure that the criticality evaluation analyzes an array of 2N damaged packages. N cannot be less than 0.5. The evaluation should consider:

- The most reactive configuration of the array (e.g., pitch, package orientation, internal moderation, and shape of the array).
- Include all HAC array variations
- Simplifications which are conservative
- Optimum interspersed hydrogenous moderation
- Full water reflection on all sides of a finite array
- The most reactive credible configuration of the packaging and its contents under hypothetical accident conditions
- Optimal spacing of packages (or multiple contents within a package). Increasing separation and adding water between packages may raise $k_{eff}$
- Optimal density for water between packages
- Results showing $k_{eff}$ as a function of water density and spacing
- Note: The most reactive package conditions may not be the same for single packages and arrays of packages.

The analysis of arrays of damaged packages should generally assume water inleakage into the individual packages (including the containment vessel). Demonstrating that an array of leaking packages remains subcritical is more straightforward than designing and demonstrating that a package does not leak. The immersion test of §71.73(c)(5) is not required if water inleakage is assumed in the criticality analysis.

If the array analysis assumes that water does not leak into the packages in arrays, the SARP should clearly justify the basis for that assumption, and the package evaluation should adequately demonstrate that the package can reliably exclude water when it is subjected to the hypothetical accident condition tests in §71.73. The justification for neglecting water inleakage should show, at a minimum, that:

- No inleakage of water occurs when the package is subjected to the immersion tests of §§71.73(c)(5) and 71.73(c)(6)
- The testing or analysis clearly demonstrates that the most unfavorable conditions for water inleakage have been addressed (e.g., initial test conditions, orientations for drop, crush, puncture, fire, and water immersion tests)
- The package is designed and fabricated in accordance with accepted codes and standards
- If the package is evaluated by analysis, the design margin is in accordance with these codes and standards. If the package is evaluated by testing, the effects of the tests on the
condition of the package can be consistently reproduced and demonstrate an adequate margin of safety

- The quality and characteristics of the tested package are representative of, and no better than, actual packages fabricated in accordance with the design specifications
- The design leakage rate for the package is sufficient to preclude water inleakage under both normal conditions of transport and hypothetical accident conditions
- The package is maintained and periodically inspected to ensure that its performance during its service life is representative of the package evaluated in the application. Fabrication, maintenance, and periodic leakage tests are conducted in accordance with ANSI N14.5.[6-12]
- The package is tested prior to each shipment to show that the leakage rate is less than that which would allow inleakage of water
- The sensitivity of the criticality analysis to water inleakage is addressed as appropriate. For example, would water inleakage into most packages in a large array be required before criticality could be achieved, or would an array with only a few leaking packages be critical?
- Any other issues relevant to reliably precluding water inleakage are addressed as appropriate.

6.3.6.2 Results
Confirm that the most reactive array conditions are evaluated and that the results of the analysis are consistent with the information presented in the summary table discussed in Section 6.3.1.3.

6.3.7 Fissile Material Package for Air Transport

6.3.7.1 Fissile Material (except Plutonium) Package for Air Transport
For packages designed to transport fissile material by air, ensure that the SARP addresses the requirements in §71.55(f), Special Requirements for Fissile Material Package Designs to be Transported by Air. Specifically, ensure that the package is designed and constructed, and its contents limited so that it would be subcritical, assuming reflection by 20 cm of water but no water inleakage, when subject to the sequential application of the following tests:

- The free drop test in §71.73(c)(1);
- The crush test in §71.73(c)(2);
- The puncture test, as specified in § 71.55(f)(1)(iii);
- Thermal test, as in §71.73(c)(4), but with a test duration of 60 minutes rather than 30 minutes; and
- The impact test, where the package impacts an unyielding surface at a velocity of 90 m/s, as specified in §71.55(f)(2). (A separate undamaged package can be used for this evaluation.)
6.3.7.2 Plutonium Package Air Transport

Although this PRG does not contain detailed guidance for the evaluation of packages designed for air transport of Type B quantities of plutonium, the requirements for packages containing Type A quantities of plutonium are summarized, and the regulatory framework for packages containing Type B quantities of plutonium are given below for completeness.

In addition to the requirements in §71.55(f) for subcriticality for packages designed for the air transport of fissile material, for packages designed to transport plutonium by air, ensure that the requirements of §71.88, Air Transport of Plutonium, are satisfied. Specifically, for packages containing plutonium that are intended to be transported by air, ensure that:

- The plutonium is contained in a medical device designed for individual human application [§71.88(a)(1)]; or
- The plutonium is contained in a material in which the specific activity is less than or equal to the activity concentration values for plutonium specified in Appendix A, Table A-2, of 10 CFR 71, and in which the radioactivity is essentially uniformly distributed [§71.88(a)(2)]; or
- The plutonium is shipped in a single package containing no more than an A₂ quantity of plutonium in any isotope or form, and is shipped in accordance with § 71.5 [§71.88(a)(3)]; or
- The plutonium is shipped in a package specifically authorized for the shipment of plutonium by air in the Certificate of Compliance. In addition, the licensee shall, through special arrangement with the carrier, require compliance with 49 CFR 175.704, U.S. Department of Transportation regulations applicable to the air transport of plutonium [§71.88(a)(4)].

For packages designed to transport plutonium by air, ensure that the package is subjected to the more severe and expanded accident conditions in 10 CFR 71.74, Accident Condition for Air Transport of Plutonium. Specifically, ensure that the package has been tested to the following conditions in the order indicated to determine their cumulative effect:

- Impact at a velocity of not less than 129 m/sec (422 ft/s) [§71.74 (a)(1)]
- A static compressive load of 31,800 kg (70,000 lbs) applied in the orientation expected to result in maximum damage at the conclusion of the test sequence [§71.74 (a)(2)]
- Puncture tests [§71.74 (a)(3) and §71.74 (a)(4)]
- Fire test from a pool fire for a period of 60 minutes [§71.74 (a)(5)]
- Immersion under at least 0.9 m (3 ft) of water [§71.74 (a)(6)]

Also, ensure that the package is subjected to the individual free-fall impact test as specified in §71.74(b)(1) and §71.74(b)(2), and the individual deep submersion test of an undamaged package subjected to an external water pressure of at least 4 MPa (600 lbs/in²) [§71.74(c)].
Ensure that a single package and an array of packages are demonstrated to be subcritical, except that the damaged condition of the package shall be considered to be that which results from the plutonium accident tests in §71.74, rather than the hypothetical accident tests in §71.73.

Additionally, for packages designed to transport plutonium by air and are subject to §71.88(a)(4), in addition to the requirements in §71.41 through §71.63, as applicable, ensure that the requirements in §71.64, *Special Requirements for Plutonium Air Shipments*, are satisfied. Specifically, ensure that for a package subject to §71.88(a)(4) is designed, constructed, and prepared for shipment so that under the tests specified in §71.74, *Accident Conditions for Air Transport of Plutonium*, that:

- The containment vessel would not be ruptured in its post-tested conditions, and the package must provide a sufficient degree of containment restricted accumulated loss of plutonium contents to not more than an $A_2$ quantity in a period of 1 week,
- The external radiation level would not exceed 1 rem/hour at a distance of 1 meter (40 in.) from the surface of the package in its post-tested condition in air, and
- A single package and an array of packages are demonstrated to be subcritical in accordance with §71.64, except that the damaged condition of the package must be considered to be that which results from the plutonium accident in §71.74, rather than the hypothetical accident test in §71.73.

6.3.8 Benchmark Evaluations

Ensure that the computer codes for criticality calculations are benchmarked against critical experiments. Verify that the analysis of the benchmark experiments uses the same computer code, computer hardware, and cross-section library as those used to calculate the $k_{\text{eff}}$ values for the package.

Additional guidance on benchmarking of nuclear criticality codes is provided in NUREG/CR-6361.[6-13] Numerous well-documented benchmark experiments have been published by the Nuclear Energy Agency, Organization for Economic Co-Operation and Development.[6-13]

6.3.8.1 Applicability of Benchmark Experiments

Review the general description of the benchmark experiments and confirm that they are appropriately referenced.

Verify that the benchmark experiments are applicable to the actual packaging design and contents. The benchmark experiments should have, to the maximum extent possible, the same materials, neutron spectra, and configuration as the package evaluations. Key package parameters that should be compared with those of the benchmark experiments include type of fissile material, enrichment, moderator-to-fissile ratio, neutron absorber, and configuration. Confirm that differences between the package and benchmarks are identified and properly considered.

In addition, the SARP should address the overall quality of the benchmark experiments and the uncertainties in experimental data (e.g., mass, density, dimensions). Ensure that these
uncertainties are treated in a conservative manner, i.e., they result in a lower multiplication factor for the benchmark experiment.

6.3.8.2 Bias Determination
Examine the results of the calculations for the benchmark experiments and the method used to account for biases, including the contribution from uncertainties in experimental data.

Ensure that a sufficient number of applicable benchmark experiments are analyzed and that the results of these benchmark calculations are used to determine an appropriate bias for the package calculations. Statistical and convergence uncertainties of both benchmark and package calculations should be addressed. Confirm that the benchmark evaluations address trends in the bias with respect to parameters such as moderator-to-fissile ratio, pitch-to-rod diameter, assembly separation, neutron absorber material, etc.

As an integral part of the code validation effort, the range of applicability for the established bias and uncertainty should be defined. The SARP should demonstrate that, considering both NCT and HAC, the package is within this range of applicability, or the SARP should define the extension of the range necessary to include the package. The range of applicability should be defined by identifying the range of important parameters and/or characteristics for which the code was (or was not) validated.

For validation using critical experiments, the bias in the calculational method is the difference between the calculated $k_{\text{eff}}$ value of the critical experiment and unity (1.0, although experimental errors and the use of extrapolation may be taken into consideration). Typically, a calculational method is deemed to have a positive bias if it overpredicts the critical condition (i.e., calculated $k_{\text{eff}} > 1.0$) and a negative bias for if it underpredicts the critical condition (i.e., calculated $k_{\text{eff}} < 1.0$). Positive biases should not be used to reduce the calculational uncertainty.

The SARP should demonstrate that the calculational method (codes and cross-section data) used to establish criticality safety has been validated against measured data that can be shown to be applicable to the package design characteristics.

The validation process should provide a basis for the accuracy of the calculational method and should enable designers and reviewers to have assurance that the $k_{\text{eff}}$ for the package will not exceed the upper subcritical limit. An upper subcritical limit for the package should be determined based on the established bias and bias uncertainties and a margin of subcriticality.

Unfortunately, it is unlikely that the complete combination of package characteristics will be found from available critical experiments, and critical experiments for large arrays of packages do not currently exist. Thus, the applicant should model a sufficient variety of critical experiments in order to adequately demonstrate that the calculational method correctly predicts $k_{\text{eff}}$ for each individual experiment that has characteristics that are also judged to be important to the $k_{\text{eff}}$ of the package (or array of packages) under normal and accident conditions.

The validation process will establish an appropriate bias and bias uncertainty for the calculation method used for the criticality safety analysis. The bias and bias uncertainty are subtracted from
the limit to generate an upper subcritical limit (USL) for the single package and package array calculations. The SARP should clearly describe how the bias and bias uncertainty are used.

The critical experiments that are selected should be briefly described in the SARP with references provided for detailed descriptions. The criticality safety analyst should consider three general sources of uncertainty: uncertainty in the experimental data; uncertainty in the calculational method; and uncertainty due to the calculational models. Thus, these uncertainties will be inherently included in the bias and the uncertainty in the bias.

There are many methods and codes used to calculate bias and bias uncertainty. Some examples are: NUREG/CR-6698,\textsuperscript{[6-15]} USLSTATS (using SCALE),\textsuperscript{[6-3]} and Whisper (sensitivity/uncertainty based methodology using MCNP).\textsuperscript{[6-14]} The validation study should describe (i.e., either directly or by reference) the method used to calculate the bias and bias uncertainty.

In addition, an appropriate administrative margin for the package ($\Delta k_m$) should be used. A 5\% $\Delta k_{\text{eff}}$ is typical for SARP NCS evaluation work,\textsuperscript{[6-21]} but maybe excessive for many package designs. Additional information on determining biases and their range of applicability is provided in NUREG/C R-5661,\textsuperscript{[6-2]} NUREG/CR-6361,\textsuperscript{[6-3]} and NUREG/CR-6698,\textsuperscript{[6-15]} and ANSI/ANS 8.24.\textsuperscript{[6-16]}

6.3.9 Appendices
Confirm that the appendices include a list of references, copies of applicable references if not generally available to the reviewer, justification of assumptions or analytical procedures, test results, photographs, computer code descriptions, input and output files, test results, and any other appropriate supplemental information.

6.4 Evaluation Findings
6.4.1 Findings
The review should ensure that the information presented supports a conclusion that the regulatory requirements in Section 6.2 above are satisfied.

The Technical Review Report (TRR) should include a conclusion similar to the following:

Based on review of the statements and representations in the SARP, the staff concludes that the nuclear criticality safety design has been adequately described and evaluated and that the package meets the nuclear criticality safety requirements of 10 CFR 71.

6.4.2 Conditions of Approval
The TRR should clearly identify any conditions of approval that should be included in Section 5 of the CoC. In addition to specifications of authorized contents and information specified on the engineering drawings, other conditions of approval applicable to the Criticality Evaluation of the SARP may include:

- Minimum CSI
- Restriction for exclusive-use shipment
• Requirement to have specific neutron absorbers in place
• Requirement to replace vacant positions in fuel assemblies with dummy rods
• Specification of the allowed extent of damage for spent fuel.
• The mass of unidentified constituents shall be assumed to be fissile and counted against the allowable limit of fissile material in the package.

6.5 References


7.0 PACKAGE OPERATIONS REVIEW

This review verifies that the operating controls and procedures for the package meet the requirements of 10 CFR 71[7-1] and are adequate to assure that the package will be operated in a manner consistent with its evaluation for approval.

The Package Operations chapter of the SARP should establish the minimum steps necessary to assure safe performance of the package under normal conditions of transport and hypothetical accident conditions. Detailed procedures, or procedures unrelated to the safe operation of the package, should not be included. Commitments specified in the Package Operations chapter of the SARP are typically included by reference into the Certificate of Compliance (CoC) as conditions of package approval. Consequently, operating procedures in the SARP cannot be site-specific.

The Package Operations review is based in part on the descriptions and evaluations presented in the General Information, Structural Evaluation, Thermal Evaluation, Containment, Shielding Evaluation, and Criticality Evaluation chapters of the SARP. Similarly, results of the Package Operations review are considered in the Acceptance Tests and Maintenance Program review and in the Quality Assurance program review. An example of the information flow for the Package Operations review is shown below in Figure 7.1.

Because the Package Operations chapter of the SARP addresses information relevant to other SARP chapters, it should be reviewed by all review team members.

7.1 Areas of Review

All operations should be reviewed to assure that the package will be operated in a manner consistent with its evaluation for approval. The Package Operations review should include the following:

7.1.1 Package Loading
- Preparation for Loading
- Loading of Contents
- Preparation for Transport

7.1.2 Package Unloading
- Receipt of Package from Carrier
- Removal of Contents from the Package

7.1.3 Preparation of Empty Package for Transport

7.1.4 Other Operations

7.1.5 Appendices
7.2 Regulatory Requirements

Regulatory requirements of 10 CFR 71 applicable to the Package Operations review are as follows:

- The application shall identify the established codes and standards used for the package design, fabrication, assembly, testing, maintenance, and use. In the absence of such codes, the application shall describe the basis and rationale used to formulate the quality assurance program. [§ 71.31(c)]
• The application shall include any special controls and precautions for transport, loading, unloading, and handling of a fissile material shipment, and any special controls in case of accident or delay. [§71.35(c)]

• The transport index of a package in a nonexclusive-use shipment shall not exceed 10, and the sum of the Criticality Safety Indices (CSI) of all packages in the shipment shall not exceed 50. [§71.47(a), §71.59(c)(1)]

• Packages that require exclusive-use shipment because of increased radiation levels shall be controlled by providing written instructions to the carrier. [§71.47(b-d)]

• The sum of the CSIs for nuclear criticality control of all packages in an exclusive-use shipment shall not exceed 100. [§71.59(c)(2)]

• The application shall include Package Operations that ensure that the package meets the routine-determination requirements of §71.87. [§71.81, §71.87]

• Unknown properties of fissile material shall be assumed to be those that will credibly result in the highest neutron multiplication. [§71.83]

• A package shall be conspicuously and durably marked with the model number, serial number, gross weight, and package identification number. [§71.85(c), §71.19(a)(2), §71.19(b)(3)]

• Prior to delivery of a package to a carrier, any special instructions needed to safely open the package shall be provided to the consignee for the consignee’s use in accordance with 10 CFR 20.1906(e). [§71.89]

• Each type B(U) or Type B(M) package design shall have on the outside of the outermost receptacle a fire resistance radiation symbol in accordance with 49 CFR 172.310(d).

7.3 Review Procedures
The following procedures are generally applicable to the review of the Package Operations chapter of the SARP. These procedures correspond to the Areas of Review listed in Section 7.1 of this PRG.

The Package Operations in the SARP should generally be listed in sequential order. Additional guidance on Package Operations is provided in NUREG/CR-4775.[7-2]

7.3.1 Package Loading
7.3.1.1 Preparation for Loading
Review the procedures for preparing the package for loading. At a minimum, the procedures should:

• Specify that the package should be loaded and closed in accordance with written procedures
• Describe any special controls and precautions for handling
• Verify that the package is in unimpaired physical condition and that all required periodic maintenance has been performed
• Ensure that the package is conspicuously and durably marked with the model number, serial number, gross weight, and package identification number
• Determine that the package is proper for the contents to be shipped, including the need for canning of damaged fuel or for a second containment vessel, if applicable
• Ensure that the use of the package complies with all other conditions of approval in the CoC.

7.3.1.2 Loading of Contents
Review the procedures for loading the contents. At a minimum, the procedures should:

• Identify any special handling equipment needed
• Describe any special controls and precautions for loading
• Verify that the package is in unimpaired condition
• Indicate the method of loading the contents
• Ensure that any required moderator or neutron absorber is present and in proper condition
• Describe the method to remove water from the package, as appropriate
• Identify any requirement to vent gases from the package or add fill gas, as appropriate
• Ensure that each closure device of the package, including seals and gaskets, is properly installed, secured, and free of defects
• Verify that the bolt torques described in the procedures are consistent with those shown on the drawings
• Confirm that the package has been loaded and closed appropriately.

7.3.1.3 Preparation for Transport
Review the procedures for preparing the package for transport. At a minimum, the procedures should:

• Ensure that non-fixed (removable) radioactive contamination on external surfaces is as low as reasonably achievable, and, depending on the availability, within the limits specified in Appendix D to 10 CFR 835, or 49 CFR 173.443, whichever is more appropriate
• Describe the radiation survey requirements to confirm that the allowable external radiation levels specified in §71.47 are not exceeded
• Describe the temperature survey requirements, as applicable, to verify that limits specified in §71.43(g) are not exceeded
• Specify the assembly verification leakage rate and ensure package closures are leak tested in accordance with ANSI N14.5[7-3]
• Ensure that any system for containing liquid is properly sealed and has adequate space or other specified provision for expansion of the liquid
• Verify that any pressure relief devices are set, and operable, as appropriate
• Ensure that any structural components that could be used for lifting or tie-down during transport are rendered inoperable for those purposes unless it meets the design requirements of §71.45
• Ensure that the tamper-indicating device(s) is/are installed
• Specify the attachment of impact limiters, personnel barriers, or similar devices as applicable
• Describe, for a fissile material shipment, any special controls and precautions for transport, loading, unloading, and handling and any appropriate actions in case of an accident or delay which should be provided to the carrier or consignee
• Identify any special controls which should be provided to the carrier for a package shipped by exclusive use under the provisions of §71.47(b)(1)(2)(3)(4)
• Identify any special controls which should be provided to the carrier for a fissile-material package in accordance with §71.35(c)
• Describe any special instructions that should be provided to the consignee for opening the package
• Ensure that the CSI for each package and the sum of the CSIs for the shipment are appropriate for the type of shipment as appropriate.

7.3.2 Package Unloading

7.3.2.1 Receipt of Package from Carrier
Review the procedures for receiving the package. At a minimum, the procedures should:

• Ensure that the package is examined for visible damage, status of the tamper-indicating device, surface contamination, and external radiation levels
• Describe any special actions to be taken if the package is damaged, if the tamper-indicating device is not intact, or if surface contamination or radiation survey levels are too high
• Identify any special handling equipment needed
• Describe any proposed special controls and precautions for handling and unloading.

7.3.2.2 Removal of Contents
Review the procedures for removing the contents. At a minimum, the procedures should:

• Describe the appropriate method to open the package
• Identify the appropriate method to remove the contents
• Ensure that the contents are completely removed.
7.3.3 Preparation of Empty Package for Transport

Review the procedures for preparing an empty package for transport. At a minimum, the procedures should:

- Verify that the package is empty
- Ensure that the packaging is marked and labeled as appropriate.
- Ensure that external surface contamination levels meet the requirements specified in Appendix D to 10 CFR 835 or 49 CFR 173.443
- Ensure that the internal surface contamination levels meet the requirements specified in 49 CFR 173.428
- Describe the package closure requirements
- Identify any other special controls or procedures as appropriate.

7.3.4 Other Operations

Confirm that the SARP identifies any other operational controls, as applicable. For example, some packages have special conditions, such as a maximum allowable shipping duration due to potential generation and accumulation of hydrogen or other flammable gas.

7.3.5 Appendices

Confirm that the appendices include a list of references, copies of applicable supporting documents, references, or specifications, if not generally available to the reviewer, test results, and any additional supplemental information, such as post-load leakage test procedure, as appropriate.

7.4 Evaluation Findings

7.4.1 Findings

The review should ensure that the information presented supports a conclusion that the regulatory requirements specified in Section 7.2 above are satisfied.

The Technical Review Report (TRR) should include a conclusion similar to the following:

Based on review of the statements and representations in the SARP, the staff concludes that the package operations described meet the requirements of 10 CFR 71 and are adequate to assure that the package will be operated in a manner consistent with its evaluation for approval.

7.4.2 Conditions of Approval

The TRR should clearly identify any conditions of approval that should be included in the CoC. The entire Package Operations chapter of the SARP is typically included by reference into the CoC as a condition of the package approval.
7.5 Reference


8.0 ACCEPTANCE TESTS AND MAINTENANCE PROGRAM REVIEW

This review verifies that the acceptance tests for the package meet the requirements of Subpart G of 10 CFR 71[8-1] and that the maintenance program is adequate to assure package performance during its service life.

The Acceptance Tests and Maintenance Program chapter of the Safety Analysis Report for Package (SARP) should establish the minimum steps necessary to assure that the package will perform throughout its service life in the manner in which it was evaluated. Detailed procedures or site-specific requirements should not be included. The procedures shall be prepared in accordance with the applicable SARP chapters. Commitments specified in the Acceptance Tests and Maintenance Program chapter of the SARP are typically included in the Certificate of Compliance (CoC) as conditions of package approval. The acceptance tests and the maintenance program shall be conducted in accordance with the Quality Assurance program described in Chapter 9 of the SARP. The acceptance test and maintenance criteria should be established according to the risk-based evaluation of components established in the Chapter 9 Q-list.

The Acceptance Tests and Maintenance Program review is based in part on the descriptions and evaluations presented in previous chapters of the SARP. Similarly, the results of this review are considered in the Quality Assurance review. In addition, the review of other chapters of the SARP may depend on the Acceptance Test and Maintenance Program review (e.g., operating procedures for leakage testing prior to shipment may depend on the maintenance leakage test). An example of the information flow for this review is shown in Figure 8.1.

Because the Acceptance Tests and Maintenance Program chapter of the SARP addresses information relevant to other SARP chapters, it should be reviewed by all review team members.

8.1 Areas of Review

The description of the acceptance tests and maintenance program should be reviewed. The review should include:

8.1.1 Acceptance Tests

- Visual Inspections and Measurements
- Weld and Component Nondestructive Examinations (NDE)
- Structural and Pressure Tests
- Leakage Tests
- Component and Material Tests
- Shielding Tests
- Thermal Tests
- Miscellaneous Tests
8.1.2 Maintenance Program

- Structural and Pressure Test
- Leakage Tests
- Component and Material Tests and Nondestructive Examination
- Thermal Tests
- Miscellaneous Tests

8.1.3 Appendices
8.2 Regulatory Requirements

Regulatory requirements of 49 CFR Part 172 and 10 CFR 71 applicable to the Acceptance Tests and Maintenance Program review are as follows:

8.2.1 Acceptance Tests

- The applicant shall identify the location, on the outermost receptacle (i.e., on the outside of the package), where the package has been plainly marked with a trefoil radiation symbol that is resistant to the effects of fire and water. [49 CFR 172.310(d)]

- The application shall identify the established codes and standards used for the package design, fabrication, assembly, testing, maintenance, and use. In the absence of such codes, the application shall describe the basis and rationale used to formulate the quality assurance program. [§71.31(c)]

- The applicant shall describe the quality assurance program for the design, fabrication, assembly, testing, maintenance, repair, modification, and use of the proposed package. [§71.37(a)]

- The applicant shall identify any specific provisions of the quality assurance program that are applicable to the particular package design under consideration, including a description of the leak testing procedures. [§71.37(b)]

- Before first use, each packaging shall be inspected for cracks, pinholes, uncontrolled voids, or other defects that could significantly reduce its effectiveness. [§71.85(a)]

- Before first use, if the maximum normal operating pressure of a package exceeds 35 kPa (5 psi) gauge, the containment system of each packaging shall be tested at an internal pressure at least 50% higher than maximum normal operating pressure to verify its ability to maintain structural integrity at that pressure. [§71.85(b)]

- Before first use, each packaging shall be conspicuously and durably marked with its model number, serial number, gross weight, and a package identification number. [§71.85(c)]

- Before first use, the fabrication of each packaging shall be verified to be in accordance with the approved design. [§71.85(c)]

- The applicant shall perform any tests deemed appropriate by the certifying authority. [§71.93(b)]

8.2.2 Maintenance Program

- The application shall identify the established codes and standards used for the package design, fabrication, assembly, testing, maintenance, and use. In the absence of such codes, the application shall describe the basis and rationale used to formulate the quality assurance program. [§71.31(c)]

- The applicant shall describe the quality assurance program for the design, fabrication, assembly, testing, maintenance, repair, modification, and use of the proposed package. [§71.37(a)]
The packaging shall be maintained in unimpaired physical condition except for superficial defects such as marks or dents. [§71.87(b)]

The presence of any moderator or neutron absorber, if required, in a fissile material package shall be verified prior to each shipment. [§71.87(g)]

The applicant shall perform any tests deemed appropriate by the certifying authority. [§71.93(b)]

Each type B(U) or Type B(M) package design shall have on the outside of the outermost receptacle a fire resistance radiation symbol in accordance with 49 CFR 172.310(d).

8.3 Review Procedures

The following procedures are generally applicable to the review of the Acceptance Tests and Maintenance Program chapter of the SARP. These procedures correspond to the Areas of Review listed in Section 8.1 of this PRG.

8.3.1 Acceptance Tests

Verify that the following tests, as applicable, are to be performed prior to the first use of each package. Information presented on each test should include a description of the test and its acceptance criteria as appropriate. Applicable sections of the quality assurance program and procedures may be referenced if applicable.

Each package shall be fabricated and assembled in accordance with the SARP drawings listed in the CoC. Verify that required packaging fabrication acceptance tests and examinations/inspections will be specified in the procurement documents and are typically performed by the Supplier, in accordance with a risk-based quality assurance program approved by the Design Authority. A manufacturing and inspection plan (MIP) developed by the Supplier typically is required, and will be verified, reviewed, and approved by the Design Agency. All personnel performing acceptance tests and examinations shall be certified/qualified in accordance with national consensus standards referenced in the SARP. Additional guidance on acceptance testing (gamma/neutron shielding, criticality control, and thermal testing) is provided in Section 3.2 of NUREG/CR-3854.[8-2]

8.3.1.1 Visual Inspections and Measurement

Ensure that inspections, test, and measurements are performed to verify that the packaging has been fabricated and assembled in accordance with the SARP drawings. Dimensions and tolerances specified on the drawings should be confirmed by measurement.

8.3.1.2 Weld and Component Nondestructive Examinations (NDE)

Verify that welding and component NDE acceptance criteria are specified to verify fabrication in accordance with the codes and/or standards cited in the SARP. Location, type, and size of the welds should be confirmed by visual examination and measurement. For weld surface and volumetric integrity, nondestructive examination and acceptance criteria should be verified as appropriate. For Class 1 containment applications, verify that the required NDE of the product forms has been completed and complies with the applicable consensus standards (for example, the NDE and acceptance criteria of base metal per the ASME B&PV Code, Section III, applicable paragraphs of article NB-2000). Weld and Component NDE personnel shall be
qualified in accordance with the applicable requirements of the referenced codes and/or standards as described in the SARP drawings and the QA Program (see Chapter 9 of the SARP). Additional guidance on weld and examination criteria is provided in NUREG/CR-3019.[8-3]

8.3.1.3 Structural and Pressure Tests
Verify that the structural or pressure tests are identified and described. Such tests should comply with §71.85(b), as well as applicable codes or standards specified in the SARP (e.g., in the Structural Evaluation chapter).

8.3.1.4 Leakage Tests
Verify that the containment system of the packaging will be subjected to the fabrication leakage test specified in ANSI N14.5.[8-4] Verify that all closures, including drains and vents, are leak-tested. The acceptable leakage criterion should be consistent with that identified in the Containment chapter of the SARP.

8.3.1.5 Component and Material Tests
8.3.1.5.1 Component Tests
Confirm that appropriate tests and acceptance criteria are specified for components that affect package performance. Examples of such components include seals, gaskets, valves, fluid transport systems, and rupture disks or other pressure-relief devices. Components should be tested to meet the performance specifications shown on the SARP drawing of the package. When tests adversely affect the continued performance of a component (e.g., rupture disks), applicable quality assurance procedures should be described to justify that the tested component is equivalent to the component that will be used in the packaging.

8.3.1.5.2 Material Tests
Verify that methods are in place to demonstrate that the materials meet the specifications shown on the SARP drawing of the package. Ensure that material examinations are performed in accordance with the codes and/or standards specified. Confirm that appropriate tests and acceptance criteria are documented for special procedures specified in the SARP for non-code materials. Tests for neutron absorbers (e.g., boron, gadolinia) and insulating materials (e.g., foams, fiberboard) should assure that minimum specifications for density and composition are achieved.

8.3.1.6 Shielding Tests
Ensure that appropriate shielding tests are specified for both neutron and gamma radiation. The tests and acceptance criteria should be sufficient to assure that no defects, voids, or streaming paths exist in the shielding.

8.3.1.7 Thermal Tests
Verify that appropriate tests are specified to demonstrate the heat transfer capability of the packaging. These tests should confirm that the heat transfer performance documented in Chapter 3, determined in the evaluation, is achieved in the fabrication process.
8.3.1.8 Miscellaneous Tests
Verify that any additional tests are described, as applicable, to demonstrate that the package has been fabricated in accordance with its approved design. Confirm that tests specified in the SARP are sufficient to meet the requirements of §71.85(a) and (b). Verify that after the acceptance tests are completed, the package will be durably marked in accordance with §71.85(c).

8.3.2 Maintenance Program
Confirm that the maintenance program is adequate to assure that packaging effectiveness is maintained throughout its service life. Verify that the Owner shall adhere to a maintenance program that conforms to all applicable paragraphs of this section. The User shall verify by direct inspection or review of QA records compliance with the requirements presented in this Section prior to package loading. Maintenance tests and inspections should be described with schedules for each test, inspection, or replacement of parts and criteria for minor refurbishment and replacement of parts, as applicable.

8.3.2.1 Structural and Pressure Tests
Verify that any periodic structural or pressure tests are identified and described. Such tests would generally be applicable to codes, standards, or other procedures specified in the SARP.

8.3.2.2 Leakage Tests
Confirm that the containment system of the packaging will be subjected to the periodic and maintenance leakage rate tests specified in ANSI N14.5.[8-4] The acceptable leakage rate criterion should be consistent with that identified in the Containment chapter of the SARP. Ensure that replacement schedules for seals are described, as appropriate.

8.3.2.3 Component and Material Tests
8.3.2.3.1 Component Tests
Verify that periodic tests and replacement schedules for components are described, as appropriate. Elastomeric seals should generally be replaced and leak tested within the 12-month period prior to shipment. Metallic seals are generally replaced prior to each shipment.

8.3.2.3.2 Material Tests
Confirm that the SARP identifies any process or component that could result in deterioration of packaging materials, including loss of neutron absorbers, reduction in hydrogen content of shields, density changes or long-term degradation of insulating materials and shock-absorbing materials, and degradation of closure systems. Appropriate tests and their acceptance criteria to ensure packaging effectiveness for each shipment should be specified.

8.3.2.4 Thermal Tests
Verify that periodic tests to assure the heat transfer capability during the service life of the packaging are described. Tests similar to the acceptance tests discussed in Section 8.3.1.7 may be applicable. The typical interval for periodic thermal tests is five years.
8.3.2.5 Miscellaneous Tests
Confirm that any additional tests are described, as applicable, to demonstrate that the package will perform throughout its service life in accordance with its approved design.

8.3.3 Appendices
Confirm that the appendices include a list of references, copies of applicable references, if not generally available to the reviewer, test results, and any additional supplemental information, as appropriate. Detailed specifications for acceptance tests that have been developed by the applicant for specific components should be included in an appendix (see Appendix C for guidance regarding acceptance test development for state-of-the-art and emerging technologies).

8.4 Evaluation Findings
8.4.1 Findings
The Technical Review Report (TRR) should include a finding similar to the following:

    Based on review of the statements and representations in the SARP, the staff concludes that the acceptance tests for the packaging meet the requirements of 10 CFR 71, and that the maintenance program is adequate to assure packaging performance during its service life.

8.4.2 Conditions of Approval
The TRR should clearly identify any conditions of approval that should be included in the CoC. The entire Acceptance Tests and Maintenance Program chapter of the SARP is typically included by reference into the CoC as a condition of package approval.

8.5 References


9.0 QUALITY ASSURANCE REVIEW

This review verifies that the applicant has a quality assurance (QA) program that meets the requirements of 10 CFR 71.10-11 and that specific QA requirements for the package are adequate to assure that it is designed, purchased, fabricated, inspected, assembled, handled, tested, cleaned, stored, used, maintained, modified, and repaired in a manner consistent with its evaluation in the Safety Analysis Report for Package (SARP).

The QA chapter of the SARP shall assure that adequate control is provided over all activities important to safety. The review focuses on two specific areas: (1) the applicant’s QA program (QAP) and (2) package-specific QA requirements applicable to all organizations that perform activities with the proposed package. Because the applicant’s QA program description presented in the SARP is site-specific, it cannot be referenced in the Certificate of Compliance (CoC) as a condition of approval. Package-specific QA requirements, however, are appropriate for all organizations and should be included as conditions of approval in the CoC. Note that Section 4 of the certificate specifies that package approval is also conditional on the fulfillment of the applicable QA requirements of 49 CFR Parts 100-185 and 10 CFR 71, Subpart H. Verify that Chapter 9 reports the status of approval of the QAP by the DOE HQ Certifying Official.

In addition to the QA program requirements in Subpart H (Quality Assurance), 10 CFR 71 includes other quality-related provisions in Subpart D (Application for Package Approval), Subpart E (Package Approval Standards), Subpart F (Package, Special Form, and LSA-III Tests), and Subpart G (Operating Controls and Procedures). Consequently, other SARP chapters also address quality-related requirements, many of which are incorporated as conditions of approval in the CoC. For example, the SARP drawings in the General Information chapter include dimensions and reference to applicable paragraphs of codes and/or standards for specification of fabrication and material requirements. Also, the requirements for operation, acceptance testing/maintenance are specified in the Package Operations chapter and in the Acceptance Tests and Maintenance Program chapter, respectively. The Structural, Thermal, Containment, Shielding, and Criticality Evaluation chapters may specify codes, standards, or other Quality Assurance/Quality Control (QA/QC)-related requirements that affect the package design, and the evaluation of the package design in these chapters addresses those components of the packaging that are important to safety. An example of the information flow for the QA review is shown in Figure 9.1.

Since the QA chapter of the SARP addresses information relevant to other SARP chapters, it should be reviewed by all review team members.

9.1 Areas of Review

The applicant’s QA program description and package-specific QA requirements should be reviewed. The QA review should include the following:

9.1.1 Description of Applicant’s QA Program
- Scope
- Program Documentation and Approval
• Summary of 18 Quality Criteria
• Code and Standards used to quantify the quality control requirements for Systems, Structures and Components (SSCs) [9-2]
• Cross-Referencing Matrix

![Figure 9.1 Example of Information Flow for the Quality Assurance Review](image)

9.1.2 Package-Specific QA Requirements
- Risk-Based Graded Approach for Structures, Systems, and Components (SSCs) Important to Safety
- Summary of Package-Specific QA/QC Criteria and Package Activities

9.1.3 Appendices

9.2 Regulatory Requirements
Regulatory requirements of 10 CFR 71 applicable to the QA review are as follows:

- The application shall describe the quality assurance program for the design, fabrication, assembly, testing, maintenance, repair, modification, and use of the package. [§71.31(a)(3), §71.37]
- The application shall identify established codes and standards proposed for the package design, fabrication, assembly, testing, maintenance, and use. In the absence of any codes and standards, the application shall describe the basis and rationale used to formulate the package quality assurance program. [§71.31(c)]
• Package activities shall be in compliance with the quality assurance requirements of Subpart H (§71.101-§71.137). A graded approach is acceptable. [§71.101(b)]

• Sufficient written records shall be maintained to furnish evidence of the quality of the packaging. These records include results of the determinations required by §71.85; design, fabrication, and assembly records; results of reviews, inspections, tests, and audits; results of maintenance, modification, and repair activities; and other information identified in §71.91(d). Records shall be retained for three years after the life of the packaging. [§71.91(b)]

• Records identified in §71.91(a) shall be retained for three years after shipment of radioactive material.

• Records shall be available for inspection. Records are valid only if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated. [§71.91(c)]

• Any significant reduction in the effectiveness of a packaging during use shall be reported to the certifying authority. [§71.95(a)(1)]

• Details of any defects with safety significance in a package after first use, with the means employed to repair the defects and prevent their reoccurrence, shall be reported. [§71.95(a)(2), §71.95(c)(4)]

• Instances in which a shipment does not comply with the conditions of approval in the CoC shall be reported to the certifying authority. [§71.95(a)(3)]

9.3 Review Procedures

The following procedures are generally applicable to the review of the QA chapter of the SARP. These procedures correspond to the Areas of Review listed in Section 9.1 of this PRG.

9.3.1 Description of Applicant’s QA Program

9.3.1.1 Scope

Confirm that the SARP identifies those safety-related package activities for which the applicant has QA responsibility. The formal structure of the QA organization shall be documented, as well as each function and assignment of responsibilities. Safety-related “Q-Items” shall be identified for package SSC’s. The level of QA effort necessary for each SSC should be summarized in a table of the required level of effort relative to implementation of each of the eighteen Subpart H QA criteria. QA activities may include design, procurement, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification. The roles and responsibilities of the applicant Design Authority and Design Agency should be documented. Applicants should be considered responsible if they perform, contract, or otherwise oversee the activity. Although applicants are typically responsible for package design, responsibility for other activities may be assigned to other organizations. For example, the applicant may design, fabricate, assemble, and perform acceptance testing of a package, but another DOE organization may assume responsibility for its use, periodic inspection, and maintenance.
9.3.1.2  Program Documentation and Approval

Verify that the applicant has an approved QA program applicable to packaging. This will likely be an “umbrella” program that provides QA requirements for all quality-related packaging activities (i.e., not specific to the package submitted for approval). This program will likely supplement the applicant’s overall site QA program. The QAP documentation should assure that written procedures, manuals, and instructions apply to all safety-related Q-activities. The SARP should specify QA program documentation by title, number, revision, and date. The approving organization, document, and date of approval should also be identified. An example of a matrix/cross-walk comparing the eighteen elements of Subpart H with a ten element QA program, including procedures, is provided in Quality Assurance Guidance for Packaging of Radioactive and Fissile Materials.\textsuperscript{9-3}

Although DOE organizations are generally required to comply with DOE O 414.1 D* and 10 CFR 830 Subpart A, QA programs for packages shall also comply with 10 CFR 71, Subpart H (and other applicable subparts). The SARP should explicitly state that the QA program complies with Subpart H. Justification for this compliance, if not cited in the approval documentation, should be presented as discussed below. In general, a QA program for packages approved under American Society of Mechanical Engineers (ASME) NQA-1\textsuperscript{9-4} or Appendix B of 10 CFR Part 50,\textsuperscript{9-5} will meet the requirements of Subpart H.

In addition to an umbrella QA program, the applicant will need to develop detailed QA procedures specific to the package proposed in the SARP. Depending on the applicant’s scope of responsibility, these procedures might address design, testing, implementation of material and fabrication requirements, control of vendor activities, acceptance tests, maintenance and operational requirements, and record keeping. The SARP should describe existing package-specific procedures and documentation.

9.3.1.3  Summary of 18 Quality Criteria

The level of detail reviewed in this section depends on the type of approval applicable to the applicant’s QA program. For example, if the applicant has a QA program that has been approved as meeting the requirements of Subpart H by DOE, significantly less review will be necessary than if the program is approved only in accordance with DOE O 414.1 D or 10 CFR 830 Subpart A. In general, programs based solely on these documents will require supplementation in order to address all Subpart H requirements.

Verify that the SARP demonstrates compliance with each of the 18 criteria of Subpart H (§71.103 to §71.137) appropriate to the scope of the applicant’s responsibilities, as reviewed in Section 9.3.1.1 above. Guidance on evaluating these criteria is provided in Regulatory Guide 7.10.\textsuperscript{9-2}

If the applicant’s QA program for packaging augments a site program based on DOE O 414.1 D or 10 CFR 830, Subpart A, the SARP should demonstrate compliance with the 18 criteria of Subpart H. The review should specifically address compliance with the requirement for audits (§71.137).

\textsuperscript{*} Earlier versions of DOE O 414.1 x may still be applicable because of contractual relationships.
9.3.1.4 Cross-Referencing Matrix

Confirm that the SARP provides a cross-referencing matrix that demonstrates that each of the 18 criteria is addressed by the applicant’s QA Program and written procedures. An example of such a matrix is presented in Table 1 of the NRC Regulatory Guide 7.10, *Format for Listing Implementing Procedures*. Because of the inter-relationship of the 18 criteria in Subpart H, more than one quality procedure will generally be applicable to each criterion.

Since information presented on the applicant’s QA program is both site-specific and subject to modification, it cannot be incorporated directly as a condition of package approval in the CoC. Site-specific methods of accomplishing tasks and implementing quality cannot generally be imposed on other organizations involved with the packaging. Similarly, a revision to the site QA program, a site organizational change, or renumbering of the QA program documentation should not necessitate a revision of the SARP. The requirement for the applicant to maintain an appropriate QA program is specified in Section 4 of the Certificate of Compliance. Additionally, compliance with packaging-specific QA requirements in Chapter 9 of the SARP is typically included by reference into the CoC as a condition of package approval.

9.3.2 Package-Specific QA/QC Requirements

The SARP should describe QA requirements for the proposed package. Requirements should be based on a risk-based graded approach, considering the importance to safety of package structures, systems, components (SSCs), and activities. The review shall address controls necessary for design, fabrication, examination, procurement, handling, storage, cleaning, assembly, testing, use, operations, maintenance, and repair to assure that the package will meet the requirements of 10 CFR 71 during its service life. Importance to safety should be based primarily on the ability of the package to provide:

- Containment of radioactive material
- Subcriticality of fissile material
- Shielding of radiation.

The risk-based graded approach shall consider the complexity and proposed use of the package and its components. In addition to the impact of malfunction or failure of the item to safety, the following additional factors should be considered in the graded approach, as described in §71.105(c):

- Design and fabrication complexity or uniqueness of the item
- Need for special controls and surveillance over processes and equipment, which are typically documented during fabrication by the supplier’s Manufacturing and Inspection Plans (MIP)
- Degree to which functional compliance can be demonstrated by examination, inspection, or test
- Quality history and degree of standardization of the item.
9.3.2.1 Risk-Based Graded Approach for Structures, Systems, and Components Important to Safety

Verify that the SARP provides a package-specific listing (Q-List) of all structures, systems, and components (SSCs) important to safety and that these SSCs are consistent with the parts list or similar information presented in the SARP drawings. Justification should be provided for any item identified on the drawings but not defined as important to safety in the Q-list. Some items not listed on the Q-list, such as adhesives, greases, tapes, etc. may cause problems to Q-items due to materials degradation issues, i.e., outgassing of detrimental gasses, such as chlorides. For these items it must be demonstrated that potential compatibility issues are discussed in the appropriate SARP chapter, with referenced specifications included in an appendix. For non-Q-items that may adversely affect Q-items, a summary compatibility table should be provided in Chapter 9.

Confirm that the SARP identifies a quality category (e.g., A, B, C) for each SSC important to safety and that these categories are appropriately defined. Ensure that the assigned categories are properly justified based on their definition, the package type, and the safety function of each SSC. Coordinate with the review of other SARP chapters as appropriate. Appendix A of NRC Regulatory Guide 7.10 provides guidance on defining quality categories and QA requirements. Definitions of typical categories and representative safety classifications for SSCs of transportation packages are also presented in Table 2 and Table 5, respectively, of NUREG/CR-6407.[9-6]

In some cases, commercial grade items and services are used for quality Categories A and B structures, systems, and components. The commercial grade item and service dedication process should be described in the SARP. Refer to ASME NQA-1, Parts 1 and 2 for further guidance on commercial grade dedication. Additionally, the DOE has developed some guidance documents on commercial grade dedication.[9-7, 9-8, 9-9] For control of state-of-the-art fabrication processes that may not be covered by consensus standard approved specifications, (i.e. ASME B&PV Code), specifications should be developed and documented in the SARP, as has been described in Chapter 1 and Appendix C.

9.3.2.2 Package-Specific QA/QC Criteria and Package Activities

Verify that the SARP addresses each of the 18 quality criteria in Subpart H as they apply to the proposed package. The SARP should identify for each criterion, as applicable, the appropriate level of QA/QC effort for package activities based on their importance to safety. Guidance on QA requirements applicable to each category is provided in Appendix A of Regulatory Guide 7.10. Other guidance is presented in Chapter 4 of NUREG/CR-6407, which also describes typical design and fabrication records maintained for each QA category. Table 9.1 below identifies typical levels of QA effort for each of the 18 criteria of Subpart H that should be considered in the review, based on quality category. Note that the omission of Category C items from QA effort may not be appropriate if they involve a condition of approval specified in the CoC. The QA program user shall establish measures to ensure that activities important to safety are accomplished using appropriate production and test equipment, suitable environmental conditions, applicable codes and standards, and proper work instructions. The QA program user should also document the assignment of responsibilities for each task and method used to verify conformance to these quality requirements.
Table 9.1 Typical Level of QA/QC Effort by Quality Category and Applicable QA Element

<table>
<thead>
<tr>
<th>QA Element/Level of Effort</th>
<th>Category A</th>
<th>Category B</th>
<th>Category C</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. QA Organization</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Responsibility established</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Authority and duties written</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>QA functions executed</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Reporting levels clearly defined</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Independence from cost and schedule assured</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>2. QA Program</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Procedures written</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Activities affecting quality controlled</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Risk-based Graded approach established</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Indoctrination and training provided</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>3. Package Design Control</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Most stringent codes and standards</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Codes and standards</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Prototype test and/or analysis</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Formal design review</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Internal peer review</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Software QA</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Commercial off-the-shelf items</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Conditions of approval controlled</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>4. Procurement Document Control</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Traceability</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Qualified vendor lists</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Suppliers required to meet Subpart H</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Commercial off-the-shelf items</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Dedicated process documented for commercial grade items and services</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>
Table 9.1 Typical Level of QA/QC Effort by Quality Category and Applicable QA Element (continued)

<table>
<thead>
<tr>
<th>QA Element/Level of Effort</th>
<th>Category A</th>
<th>Category B</th>
<th>Category C</th>
</tr>
</thead>
<tbody>
<tr>
<td>5. Instructions, Procedures, and Drawings</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Written and documented</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Quantitative acceptance criteria</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Changes to conditions of approval listed in certificate are controlled</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>6. Document Control</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Controlled issue</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Controlled changes</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>7. Control of Purchased Material, Equipment, and Services</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Source evaluation and selection</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Inspection at contractor</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Formal receiving inspection</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Audits or surveillance at vendor plants</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Evidence of QA at contractor</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Objective proof that all specifications are met</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Commercial grade item/services dedication</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Incoming inspection for damage only</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Identification and Control of Materials, Parts, and Components</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive identification and traceability</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Identification and traceability to heats, lots, or other groupings</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Identification in SARP drawings</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>9. Control of Special Processes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fabrication, Welding, and NDE performed with qualified/certified personnel and procedures</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Qualification records and training of personnel</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Specified critical operations by qualified personnel</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>No special processes</td>
<td></td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>
### Table 9.1  Typical Level of QA Effort by Quality Category and Applicable QA Elements

<table>
<thead>
<tr>
<th>QA Element/Level of Effort</th>
<th>Category A</th>
<th>Category B</th>
<th>Category C</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>10. Internal Inspection</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Documented inspection of all specifications</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Process monitoring required by quality control personnel</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Examination, measurement, or test of material or processed product to assure quality</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Inspectors independent of those performing operations</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Qualified inspectors only</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Visual receiving inspection only</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td><strong>11. Test Control</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Written test program</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Written test procedures</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Documentation of testing and evaluation</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Observation/documentation of supplier acceptance tests/inspections as appropriate</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>No documentation of physical tests required</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td><strong>12. Control of Measuring and Test Equipment</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tools, gauges, and instruments in formal calibration program</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Only qualified inspectors</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td><strong>13. Handling, Storage, and Shipping Control</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Written plans and procedures</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Routine handling</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td><strong>14. Examination, Test, and Operating Status</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Individual items identified as to status or condition</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Status indicated by stamps, tags, labels, etc.</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Nondestructive examination (NDE) and acceptance criteria per SARP drawings</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Visual inspection only</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td><strong>15. Nonconforming Materials, Parts, or Components</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Written procedures to prevent inadvertent use</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Nonconformance documented and closed</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Disposal (scrap) without records</td>
<td></td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>
Table 9.1  Typical Level of QA Effort by Quality Category and Applicable QA Elements (continued)

<table>
<thead>
<tr>
<th>QA Element/Level of Effort</th>
<th>Category A</th>
<th>Category B</th>
<th>Category C</th>
</tr>
</thead>
<tbody>
<tr>
<td>16. Corrective Action</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Conditions adverse to quality identified and corrected</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Root cause and corrective action documented</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Safety significant events reported</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>17. QA Records</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Design and use records</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Results of reviews, inspections, tests, audits, surveillances, and materials analysis</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Personnel qualifications</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Records of design, fabrication, acceptance testing, and maintenance retained for life of package plus 3 years</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Shipping records retained for 3 years after shipment</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Records managed by a written procedure for retention and disposal</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Special Form Qualification Report</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>18. Audits</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Written plan of periodic audits</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Implementation by written procedures</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Lead auditor qualified per NQA-1</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>All auditors qualified</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>

In discussing the 18 quality criteria and the general areas illustrated in Table 9.1, the SARP should also identify specific QA requirements applicable to:

- Material specifications
- Fabrication specifications
- Package operations
- Acceptance tests
- Maintenance program
- Package records.

Requirements for many fabrication processes (e.g., welding, brazing, heat treating, and nondestructive examination) are often included in the code or standard used for design and fabrication (and specified on the SARP drawings), and special processes (e.g., additive
manufacturing, pouring lead or resin shielding, flow forming, applying special coatings, and injecting foam, etc.) are generally specified by more detailed procedures (see Appendix C for guidance of documentation recommendations) developed by the applicant, to ensure that the process is appropriately controlled. Similarly, many material requirements may be specified by codes or standards, but some components (e.g., neutron absorbers, honeycomb, or special foams) may need to be specified by other means.

Quality assurance requirements for all Package Operations and Acceptance Tests/Maintenance Program presented in the SARP should be addressed as appropriate. Because the procedures and tests specified in the Package Operations chapter and Acceptance Tests and Maintenance Program chapter are those important to the safe operation and performance of the package throughout its service life, each activity described in these chapters of the SARP should be subject to the quality assurance requirements of Subpart H, including (but not limited to) written procedures, training of personnel, fabrication records, including QA sign-off/dates at key witness/hold points, reviews, documentation, nonconformance control, record retention, and audits. Justification should be provided for any activity presented in these chapters that is not subject to Subpart H QA requirements.

Verify that the SARP identifies package records that affect quality. General requirements for package records are specified in §71.91 and §71.135. General guidance and examples on types of records that should be retained for each quality category is provided in Chapter 4 of NUREG/CR-6407.[9-6] Retention periods for records should be consistent with the requirements of §71.91.

The review should also address reporting requirements of §71.95. The QA program should ensure that occurrences of these events are reported to the DOE Headquarters Certifying Official (HCO).

9.3.3 Appendices
Confirm that the appendices include a list of references, copies of appropriate references not generally available to the reviewer, audit results, documentation of the QA of the software and analyses supporting the SSC’s, and other appropriate supplemental information (See Appendices C and D and NUREG/BR-0167[9-10] for recommendation of key information supporting the Design/Analysis and fabrication found in Chapters 2, 3, 5, and 6).[9-11] Detailed QA procedures should not be provided in the SARP but should be summarized and described in a table and may be requested during the SARP review.

9.4 Evaluation Findings
9.4.1 Findings
The reviewer should ensure that the information presented supports a conclusion that the regulatory requirements in Section 9.2 above are satisfied.

The TRR should include a conclusion similar to the following:

Based on review of the statements and representations in the SARP, the staff concludes that the quality assurance program has been adequately described and meets the quality assurance requirements of 10 CFR 71.
9.4.2 Conditions of Approval

The Technical Review Report (TRR) should clearly identify any conditions of approval that should be included in the CoC. In addition to information specified on the SARP drawings, package operations, and acceptance tests/maintenance program, other conditions of approval that may be applicable to the Quality Assurance chapter of the SARP include those items discussed in Section 9.3 above.

Care should be taken to ensure that conditions of approval apply to all organizations that may be involved in package activities. Conditions of approval should not include site-specific requirements or procedures.
9.5 References


APPENDIX A: DEFINITIONS

A1 The maximum activity of special form radioactive material permitted in a Type A package. [10 CFR 71.4]

A2 The maximum activity of radioactive material, other than special form, low specific activity, and surface contaminated object material, permitted in a Type A package. [10 CFR 71.4]

Breached Spent Fuel Rod Spent fuel rod with cladding defects that permit the release of gas from the interior of the fuel rod. A breached spent fuel rod may also have cladding defects sufficient to permit the release of fuel particulate. A breach may be limited to a pinhole leak, hairline crack, or may be a gross breach.

Can for Damaged Fuel A metal enclosure that is sized to confine one damaged spent fuel rod or assembly. A fuel can for damaged spent fuel with damaged spent-fuel assembly contents must satisfy fuel-specific and system-related functions for undamaged SNF required by the applicable regulations.

Carrier A person engaged in the transportation of passengers or property by land or water as a common, contract, or private carrier, or by civil aircraft. [10 CFR 71.4]

Certificate Holder A person who has been issued a Certificate of Compliance or other package approval. [10 CFR 71.4]

Certificate of Compliance A certificate issued by DOE approving for use, with specified limitations, a specific package. Certificates of compliance are also issued by NRC.

Close Reflection by Water Immediate contact by water of sufficient thickness for maximum reflection of neutrons. [10 CFR 71.4]

Closed Transport Vehicle A transport vehicle or conveyance equipped with a securely attached exterior enclosure that during normal transportation restricts the access of unauthorized persons to the cargo space containing the Class 7 (radioactive) materials. The enclosure may be either temporary or permanent, and in the case of packaged materials may be of the “see-through” type, and shall limit access from the top, sides, and bottom. [49 CFR 173.403]

Commercial Grade Dedication A process whereby an item or service that performs a nuclear safety function, that was not manufactured, developed, or performed under a qualified ASME NQA-1 Quality Assurance Program shall be dedicated in accordance with the requirements of ASME NQA-1-1a-2009, Subpart 2.14 or NQA-1-2004 with current NQA-1 addenda, to provide reasonable assurance that the item or service will successfully perform its intended safety function in accordance with the requirements of NQA-1.

Confirmatory Analysis Use of alternate calculations/methods to verify correctness of the original calculations or analyses.
<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contamination</td>
<td>Presence of a radioactive substance on a surface in quantities in excess of $0.4 \text{ Bq/cm}^2 (1 \times 10^{-5} \mu\text{Ci/cm}^2)$ for beta and gamma emitters and low toxicity alpha emitters, or $0.04 \text{ Bq/cm}^2 (1 \times 10^{-6} \mu\text{Ci/cm}^2)$ for all other alpha emitters.</td>
</tr>
<tr>
<td>Consignment</td>
<td>Each shipment of a package or groups of packages or load of radioactive material offered by a shipper (consignor) for transport. [10 CFR 71.4]</td>
</tr>
<tr>
<td>Containment System</td>
<td>The assembly of components of the packaging intended to retain the radioactive material during transport. [10 CFR 71.4]</td>
</tr>
<tr>
<td>Conveyance</td>
<td>For transport by public highway or rail, any transport vehicle or large freight container; for transport by water, any vessel or any hold, compartment, or defined deck area of a vessel, including any transport vehicle on board the vessel; and for transport by aircraft, any aircraft. [10 CFR 71.4]</td>
</tr>
<tr>
<td>Criticality Safety Index</td>
<td>The dimensionless number (rounded up to the next tenth) assigned to and placed on the label of a fissile material package, to designate the degree of control of accumulation of packages containing fissile material during transportation [§10CFR71.4].</td>
</tr>
<tr>
<td>Damaged Spent Nuclear Fuel</td>
<td>Fuel with known or suspected cladding defects greater than a hairline crack or a pinhole leak. In general, any fuel rod or fuel assembly that cannot fulfill its fuel-specific or system-related functions.</td>
</tr>
<tr>
<td>Design Authority</td>
<td>The Design Authority is responsible for the following:</td>
</tr>
<tr>
<td></td>
<td>- Developing, documenting, or modifying package designs and developing, conducting, and documenting the prototype tests</td>
</tr>
<tr>
<td></td>
<td>- Establishing and maintaining the SARP drawings and any package modification records</td>
</tr>
<tr>
<td></td>
<td>- Reviewing and approving all changes to and final acceptance of the package design</td>
</tr>
<tr>
<td></td>
<td>- Securing regulatory concurrence of the SARP and CoC</td>
</tr>
<tr>
<td></td>
<td>- The above activities may be delegated as long as the Design Authority retains the oversight responsibilities.</td>
</tr>
<tr>
<td>Design Agency</td>
<td>The Design Agency is responsible for the following activities:</td>
</tr>
<tr>
<td></td>
<td>- Procurement, fabrication, handling, shipping, storage, cleaning, assembly, periodic inspection, acceptance testing, maintenance, repair, and modification of the packages</td>
</tr>
</tbody>
</table>
• Ensuring that the required tests demonstrate a package design that meets the applicable regulations

• Performing confirmatory engineering analyses and evaluations of the package design features and modifications as required for compliance with applicable regulations or site package safety basis documents

• Reviewing and approving all design changes affecting safety, configuration, and functionality that are defined in the SARP, before requesting approval from the design authority

• Reviewing the package’s safety-related items (i.e., Q-list) and the appropriate level of quality assurance/quality control to meet the determined risk-based quality assurance levels according to the NRC Regulatory Guides

Exclusive Use  The sole use by a single consignor of a conveyance for which all initial, intermediate, and final loading and unloading are carried out in accordance with the direction of the consignor or consignee. The consignor and the carrier shall ensure that any loading or unloading is performed by personnel having radiological training and resources appropriate for safe handling of the consignment. The consignor shall issue specific instructions, in writing, for maintenance of exclusive use shipment controls, including the vehicle survey requirement of § 173.443(c) as applicable, and include them with the shipping paper information provided to the carrier by the consignor. [10 CFR 71.4]

Floodable voids and flux traps  The flux trap or floodable void concept is used for designing the spent fuel basket/cask.

Spent fuel baskets constructed of square tubes with boron neutron absorber sheets may not provide sufficient neutronic isolation to adjacent fuel cells because boron is a thermal neutron absorber and fast neutrons can pass unhindered between adjacent cells.

One method of improving the neutron capture capability of a boron neutron-absorber material is to insert gaps between two sheets of neutron-absorber material. Neutron-absorber panels are placed on either side of the water gap to establish the flux trap. One approach to providing a gap is to insert structural spacers between adjacent tubes.

When the cask basket is filled with water during loading and unloading or in a hypothetical accident scenario, the gap between neutron-absorber sheets contains water, which moderates neutrons. The moderated neutrons are slowed to energies which may be captured by boron plates, thus causing the absorption of greater numbers of neutrons and improving the neutronic
isolation of adjacent fuel cells. The water gap, sandwiched between two neutron absorber sheets, is often called a "flux trap" because the neutron flux is reduced in the water gap.

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fissile Material</td>
<td>Plutonium-239, plutonium-241, uranium-233, uranium-235, or any combination of these radionuclides. Unirradiated natural uranium and depleted uranium, and natural uranium or depleted uranium that has been irradiated in thermal reactors only are not included in this definition. Certain exclusions from fissile material controls are provided in 10 CFR 71.15. [10 CFR 71.4]</td>
</tr>
<tr>
<td>Fissile Material Package</td>
<td>A fissile material packaging together with its fissile material contents. [10 CFR 71.4]</td>
</tr>
<tr>
<td>Low Specific Activity Material</td>
<td>Radioactive material with limited specific activity that satisfies the descriptions and limits specified in 10 CFR 71.4.</td>
</tr>
<tr>
<td>Maximum Normal Operating</td>
<td>The maximum gauge pressure that would develop in the containment system in a period of one year under the heat condition specified in 10 CFR 71.71(c)(1), in the absence of venting, external cooling by an ancillary system, or operational controls during transport. [10 CFR 71.4]</td>
</tr>
<tr>
<td>Natural Thorium</td>
<td>Thorium with the naturally occurring distribution of thorium isotopes (essentially 100 weight percent thorium 232). [10 CFR 71.4]</td>
</tr>
<tr>
<td>Normal Form Radioactive</td>
<td>Radioactive material that has not been demonstrated to qualify as Special Form radioactive material. [10 CFR 71.4]</td>
</tr>
<tr>
<td>Maximum Interspersed</td>
<td>The presence of hydrogenous material between packages to such an extent that the maximum nuclear reactivity results. [10 CFR 71.4]</td>
</tr>
<tr>
<td>Hydrogenous Moderation</td>
<td>The packaging together with its radioactive contents as presented for transport. [10 CFR 71.4]</td>
</tr>
<tr>
<td>Packaging</td>
<td>The assembly of components necessary to ensure compliance with the packaging requirements of 10 CFR 71. It may consist of one or more receptacles, absorbent materials, spacing structures, thermal insulation, radiation shielding, and devices for cooling or absorbing mechanical shocks. The vehicle, tie-down system, and auxiliary equipment may be designated as part of the packaging. [10 CFR 71.4]</td>
</tr>
<tr>
<td>Term</td>
<td>Definition</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Quality Control</td>
<td>Those quality assurance actions related to control of the physical characteristics and quality of the material or component to predetermined requirements [10 CFR 71.101]</td>
</tr>
<tr>
<td>Quality Assurance</td>
<td>All planned and systematic actions necessary to provide adequate confidence that a system or component will perform satisfactorily in service. [10 CFR 71.101]</td>
</tr>
<tr>
<td>Q-Item</td>
<td>Structures, Systems, or Components (SSCs) important to safety</td>
</tr>
<tr>
<td>Q-Activities</td>
<td>Package activities important to safety</td>
</tr>
<tr>
<td>Radiation Level</td>
<td>The radiation dose-equivalent rate expressed in millisievert(s) per hour or mSv/h (millirem(s) per hour or mrem/h). Neutron flux densities may be converted into radiation levels according to Table 1, 49 CFR 173.403. [49 CFR 173.403]</td>
</tr>
<tr>
<td>Radioactive Contents</td>
<td>A Class 7 (radioactive) material together with any contaminated liquids or gases within the package. [49 CFR 173.403]</td>
</tr>
<tr>
<td>Radioactive Material</td>
<td>Any material containing radionuclides where both the activity concentration and the total activity in the consignment exceed the values specified in the table 49 CFR 173.436 values derived according to the instructions in 49 CFR 173.433.</td>
</tr>
<tr>
<td>Reference Air Leakage Rate</td>
<td>The allowable leakage rate converted to reference cubic centimeters per second. [ANSI N14.5]</td>
</tr>
<tr>
<td>Reference Cubic Centimeter Per Second (ref·cm³/s)</td>
<td>A volume of one cubic centimeter of dry air per second at one atmosphere absolute pressure (760 mm Hg) and 25°C. [ANSI N14.5]</td>
</tr>
<tr>
<td>Safety Evaluation Report</td>
<td>A report issued by the DOE Headquarters Certifying Official that documents DOE’s review of the package for compliance with DOE O 460.1D and 10 CFR 71.</td>
</tr>
<tr>
<td>Special Form Radioactive Material</td>
<td>Radioactive material that satisfies the conditions specified in 10 CFR 71.75.</td>
</tr>
<tr>
<td>Specific Activity of a Radionuclide</td>
<td>The radioactivity of the radionuclide per unit mass of that nuclide. The specific activity of a material in which the radionuclide is essentially uniformly distributed is the radioactivity per unit mass of the material. [10 CFR 71.4]</td>
</tr>
<tr>
<td>Term</td>
<td>Definition</td>
</tr>
<tr>
<td>------</td>
<td>------------</td>
</tr>
<tr>
<td><strong>Spent Nuclear Fuel or Spent Fuel</strong></td>
<td>Fuel that has been withdrawn from a nuclear reactor following irradiation, has undergone at least 1 year of decay since being used as a source of energy in a power reactor, and has not been chemically separated into its constituent elements by reprocessing. Spent fuel includes the special nuclear material, byproduct material, source material, and other radioactive materials associated with fuel assemblies. [10 CFR 72.3]</td>
</tr>
<tr>
<td><strong>Structures, Systems, or Components (SSCs)</strong></td>
<td>Packaging items found on the parts list of the SARP drawings. The SSC's must be analyzed to determine whether their functions or physical characteristics are important to safety, and items classified as important to safety are included in Chapter 9, the Q-List (for more detail, see Reference 9-6, Appendix A, paragraphs 1, 2, and 3.).</td>
</tr>
<tr>
<td><strong>Surface Contaminated Object</strong></td>
<td>A solid object that is not itself classed as radioactive material, but which has radioactive material distributed on any of its surfaces. SCO shall be in one of two groups with surface activity not exceeding the limits specified in 10 CFR 71.4.</td>
</tr>
<tr>
<td><strong>Technical Review Report</strong></td>
<td>A report prepared by the DOE review staff that documents the technical review of the package for compliance with DOE O 460.1D and 10 CFR 71. The TRR provides the justification for the technical information included in the SER.</td>
</tr>
<tr>
<td><strong>Transport Index</strong></td>
<td>The dimensionless number (rounded up to the next tenth) placed on the label of a package, to designate the degree of control to be exercised by the carrier during transportation. The transport index is determined as follows: (1) for non-fissile material packages, the number determined by multiplying the maximum radiation level in millisievert (mSv) per hour at one meter (3.3 ft) from the external surface of the package by 100 (equivalent to the maximum radiation level in millirem per hour at one meter (3.3 ft)).</td>
</tr>
<tr>
<td><strong>Type A Quantity</strong></td>
<td>A quantity of radioactive material, the aggregate radioactivity of which does not exceed $A_1$ for special form radioactive material, or $A_2$ for normal form radioactive material, where $A_1$ and $A_2$ are given in Table A.1 of 10 CFR 71, or may be determined by procedures described in Appendix A of 10 CFR 71. [10 CFR 71.4]</td>
</tr>
<tr>
<td><strong>Type A Packaging</strong></td>
<td>A packaging approved to transport a Type A quantity of radioactive contents.</td>
</tr>
<tr>
<td><strong>Type B Package</strong></td>
<td>A Type B packaging together with its radioactive contents. On approval, a Type B package design is designated as B(U) unless the package has a maximum normal operating pressure of more than 700 kPa (100 psi) gauge or a pressure relief device that would allow the release of radioactive material to the environment under the tests specified in §71.73 (hypothetical</td>
</tr>
</tbody>
</table>
accident conditions), in which case it will receive a designation B(M). B(U) refers to the need for unilateral approval of international shipments. B(M) refers to the need for multilateral approval of international shipments. There is no distinction made in how packages with these designations may be used in domestic transportation. To determine their distinction for international transportation, see DOT regulations in 49 CFR Part 173. A Type B package approved before September 6, 1983 was designated only as Type B. Limitations in its use are specified in §71.19. [10 CFR 71.4]

<table>
<thead>
<tr>
<th>Type B Packaging</th>
<th>A packaging approved to transport a Type B quantity of radioactive contents.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type B Quantity</td>
<td>A quantity of radioactive material greater than a Type A quantity. [10 CFR 71.4]</td>
</tr>
<tr>
<td>Uranium—Natural</td>
<td>Uranium with the naturally occurring distribution of uranium isotopes (approximately 0.711 weight percent uranium-235, and the remainder essentially uranium-238). [10 CFR 71.4]</td>
</tr>
<tr>
<td>Uranium—Depleted</td>
<td>Uranium containing less uranium-235 than the naturally occurring distribution of uranium isotopes. [10 CFR 71.4]</td>
</tr>
<tr>
<td>Uranium—Enriched</td>
<td>Uranium containing more uranium-235 than the naturally occurring distribution of uranium isotopes. [10 CFR 71.4]</td>
</tr>
</tbody>
</table>
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APPENDIX B: SUMMARY OF CHANGES
RESULTING FROM THE 2004 REVISION OF 10 CFR 71

The attached table summarizes changes resulting from the 2004 revision of 10 CFR 71. The primary purpose of this revised rule was to conform NRC regulations to those of the International Atomic Energy Agency.*

Package designs that satisfy the 1996 revision of 10 CFR 71 are designated with the identification number suffix “-85.” The changes listed in this appendix are applicable to all packages with initial approval after April 1, 1996, and to other applications requesting the addition of the “-85” suffix. Package designs that satisfy the 2004 revision of 10 CFR 71 are designated with the identification number suffix “-96.” The changes listed in this appendix are applicable to all packages with initial approval after December 31, 2004, and to other applications requesting the addition of the “-96” suffix. Because DOE generally expects that its packages comply with the most current regulations, these changes should also be addressed during the re-certification of previously approved DOE packages.

Subsequent to the 1996 revision of 10 CFR 71, two changes have been promulgated: (1) several additional restrictions for fissile material exemptions and general license provisions, and (2) an additional exemption from the double containment requirements for plutonium. These changes are also addressed in the table below.

Changes in the following general areas are excluded from the table because they are seldom applicable to packages certified by DOE: limited specific activity (LSA), surface contaminated objects (SCO), air shipments of plutonium, and special form qualification. The reviewer is cautioned that if these areas are applicable to the package, the changes may be very significant.

Based on review experience to date, the following changes to 10 CFR 71 appear to be the most significant for packages reviewed by DOE:

- Reflection requirements for the criticality analysis of the containment system of a single package, §71.55(b)(3)
- Replacement of Fissile Class by a Criticality Safety Index (CSI) based on criticality control, and a possible change in the number of packages that shall be analyzed in an array of previous Fissile Class III or Fissile Class I packages, §71.59 and §71.4
- Requirement for dynamic crush test of certain lightweight, low-density packages with significant quantities of radioactive material, §71.73(c)(2)
- Thermal test requirements under hypothetical accident conditions, §71.73(c)(4)
- Reduction in $A_2$ value for uranium enriched between 5% and 20%, Table A-1.

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SECTION-BY-SECTION ANALYSIS

Several sections in Part 71 have been redesignated in this rulemaking to improve consistency and ease of use. For some sections, only the section number is changed. However, for other sections, revisions are being made to the regulatory language. The following table is provided to aid the public in understanding the numerical changes to sections of Part 71.

Redesignation Table

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Subpart A—General Provisions

Section 71.0 Purpose and Scope

Paragraph (d) has been reformatted into three paragraphs to simplify this regulation and to better use plain language. Paragraph (d)(1) indicates that general licenses, for which no NRC package approval is required, are issued in new §71.20 through §71.23. This change reflects the removal of existing §71.22 and §71.24 (re-designated §71.24 and §71.25 (Reserved)). Paragraph (d)(2) indicates that an application for package approval shall be completed in accordance with Subpart D. Paragraph (d)(3) continues to require a licensee transporting, or delivering material to a carrier for transport, to meet the requirements of the applicable portions of Subparts A, G, and H.

New paragraph (e) has been added to indicate that persons who hold, or apply for, a Part 71 CoC for Type AF, Type B, Type BF, Type B(U)F, or Type B(M)F packages are within the scope of Part 71 regulations.
Existing paragraphs (e) and (f) have been re-designated as new paragraphs (f) and (g), respectively. The rule text in new paragraph (f) is the same as existing paragraph (e) text. New paragraph (g) has been revised to reflect the re-designation of existing §71.11 as new §71.8.

Section 71.1 Communications and Records

In §71.1, paragraph (a) has been revised to indicate that documents submitted to the NRC should be addressed to the attention of the “Document Control Desk,” not the “Director of the Office of Nuclear Material Safety and Safeguards.” Provisions have also been added to provide requirements when a due date for a document falls on a Saturday, Sunday, or Federal holiday. In that case, the document would be due the next Federal workday. This change is identical to a change made to §72.4 in a recent Part 72 final rule (see 64 FR 33178; June 22, 1999).

Section 71.2 Interpretations

No changes were made to the text of this section; however, it has been retained in the revision of this subpart for completeness.

Section 71.3 Requirement for License

No changes were made to the text of this section; however, it has been retained in the revision of this subpart for completeness.

Section 71.4 Definitions

The existing definitions for “A_1,” “Fissile material,” “Low Specific Activity (LSA) material,” “Package,” and “Transport index (TI)” are revised as conforming changes. New definitions for “A_2,” “Certificate of Compliance,” “Consignment,” “Criticality Safety Index (CSI),” “Deuterium,” “U.S. Department of Transportation (DOT),” “Graphite,” “Spent fuel,” and “unirradiated uranium” have been added as conforming changes.

The definition of “A_1” has been revised to split the previous combined definition for “A_1” and “A_2” into two individual definitions. This approach is consistent with the standard in TS-R-1. Furthermore, no change has been made to the current technical content of the definition for “A_1”; however, the text is revised to improve readability.

A definition for “A_2” has been added because the previous joint definition for “A_1” and “A_2” has been split into two definitions. (See also definition for “A_1.”)

A definition for “Certificate of Compliance (CoC)” has been added. This definition is similar to the definition for the same term found in § 72.3.

A definition for “Consignment” has been added.

A definition of “Criticality Safety Index (CSI)” has been added.

A definition of “Deuterium” has been added that applies to new §71.15 and §71.22.

A definition of “U.S. Department of Transportation (DOT)” has been added.
The definition of “Fissile material” has been revised by removing $^{238}$Pu from the list of fissile nuclides; clarifying that “fissile material” means the fissile nuclides themselves, not materials containing fissile nuclides; and re-designating the reference to exclusions from fissile material controls from §71.53 to new §71.15.

A definition of “Graphite” has been added that applies to new §71.15 and §71.22.

The definition of “Low Specific Activity (LSA)” material (LSA-I, LSA-II, and LSA-III) has been revised to be consistent with DOT, and to reflect the existence of §71.77 (§71.77 provides requirements on the qualification of LSA-III material).

A definition for “Optimum interspersed hydrogenous moderation” has been added (the definition itself was included in the proposed rule §71.4, but, inadvertently, no mention of that fact was made in this Section).

The definition of “Package” has been revised by clarifying in paragraph (1) that Fissile material package also means a Type AF, Type BF, Type B(U)F, or Type B(M)F package. New paragraph (2) has been added defining Type A packages in accordance with DOT regulations contained in 49 CFR Part 173. Existing paragraph (2) defining Type B packages has been re-designated as subparagraph (3). No changes have been made to the re-designated text.

A definition of “Spent nuclear fuel” or “Spent fuel” has been added. This definition is the same as that currently found in §72.3.

The definition for “Transport index (TI)” has been revised to reflect the new definition of Criticality Safety Index; however, the method for determining the TI of a package, based on the package’s radiation dose rate, remains unchanged.

A definition for “unirradiated uranium” has been added as it is part of the LSA-I definition.

**Section 71.5 Transportation of Licensed Material**

No changes were made to the text of this section; however, it has been included in the revision of this subpart for completeness.

**Section 71.6 Information Collection Requirements: OMB Approval**

This section has been redesignated from Subpart B, Exemptions, to Subpart A, General Provisions. Paragraph (b) of this section has been revised as a conforming change to reflect the addition of new information collection requirements. Additionally, the existing information collection requirement in Appendix A to Part 71, paragraph II, was inadvertently omitted from the list of approved information collection requirements in a previous rulemaking; consequently, NRC staff has added Appendix A, paragraph II, to paragraph (b) to correct this error. Furthermore, the reference to §71.6a has been removed, because no such section currently exists in Part 71.

**Section 71.7 Completeness and Accuracy of Information**

This section has been redesignated from Subpart B, Exemptions, to Subpart A, General Provisions. Further, paragraphs (a) and (b) have been revised by adding the terms “certificate holder” and “applicant for a CoC.”
Section 71.8  Deliberate Misconduct
This section has been redesignated from Subpart B, Exemptions, to Subpart A, General Provisions. Further, in Subpart A, §71.11 has been re-designated as §71.8. However, the current text of §71.11 has not changed in the re-designated §71.8.

Section 71.9  Employee Protection
New §71.9 has been added to provide requirements on employee protection. Currently, requirements relating to the protection of employees against firing or other discrimination when the employee engages in certain “protected activities” are provided under the parts of Title 10 for which a specific license was issued to possess radioactive material. However, no provisions were provided in Part 71 relating to the protection of employees against firing or other discrimination when employees engage in certain “protected activities” when they are the employees of a certificate holder or applicant for a CoC.

The NRC believes these employees should also be afforded the same rights and protection as is currently afforded employees of licensees. The new section is identical to the existing § 72.10, “Employee protection.” By including licensees in the new §71.9, the NRC recognizes that the potential for duplication occurs for licensees regulated under multiple Title 10 parts. However, the NRC believes that by including licensees along with certificate holders and applicants for a CoC, improved regulatory clarity would be achieved, and any potential confusion would be minimized.

Section 71.10  Public Inspection of Application
A new section has been added indicating that applications and documents submitted to the Commission, in connection with an application for a package approval, shall be available for public review in accordance with the provisions of Parts 2 and 9. This new section is similar to existing §72.20. Existing §71.10 has been redesignated §71.14 with changes to the text as discussed under §71.14, below.

Section 71.11  (Reserved)
This section has been redesignated from Subpart B, Exemptions, to Subpart A, General Provisions, and is reserved. Existing §71.11 has been re-designated as §71.8.

Subpart B—Exemptions

Section 71.12  Specific Exemptions
Existing §71.8 has been redesignated as §71.12. No changes have been made to the contents of this section. Existing §71.12 has been re-designated as §71.17, with changes to the text as discussed under §71.17, below.

Section 71.13  Exemption of Physicians
Existing §71.9 has been re-designated as §71.13. No changes have been made to the contents of this section. Existing §71.13 has been re-designated as §71.19, with changes to the text as discussed under §71.19, below.
Section 71.14 Exemption for Low-Level Materials

Existing §71.10 has been redesignated as §71.14. Existing §71.14 has been redesignated as §71.20, with no changes to the text.

In new §71.14, paragraph (a) has been revised by removing the existing single 70 Bq/g (0.002 μCi/g) specific activity value. Additionally, paragraph (a) has been reformatted by adding two new paragraphs. Subparagraph (a)(1) provides an increased exemption for natural radioactive materials and ores. Subparagraph (a)(2) provides an exemption for radioactive material based on the “Activity Concentration for Exempt Material” and the “Activity Limit for Exempt Consignment” found in Table A-2 in Appendix A to Part 71.

Paragraph (b) has been revised to consolidate the exemption provisions for LSA and SCO material. The LSA and SCO exemptions contained in existing paragraphs (b)(2) and (c) of this section have been consolidated into a revised paragraph (b)(3). The reference to material exempt from classification as fissile material has been revised from §71.53 to §71.15, because of the redesignation of the section.

Existing paragraph (b)(3) has been removed. The 0.74-TBq (20-Ci) exemption for special form americium and special form plutonium has been removed. However, the 0.74-TBq (20-Ci) exemption for special form plutonium-244, transported in domestic commerce, has been retained as new paragraph (b)(2). For international shipments, the A₁ quantity limit for special form plutonium-244 continues to apply.

Section 71.15 Exemption from Classification as Fissile Material

Existing §71.53 has been re-designated as §71.15, and relocated to Subpart B with the other Part 71 exemptions. This section has been revised by providing mass-ratio based limits in classifying fissile-exempt material. This approach removes the concentration- and consignment-based limits of the current §71.53 and returns to package-based mass limits, with required minimum ratios of nonfissile-to-fissile mass.

The title has been changed to “Exemption from classification as fissile material.”

New paragraph (a) has been added and allows for small samples of fissile material to be shipped. In paragraph (b), the fissile mass per package is limited to 15 grams with a nonfissile-to-fissile mass ratio of 200:1. In paragraph (c), provided there is less than 150 g of fissile material per 360 kg ratio of nonfissile-to-fissile material is also raised to 2000:1. The mass of any lead, graphite, beryllium, and deuterium in the package cannot be included in determining the nonfissile material mass.

In current §71.53, paragraph (c) has been redesignated as paragraph (e) and has been reformatted and revised to clarify that the nitrogen to uranium atomic ratio, for shipments of liquid uranyl nitrate, shall be greater than or equal to 2.0. A new requirement has been added specifying the use of DOT Type A packaging.

In current §71.53, paragraph (d) has been redesignated as paragraph (f) and has been reformatted and revised to clarify the mass limits for plutonium. No substantive changes have been made to this paragraph.
Section 71.16 (Reserved)
This section has been redesignated from Subpart C, General Licenses, to Subpart B, Exemptions, and is reserved. Further, existing §71.16 has been re-designated as §71.21. However, the current text of §71.16 has not been changed in the re-designated §71.21.

Subpart C—General Licenses

Section 71.17 General License: NRC-Approved Package
Existing §71.12 has been re-designated as §71.17. The text of paragraphs (a) and paragraph (b) has not been changed.

Paragraph (c)(3) has been revised using plain language and to reflect the NRC’s requirement to address information submitted to the NRC to the attention of the NRC’s Document Control Desk, in accordance with §71.1.

Paragraph (d) has not been changed.

Paragraph (e) has been revised to reflect the redesignation of §71.13 to §71.19. No other change was made for this paragraph.

Section 71.18 Reserved

Section 71.19 Previously Approved Package
Existing §71.13 has been re-designated as §71.19. Paragraph (a) has been revised to reflect the current package designators (e.g., B(U)F, B(M)F, AF) and to reflect the re-designation of §71.12 to §71.17. Additionally, the contents of paragraph (a)(2) have been removed to reflect that these packages are no longer recognized internationally. Existing paragraph (a)(3) has been re-designated as (a)(2) with no change to the contents. Also, an expiration date for grandfathering these packages has been established in new paragraph (a)(3). Paragraph (b) has been updated to remove the LSA packages, as these packages no longer exist, and to reflect the re-designation of §71.12 to §71.17. No other changes were made. A new paragraph (c) has been added to reflect the type B(U) and B(M) packages that have met the requirements of IAEA Safety Series 6 1985 (as amended 1990) and to correct a typographical error. Additionally, a date by which fabrication of these packages must be complete has been added. Existing paragraph (c) has been re-designated as paragraph (d). Existing paragraph (d) has been re-designated as paragraph (e) and updated to reflect the identification number suffix of “-96” for previously approved package designs that have been resubmitted for review by the NRC and have been approved, and to remove the package designated as Type A from this paragraph.

Section 71.20 General License: DOT Specification Container
Existing §71.14 has been re-designated as §71.20. No changes have been made to the contents of paragraphs (a) through (d). New paragraph (e) has been added to indicate that these types of packages will be phased out 4 years after the effective date of this final rule.
**Section 71.21  General License: Use of Foreign Approved Package**

Existing §71.16 has been re-designated as §71.21. No changes have been made to the contents of this section.

**Section 71.22  General License: Fissile Material**

Existing § 71.18 has been re-designated as §71.22. The current §71.22 has been removed. This section has been amended by consolidating and simplifying the current fissile general license provisions contained in existing §71.18, §71.20, §71.22, and §71.24 into a new §71.22. The new §71.22, while retaining some of the provisions of the existing general licenses, principally uses mass-based limits and a Criticality Safety Index (CSI). Concentration-based limits have been removed. Exceptions relating to plutonium-beryllium sealed sources in existing §71.18 and §71.22 have been relocated to new §71.23. The values contained in new Tables 71-1 and 71-2 have been revised from the values contained in the table in existing §71.22 and in Table 1 in existing §71.20, respectively; and are based on new minimum critical mass calculations described in NUREG/CR-5342. In some instances, the allowable mass limit has been increased from the current limits in existing §71.18, §71.20, §71.22, and §71.24; in other instances, the allowable mass limit has been reduced. The values contained in new Tables 71-1 and 71-2 are used as the variables X, Y, and Z in the equation in paragraph (e)(1).

The title has been revised to indicate that this general license is not restricted to a specific type of fissile material shipment.

Paragraph (a) has been revised to require that fissile material shipped under this general license be contained in a DOT Type A package. Additionally, while the existing exception from Subparts E and F requirements has been maintained, the DOT Type A package regulations of 49 CFR Part 173 have also been specified.

Paragraph (b) remains unchanged.

Paragraph (c) has been revised to remove the specific gram limits for uranium and plutonium but retains the existing Type A quantity limit. Revised gram limits have been relocated to new Table 71-1, which is associated with new paragraphs (d) and (e). A requirement has also been added to limit the amount of special moderating materials beryllium, graphite, and hydrogenous material enriched in deuterium present in a package to less than 500 g.

Existing paragraph (d) has been removed. Revised gram limits for fissile material mixed with material having a hydrogen density greater than water (i.e., a moderating effectiveness greater than H₂O) have been placed in new Table 71-1. A note has been added to new Table 71-1 to indicate “when mixtures of moderating substances are present, the lower mass limits shall be used if more than 15 percent of the moderating substance has an average hydrogen density greater than H₂O.”

New paragraph (d) has been added to require that shipments of packages containing fissile material be labeled with a CSI, that the CSI per package be less than or equal to 10, and that the sum of the CSIs in a shipment of multiple fissile material packages be limited to less than or equal to 50 for a nonexclusive use conveyance, and to less than or equal to 100 for an exclusive use conveyance.

Existing Paragraphs (e) and (f) have been removed.
New paragraph (e) has been added to require that the CSI be calculated via a new equation for any of the fissile nuclides. Guidance on applying the equation and the mass limit input values of Tables 71-1 and 71-2 is also contained in this paragraph.

Section 71.23 General License: Plutonium-Beryllium Special Form Material
The existing §71.20, “General license: Fissile material, limited moderator per package,” has been removed. A new section on the shipment of plutonium-beryllium (Pu-Be) special-form fissile material (i.e., sealed sources) has been added as a new §71.23. New §71.23 consolidates regulations on shipment of Pu-Be sealed sources contained in existing §71.18 and §71.22 into one location in Part 71. The new §71.23 reduces the maximum quantity of fissile plutonium Pu-Be sealed sources that could be shipped on a single conveyance through changes in the mass limits and calculation of the CSI. Currently, a Pu-Be sealed source package can contain up to 400 g of fissile plutonium with a CSI equal to 10. Consequently, the current conveyance limits are 4,000 g per shipment for an exclusive-use vehicle and 2,000 g per shipment for a nonexclusive use vehicle. The new §71.23 increases the maximum CSI per package from 10 to 100; however, the maximum quantity of plutonium per conveyance (i.e., shipment) would be reduced to 1,000 g. The 1,000-g per shipment limit and 240 g of fissile plutonium limit are equivalent to those in new §71.23(c)(2) (1,000 g per shipment and 200 g of fissile plutonium). The 240 g versus 200 g of fissile plutonium per package is due to the increased confidence that the fissile plutonium, within a sealed source capsule, would not escape from the capsule during an accident and reconfigure itself into an unfavorable geometry.

New §71.23 has been titled: “General license: Plutonium-beryllium special form material.” Paragraph (a) describes the applicability of this section, exceptions to the requirements of Subparts E and F, and the requirement to ship Pu-Be sealed sources in DOT Type A packages.

Paragraph (b) requires that shipments of Pu-Be sealed sources be made under an NRC-approved QA program.

Paragraph (c) requires a 1,000 g per package limit. In addition, plutonium-239 and plutonium-241 constitute only 240 g of the 1,000 g limit.

Paragraph (d) requires that a CSI be calculated per paragraph (e), and the CSI shall be less than or equal to 100. For shipments of multiple packages, the sum of the CSIs is limited to less than or equal to 50 for a nonexclusive use conveyance and to less than or equal to 100 for an exclusive use conveyance.

Paragraph (e) provides an equation to calculate the CSI for Pu-Be sources. This equation is based upon the 240-g mass limit for fissile nuclide plutonium-239 and plutonium-241 in paragraph (c).

Section 71.24 (Reserved)

Section 71.25 (Reserved)
Existing §71.22 and §71.24 have been redesignated as §71.24 and §71.25. New §71.24 and §71.25 have been removed and reserved.
Subpart E—Application for Package Approval

Section 71.41 Demonstration of Compliance
Paragraph (a) has been revised to require that a Type B package which contains radioactive contents with activity greater than $10^5 A_2$ of any radionuclide shall meet the enhanced deep immersion test found in §71.61. A new paragraph (d) has been added to provide special package authorizations.

Section 71.51 Additional Requirements for Type B Packages
Paragraph (a) has been revised to remove the reference to §71.52, because the requirements of §71.52 have expired. Paragraph (d) has been added to require that a package which contains radioactive contents with activity greater than $10^5 A_2$ of any radionuclide shall also meet the enhanced deep immersion test found in §71.61.

Section 71.53 Fissile Material Exemptions (Reserved)
This section has been removed and reserved; its contents have been moved to §71.15.

Section 71.55 General Requirements for Fissile Material Packages
New paragraphs (f) and (g) have been added. Paragraph (f) specifies design and testing for fissile material package designs for transport by aircraft, and paragraph (g) addresses UF₆ criticality exception from §71.55(b). Additionally, as a conforming change, paragraph (b) has been updated to support new paragraph (g).

Section 71.59 Standards for Arrays of Fissile Material Packages
Paragraphs (b) and (c) have been revised to use the term CSI (criticality safety index).

Paragraph (b) has been revised to refer to a CSI rather than a TI for nuclear criticality control. The method for calculating a CSI is the same as the existing method for a TI for nuclear criticality control.

Paragraph (c) has been revised to provide direction to licensees when the CSI is exactly equal to 50 and to use plain language. Subparagraph (1) has been revised by replacing the term “not in excess of 10,” with the term “less than or equal to 50.” New paragraph (c)(2) has been added to provide for shipment of packages with a CSI of less than 50 on an exclusive use conveyance. The current conveyance limit of 100 has been retained. Existing paragraph (c)(2) has been redesignated as new paragraph (c)(3) and has been revised by replacing the term “in excess of 10,” with the term “greater than 50.” These three changes: (1) Provide greater clarity and mathematical consistency among paragraphs (c)(1), (c)(2), and (c)(3); (2) clarify the CSI limits for storage incident to transport; and (3) increase the CSI limit per package from 10 to 50 for shipments made with nonexclusive use conveyances.

Section 71.61 Special Requirements for Type B Packages Containing More Than $10^5 A_2$
This section has been revised to require an enhanced water immersion test for packages used for radioactive contents with activity greater than $10^5 A_2$. The title of this section has also been revised to reflect that the scope has been broadened beyond irradiated nuclear fuel.
Section 71.63 Special Requirement for Plutonium Shipments
The title has been revised to reflect only a single “requirement” rather than multiple requirements.

Paragraph (b) has been removed.

The designation of the remaining text as paragraph (a) has been removed, because only one paragraph remains. The text of former paragraph (a) has been revised to use plain language. The 0.74-TBq (20-Ci) limit and solid form requirement have been retained.

Section 71.73 Hypothetical Accident Conditions
A new paragraph (c)(2) has been added to require a crush test for fissile material packages.

Subpart G—Operating Controls and Procedures

Section 71.88 Air Transport of Plutonium
Paragraph (a)(2) has been revised to remove the 70-Bq/g (0.002-μCi/g) specific activity value and substitute activity concentration values for plutonium found in Appendix A, Table A-2, of this part. This revision is a conforming change to the revision to new §71.14 to ensure consistent treatment of plutonium between these two sections.

Section 71.91 Records
As a conforming change to Subpart H, paragraphs (b) and (c) have been redesignated as paragraphs (c) and (d), respectively, and are revised by adding the terms “certificate holder” and “applicant for a CoC.” New paragraph (b) has been added to require a certificate holder to keep records on the model, serial number, and date of manufacture of a packaging. These requirements are similar to the requirements in paragraph (a), though less information is required. No change has been made to paragraph (a).

Section 71.93 Inspection and Tests
As a conforming change to Subpart H, paragraphs (a) and (b) have been revised by adding the terms “certificate holder” and “applicant for a CoC.” Paragraph (c) has been revised to require the certificate holder to notify the NRC before it begins fabrication of a packaging that can contain material having a decay heat load in excess of 5 kW or a maximum normal operating pressure of 103 kPa (kilo Pascals) (15 ft-lb/in²) gauge. This notification could be for either fabricating a single packaging or the beginning of a campaign for fabricating multiple packagings. This notification is in accordance with the requirements of §71.1, rather than an NRC Regional Administrator. This change in notification location reduces confusion in identifying the appropriate Regional Administrator when the certificate holder and fabrication location are overseas. Licensees have been removed from this paragraph because the NRC believes that requiring a licensee, who does not own the packaging, to notify the NRC in advance of a packaging fabrication, when the licensee may not use the packaging for years, is inappropriate and an unreasonable burden. The NRC believes that requiring certificate holders and applicants for a CoC to notify the NRC in advance of fabricating a packaging(s) would allow the NRC adequate opportunity to inspect these activities. This change is similar to the current requirement in §72.232(d) for Part 72 certificate holders or applicants for a CoC to notify the
NRC 45 days before starting the fabrication of the first storage cask under a Part 72 CoC. This action improves the harmonization between these two regulations in Parts 71 and 72.

Section 71.95 Reports
The existing introductory text and paragraphs (a), (b), and (c) have been combined into a new paragraph (a) which requires a licensee, after requesting the certificate holder’s input, to submit a written report to the NRC in certain circumstances. The requirement for the licensee to request input from the certificate holder during development of the written event report will ensure that design deficiency issues have been thoroughly considered. The licensee will also be required to provide the certificate holder with a copy of the written event report, after the report is submitted to the NRC. This will permit the certificate holder to monitor and trend the package performance information, arising from package use by multiple licensees. Additionally, requirements on timing and submission location for the written reports have been relocated to new paragraph (c). Furthermore, the 30-day reporting requirement has been lengthened to a 60-day reporting requirement.

The existing paragraph (c) has been redesignated as paragraph (b) and revised for clarity.

New paragraphs (c) and (d) have been added to provide requirements on the timing, submission location, form, and content of the written reports.

Section 71.100 Criminal Penalties
Section 223 of the Atomic Energy Act of 1954, as amended, (the Act) provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. The Commission stated in a final rule on “Clarification of Statutory Authority for Purposes of Criminal Enforcement” (57 FR 55082; November 24, 1992), that substantive rules under sections 161b, 161i, or 161o of the Act include those rules that create “duties, obligations, conditions, restrictions, limitations, and prohibitions.” For the NRC to consider the possibility of criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any substantive regulations, the NRC must have clearly identified to affected parties which regulations in Part 71 are substantive rules. Accordingly, paragraph (b) of this section identifies those Part 71 regulations that the NRC does not consider as substantive regulations. Thus, willful violation of, attempted violation of, or conspiracy to violate any of the regulations listed in paragraph (b) is not subject to possible criminal sanctions.

Paragraph (b) of this section has been revised as a conforming change. The NRC has reviewed new §71.10 and considers that this regulation is not a substantive rule. Therefore, new §71.10 has been added to the list of sections in paragraph (b). The NRC reviewed new § 71.9, §71.18, and §71.23 and considers that these regulations are substantive rules. Therefore, these sections have not been added to paragraph (b). Additionally, the NRC has reviewed the existing §71.9, §71.10, and §71.53 and concluded these sections should be recharacterized as substantive rules. Therefore, new §71.13, §71.14, and §71.18 have not been included in paragraph (b). Additionally, existing §§ 71.52 and 71.53 have been removed from paragraph (b), because these section numbers have been removed from Part 71.
Subpart H—Quality Assurance

Section 71.101 Quality Assurance Requirements
Paragraph (a) has been revised by adding two new sentences to the end of the paragraph specifying responsibilities for certificate holders and applicants for a CoC.

Paragraph (b) has been revised to add the terms “certificate holder” and “applicant for a CoC.” The second sentence has been revised to provide greater clarity and consistency within Subpart H by referring to “the QA requirement’s importance to safety.”

Paragraph (c) has been revised by redesignating the existing text as paragraph (c)(1), and new text has been added on submitting QA programs in accordance with the requirements of §71.1. New paragraph (c)(2) has been added to provide equivalent requirements on the submission of QA programs for certificate holders and applicants for a CoC.

Paragraph (f) has been revised to allow the use of existing NRC-approved Part 71 and Part 72 QA programs, in lieu of submitting a new QA program. Additionally, the terms “certificate holder” and “applicant for a CoC” have been added.

Paragraph (g) has been revised by making a minor change to clarify that §34.31(b) is located in chapter I of title 10 of the Code of Federal Regulations. Additionally, as a conforming change, §71.12(b) has been redesignated as §71.17(b).

Section 71.103 Quality Assurance Organization
Paragraph (a) has been revised by adding the terms “certificate holder” and “applicant for a CoC.”

Section 71.105 Quality Assurance Program
Paragraphs (a) through (d) have been revised by adding the terms “certificate holder” and “applicant for a CoC.”

Section 71.107 Package Design Control
Paragraph (a) has been revised by adding the terms “certificate holder” and “applicant for a CoC.” Further, the last sentence has been revised to improve clarity and consistency within Subpart H by referring to “processes that are essential to the functions of the materials, parts, and components that are important to safety.”

Paragraph (b) has been revised by adding the terms “certificate holder” and “applicant for a CoC.” Additionally, the last sentence of paragraph (c) has been revised by replacing the text “changes in the conditions specified in the package approval require NRC approval ***.” with “changes in the conditions specified in the CoC require NRC prior approval ***.”

Section 71.109 Procurement Document Control
This section has been revised by adding the terms “certificate holder” and “applicant for a CoC.”

Section 71.111 Instructions, Procedures, and Drawings
This section has been revised by adding the terms “certificate holder” and “applicant for a CoC.”
Section 71.113  Document Control
This section has been revised by adding the terms “certificate holder” and “applicant for a CoC.”

Section 71.115  Control of Purchased Material, Equipment, and Services
Paragraphs (a) through (c) have been revised by adding the terms “certificate holder” and “applicant for a CoC.”

Section 71.117  Identification and Control of Materials, Parts, and Components
This section has been revised by adding the terms “certificate holder” and “applicant for a CoC.”

Section 71.119  Control of Special Processes
This section has been revised by adding the terms “certificate holder” and “applicant for a CoC.”

Section 71.121  Internal Inspection
This section has been revised by adding the terms “certificate holder” and “applicant for a CoC.”

Section 71.123  Test Control
This section has been revised by adding the terms “certificate holder” and “applicant for a CoC.”

Section 71.125  Control of Measuring and Test Equipment
This section has been revised by adding the terms “certificate holder” and “applicant for a CoC.”

Section 71.127  Handling, Storage, and Shipping Control
This section has been revised by adding the terms “certificate holder” and “applicant for a CoC.”

Section 71.129  Inspection, Test, and Operating Status
Paragraph (a) has been revised by adding the terms “certificate holder” and “applicant for a CoC.”

Section 71.131  Nonconforming Materials, Parts, or Components
This section has been revised by adding the terms “certificate holder” and “applicant for a CoC.”

Section 71.133  Corrective Action
This section has been revised by adding the terms “certificate holder” and “applicant for a CoC.”

Section 71.135  Quality Assurance Records
This section has been revised by adding the terms “certificate holder” and “applicant for a CoC.”

Section 71.137  Audits
This section has been revised by adding the terms “certificate holder” and “applicant for a CoC.”

Appendix A to Part 71—Determination of $A_1$ and $A_2$
No changes have been made in paragraphs I, III, and V; however, these paragraphs have been included due to revising Appendix A, in its entirety.
Paragraph II has been revised to use plain language and has been redesignated as subparagraph II(a). The intent of existing paragraph II has not been changed; however, the reference to existing Table A-2 has been revised as a conforming change to the new Table A-3. New paragraph II(b) has been added to provide direction on determining exempt material activity concentration and exempt consignment activity values when a radionuclide has been identified as a constituent of a proposed shipment, but the individual radionuclide is not listed in Table A-2. Consequently, the structure of paragraphs II(a) and II(b) is the same. New paragraph II(c) has been added to provide direction to licensees on how to submit requests for Commission prior approval of either $A_1$ and $A_2$ values or exempt material activity concentration and exempt consignment activity values, for radionuclides that are not listed in Tables A-1 and A-2, respectively.

Paragraph IV has been revised by adding new paragraphs (e) and (f) to provide equations to use in determining a consolidated exempt material activity concentration and exempt consignment activity value when a shipment contains multiple radionuclides. The existing text describing an alternative method for calculating the $A_1$ or $A_2$ value of a mixture has been re-designated as paragraphs (c) and (d). No changes have been made from the existing equations.

Appendix A, Table A-1—$A_1$ and $A_2$ Values for Radionuclides
This Table has been revised to reflect the values from TS-R-1.

Appendix A, Table A-2—Exempt Material Activity Concentrations and Exempt Consignment Activity Limits for Radionuclides
A new Table A-2 has been added to Appendix A of Part 71. This table contains the values of Exempt Material Activity Concentrations and Exempt Consignment Activity Limits for selected radionuclides. Table A-2 is referenced in new §71.14(a)(2) and is used in §71.14 to determine when concentrations of material are not considered radioactive material, for the purposes of transportation.

Appendix A, Table A-3—General Values for $A_1$ and $A_2$
The existing Table A-2 has been re-designated as new Table A-3, and the values have been revised to reflect the changes from TS-R-1.

Appendix A, Table A-4—Activity Mass Relationships for Uranium
The existing Table A-3 has been re-designated as new Table A-4. No changes have been made to the values contained in new Table A-4.
APPENDIX C: SUMMARY OF ISSUES AND TERMS RELEVANT TO MATERIALS, FABRICATION, AND QUALITY ASSURANCE

Issues related to package materials, fabrication, quality assurance/quality control are interlaced among all chapters in the Safety Analysis Report for Packages (SARP). Although some aspects of the review are relatively straightforward (e.g., thermal properties of materials should be discussed in the Thermal Evaluation chapter), other issues may not be clearly aligned with the chapters of the SARP format. Consequently, the review of materials, fabrication, and quality assurance/quality control should address all SARP chapters to ensure that these areas have been properly evaluated.

Tables C.1 and C.2 provide a summary of typical issues that should be reviewed for materials and fabrication, respectively. The reviewer is cautioned not to use these tables as a simple “yes or no” checklist, but to consider each package and its specific issues on a case-by-case basis.

As noted in Chapter 1 of this PRG, information on materials and fabrication which is indicated on SARP drawings may be described in additional detail in a separate materials and fabrication specifications.

Tables C.3, C.4, and C.5 provide summaries of welding and nondestructive examination terms, fabrication quality assurance/quality control terms, and guidance on the development of specifications for state-of-the-art, emerging technology fabrication processes, respectively.
### Table C.1 Review of Materials

| Identification of Packaging Components | • Is each packaging component important to safety (Q-item) depicted on the SARP drawings and identified on the drawing parts list or by other appropriate means?  
• Is each packaging component not identified on the SARP drawings properly justified as not important to safety (non-Q-item)?  
• Have potential non-Q materials compatibility issues (that may affect Q-items) been discussed in the appropriate SARP chapter?  
• Have materials issues relative to containment/confinement, shielding (radiation and thermal), criticality control, and operational conditions been identified?  
• Have specific material description, characterization, and quality control requirements been identified relative to the risk-based Q category of the packaging structures, system, or component (SSC)? |
| --- | --- |
| Material Specifications of Packaging Components | • Is the material and product form of each packaging component specified on the SARP drawings?  
• Is an authoritative material specification (e.g., ASME, ASTM, AWS, commercial equivalent) designated on the drawings for each material/product form? Is the material specification appropriate for the code or consensus standard applicable to the packaging?  
• For materials without an applicable specification, are the material properties to be controlled properly specified on the drawings? Examples include minimum/maximum densities of foam, fiberboard, and similar materials, and minimum density neutron absorbing nuclides. Are these properties consistent with those used in the package evaluation?  
• Is an appropriate nondestructive examination (NDE) process with acceptance criteria specified for each material/product form on the drawings? |
| Material Properties | • Are material properties, including minimum/maximum values relevant to the SARP evaluation specified in the SARP?  
• Are the material properties specified appropriate over the operating range, including for the temperatures, pressures, and other operational conditions / environments under normal conditions of transport and hypothetical accident conditions?  
• Have the material properties that are influenced by the processing history including melting, casting, thermal-mechanical working, and heat treatment been determined?  
• Have appropriate test requirements for materials been established in the SARP?  
• Have sealing materials, especially for the containment boundary, been described and characterized by specifications and operational controls? (e.g., Gaskets and O-rings are not covered by the ASME B&PV Code.)  
• For package fasteners, have the descriptions included adequate strength/ toughness and pre-load requirements?  
• Is any packaging material subject to brittle fracture by cold or other mechanisms (e.g., hydrogen embrittlement) been identified?  
• Are the criteria of RG 7.11 or 7.12 satisfied?  
• Has embrittlement by other mechanisms (e.g., fabrication processes) been properly addressed?  
• Have other fracture toughness issues been identified in the SARP for specific materials/product forms? (e.g., aluminums, castings, welded stainless steels, etc.)  
• Is any material subject to chemical, galvanic, or other reaction (e.g., radiolysis) with other materials or with the contents? If so, have these issues been properly addressed in the package evaluation?  
• Is any material subject to radiation damage? If so, has this issue been properly addressed?  
• Is the material subject to stress-assisted corrosion?  
• Should any material or component be inspected and/or replaced prior to each use?  
• Are appropriate types of inspections and acceptance criteria specified? |

| Brittle Fracture | Chemical, Galvanic, and Other Reactions | Package Operations |
### Table C.1 Review of Materials (continued)

<table>
<thead>
<tr>
<th>Acceptance Testing and Maintenance Program</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Should any material or component be subject to acceptance testing or nondestructive examination prior to first use?</td>
<td></td>
</tr>
<tr>
<td>• Should any material or component be inspected, maintained, and/or replaced as part of a periodic maintenance program? Is the period and type of inspection appropriate? Is the maintenance or replacement schedule appropriate?</td>
<td></td>
</tr>
<tr>
<td>• Are the requirements for acceptance testing and maintenance specified?</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Quality Assurance</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Has each component been properly categorized as to its importance to safety (Q-Category A, B, or C) and the required material pedigree / traceability been established?</td>
<td></td>
</tr>
<tr>
<td>• Have appropriate controls been established in the Quality Assurance chapter to assure that risk-based quality requirements are met, depending on the Q-category of each component?</td>
<td></td>
</tr>
<tr>
<td>• Has appropriate documentation been specified to document that the quality assurance/quality control requirements are met for base/consumable materials over the applicable processing history?</td>
<td></td>
</tr>
</tbody>
</table>
### Table C.2 Review of Fabrication

| Identification of Packaging Components | • Is each packaging component important to safety depicted on the SARP drawings and identified in the parts list or by other appropriate means?  
• Is each packaging component not identified on the SARP drawings properly justified as not important to safety?  
• Have all safety-related fabrication details been well-characterized on the drawings or in the SARP, with regard to an appropriate code, consensus standard, or applicant-developed specification?  
• For Q-items, is the base metal manufacturing process identified (i.e., casting, forging, flow forming, rolling, extrusion, additive manufacturing, etc.), as well as the safety-related component fabrication process (i.e., machining, welding, heat treatment, etc.)?  
• For high risk Q-items, will the critical fabrication steps be defined in a Manufacturing & Inspection Plan (MIP) by the supplier? |
| Welds and Brazes | • Is the location, type, size, welding/brazing process (if applicable due to Q-item designation), and method of nondestructive examination (with acceptance criteria) for each weld/braze specified on the drawings or in the SARP?  
• Is a code or consensus standard requirement for each weld/braze configuration, procedure, and personnel performance qualification specified on the drawings? Is all of the joining information consistent with this code or standard?  
• Is the code or standard for the welding and fabrication appropriate for safety related components (see NUREG/CR-3019 and NUREG/CR-3854)? |
| Codes and Standards for Fabrication Processes | • Is an appropriate code or standard for fabrication of each packaging component specified on the drawings, commensurate with the risk-based Q-list?  
• For components without an applicable specification (e.g., lead shielding), is the fabrication process sufficiently described, controlled, and specified on the drawings or the SARP or in an applicant developed specification?  
• Are appropriate nondestructive examination and acceptance criteria requirements for each SSC specified on the drawing, commensurate with the Q-list?  
• Is the package evaluation consistent with its fabrication specifications? |
| Package Operations | • Are components or features required to be inspected prior to and after each fabrication/repair? |
Table C.2 Review of Fabrication (continued)

| Acceptance Testing and Maintenance Program | • Are appropriate acceptance tests and documentation specified to address fabrication issues of SSCs (e.g., uniformity of lead, nondestructive examination prior to and after fabrication, etc.)?  
  • Are any components or features required to be inspected, maintained, and/or replaced as part of a periodic maintenance program? Is the period, type of inspection, and acceptance criteria appropriate? Is the maintenance or replacement schedule appropriate?  
  • Are the requirements for acceptance testing and maintenance specified in the SARP Chapter 8 Acceptance Tests and Maintenance Program? |
| Summary of Quality Control Applied to Fabrication | • Has each component been properly categorized as to its importance to safety? (see Q-List in Chapter 9)  
  • Have or will fabrication activities for Q-Items been approved and controlled by the Design Agency through administrative and technical procedures? Are training and qualification requirements for fabrication personnel properly specified?  
  • Are the fabrication processes consistent with the codes or standards used for the design or specified in the procurement document?  
  • Are equipment and procedures appropriate and qualified?  
  • Has evidence been provided that fabrication process acceptance criteria are appropriate and will be completely satisfied?  
  • Have appropriate quality control been established to assure that the quality assurance program requirements are satisfied?  
  • Has appropriate procedures been documented to confirm that quality records will be maintained? |
<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Arc Welding (AW)</strong></td>
<td>A group of welding processes that produces coalescence of metals by heating them with an arc, with or without the application of pressure, and with or without the use of a filler metal</td>
</tr>
<tr>
<td><strong>Autogenous Weld</strong></td>
<td>A fusion weld made without the addition of filler metal</td>
</tr>
<tr>
<td><strong>Complete Joint Penetration, Complete Fusion</strong></td>
<td>Successively fusing together adjacent layers of weld metal or weld metal/base metal, and penetration of the full thickness of the base metal in a groove weld joint.</td>
</tr>
<tr>
<td><strong>Flux</strong></td>
<td>A fusible mineral material which is melted by the welding arc, and serves to stabilize the welding arc, shield all or part of the molten weld pool from the atmosphere and may or may not evolve shielding gas by its decomposition.</td>
</tr>
<tr>
<td><strong>Heat Affected Zone (HAZ)</strong></td>
<td>That portion of the base metal which has not been melted, but whose mechanical properties or microstructures have been altered by the heat of welding or cutting</td>
</tr>
<tr>
<td><strong>Nondestructive Examination (NDE)</strong></td>
<td>The process of evaluating welds, heat affected zones, and base metal for discontinuities or differences in material characteristics without damaging the serviceability of the part or the component. Common NDE processes for qualification of packagings are visual inspection (VT), liquid penetrant (PT), eddy current (ET), magnetic particle (MT), radiography (RT), ultrasonics (UT), and phased array (PAUT) examinations.</td>
</tr>
<tr>
<td><strong>Procedure Qualification Record (PQR)</strong></td>
<td>A document providing the actual welding variable values used to produce an acceptable test weld, with the actual results of tests and/or examinations to qualify a WPS.</td>
</tr>
<tr>
<td><strong>Shielding Gas</strong></td>
<td>Protective gas used to prevent atmospheric contamination of the molten weld pool, and to stabilize the welding arc.</td>
</tr>
<tr>
<td><strong>Weldability</strong></td>
<td>The capacity of a metal to be welded under imposed fabrication conditions into a specific suitably designed structure and to perform satisfactorily during its intended service</td>
</tr>
<tr>
<td><strong>Welder/Welding Operator Performance Qualification Record (WPQ)</strong></td>
<td>A record of the qualification tests that includes the welding process essential variable values, the type of test specimens/test results, and the metal/thickness range qualified.</td>
</tr>
<tr>
<td><strong>Welding Procedure Specification (WPS)</strong></td>
<td>A document providing in detail the required process variables with allowable tolerances for specific applications to assure repeatability by properly qualified welders or welding operators.</td>
</tr>
</tbody>
</table>
### Table C.4 Fabrication Quality Assurance/Quality Control Terms

<table>
<thead>
<tr>
<th>Term</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Certified Material Test Report (CMTR)</td>
<td>A signed, dated, or otherwise authenticated document, approved by qualified personnel, that contains sufficient data and information to verify the actual properties of material and the actual results of all required tests, consistent with the heat/lot of material.</td>
</tr>
<tr>
<td>Corrective Active</td>
<td>Measures taken to correct conditions adverse to quality and, where necessary to preclude repetition</td>
</tr>
<tr>
<td>Graded Approach</td>
<td>A systematic analysis of each SSC of a package to assess its safety significance resulting from a malfunction or failure</td>
</tr>
<tr>
<td>Hold Point</td>
<td>A point in the fabrication process beyond which work shall not proceed until the QA representative has verified in writing that the designated activity (fabrication step, inspection, test, etc.) is acceptable.</td>
</tr>
<tr>
<td>Implementing Procedures</td>
<td>A detailed written instruction that is prepared in response to a requirement that describes a sequence of events or steps that are to be taken</td>
</tr>
<tr>
<td>Manufacturing &amp; Inspection Plan (MIP)</td>
<td>A document submitted to the design agency by the supplier that details all fabrication administrative controls and interim data reports at key witness/hold points relative to each major manufacturing step of the SSCs consistent with the Q-list designations.</td>
</tr>
<tr>
<td>Nonconformance</td>
<td>A deficiency in characteristics, documentation, or procedure that renders the quality of an item or activity to be unacceptable</td>
</tr>
<tr>
<td>Procurement Document</td>
<td>May include any or all of the following: Purchase requisitions, work authorization letters, drawings, contracts, specifications, instructions, acceptance criteria as defined in a referenced Code, or any other documentation that provides a means for obtaining the required level of quality of packaging SSCs as defined in the QAP or the SARP</td>
</tr>
<tr>
<td>Quality Control</td>
<td>Those quality assurance actions related to control of the physical characteristics and quality of the material or component to predetermined requirements</td>
</tr>
<tr>
<td>Quality Assurance</td>
<td>All of those planned and systematic actions that are necessary to provide adequate confidence that a system or component will perform satisfactorily in service</td>
</tr>
<tr>
<td>Quality Assurance Program (QAP)</td>
<td>The overall program or management system established to assign responsibilities and authorities, define policies and requirements, and provide for the performance and assessment of work. The QAP provides control over activities affecting quality to an extent consistent with their importance to safety and includes monitoring activities against criteria. The implementing procedures in the QAP provide special controls, processes, test equipment, tools, and skills to attain the required quality of activities and items, and verification of the quality</td>
</tr>
</tbody>
</table>
**Table C.4 Fabrication Quality Assurance/Quality Control Terms (continued)**

<table>
<thead>
<tr>
<th>Supplier</th>
<th>An individual or organization that furnishes items or services in accordance with the procurement document</th>
</tr>
</thead>
<tbody>
<tr>
<td>Traceability</td>
<td>The ability to track the history, application, material, pedigree, or location of an item and/or activities by means of documentation</td>
</tr>
<tr>
<td>QA Record</td>
<td>A completed document that furnishes evidence of the quality of items and/or activities affecting quality</td>
</tr>
<tr>
<td>Q-Item</td>
<td>A packaging structure, system, or component (SSC) that possesses physical characteristics or functions which are important to safety</td>
</tr>
<tr>
<td>Q-List Implementation</td>
<td>A list of packaging components identified on the SARP drawings or within the SARP that are important to safety (SSCs) is established. Categories A, B, or C are assigned to each SSC on the Q-list based on the risked-based importance to safety. QA/QC controls are established through technical and administrative implementing procedures within the QAP with a level of rigor commensurate with the quality category established.</td>
</tr>
<tr>
<td>Verification</td>
<td>The act of reviewing, inspecting, testing, checking, assessing, auditing, or otherwise determining and documenting whether or not items, processes, services, or documents conform to specified requirements</td>
</tr>
</tbody>
</table>

**Table C.5 State-of-the-Art Emerging Technology Fabrication Processes - Guidance on Development of Specifications in Support of the SARP**

For state-of-the-art, emerging manufacturing technologies in the SARP that may not be associated with existing, authoritative specifications such as additive manufacturing (AM), a specification must be developed and included in the appropriate appendix, that includes key process details required for the process control and qualification, as well as the acceptance criteria of the manufactured products. Examples of applicable AM technologies may include:

- Fused Deposition Modeling (FDM)
- Selective laser sintering (SLS)
- Stereolithography (SLA)
- Laser-Based Directed Energy Deposition (DED)
- Laser and Electron Beam Powder-Bed Fusion (L-PBF or E-PBF).

For established terminology, see ASTM F2792-12a[C-1] and the February 2020 Welding Journal articles that include a current summary articles on the *Developments in Metal Additive Manufacturing*. Also, for additional details on the AM of metals current process developments, see the FABTECH Conference, November 2019, which included two sessions on AM.
Utilizing the advantage of computer technology, the AM process has been defined as dispensing materials following programmed tool paths, layer by layer to make three-dimensional (3D) objects, as opposed to traditional subtractive manufacturing methods, such as milling, drilling, and machining. The tool path patterns can be generated to be selectively different from layer to layer. Each point in a layer can have different material compositions, different densities, and different geometric connections within constraints, so that multiple objectives can be achieved in design/manufacturing, such as light weight, low volume, high stiffness, and variable (non-isotropic) thermal and mechanical properties.

This broad definition of AM may include the use of thermoplastic and thermosetting polymers, metals, composites, fibers, and ceramics. See the research papers by Castro, et.al.,[C-6] and Onagoruwa, et.al.,[C-7] for information on the additive manufacturing of ceramics and composites.

Examples of a few key material and process details that may be included in an applicant-developed specification for state-of-the art or emerging technologies in support of the SARP may include:

- **For Metals:**
  - “build” feedstock purity (i.e., percentage of powder discontinuities)
  - thermal/mechanical processing parameters
  - component resulting properties and microstructure
  - product form process input
  - preheat
  - anticipated laser induced distortion/residual stress and the required post-production heat treatment cycles
  - production NDE
  - acceptance criteria.

- **For Ceramics and composites:**
  - same elements as for metals
  - details on the binder system used
  - resulting properties and desired crystal structures.

- **For Polymer Resins:**
  - composition and molecular structures
  - molecular weight and degree of polymerization
  - matching coefficient of thermal expansion required to prevent undesired crystal structures (after the curing process)
  - if applicable, thermoplastic and thermosetting parameters
  - allowable defect population and diffusion
  - product examination and testing with acceptance criteria.
Appendix C References

[C-1] ASTM F2792-12a, Standard Terminologies for Additive Manufacturing Technologies, 2016 West Conshohocken, PA ASTM Int. PP 12-14


[C-7] Onagoruwa, S., et. al., Fused Deposition of Ceramics (FDC) and Composites, School of Mechanical and Materials Engineering, Washington State University, Pullman, WA, 99164-2920, 2001.
APPENDIX D: QUALITY ASSURANCE OF SOFTWARE AND ANALYSES

Five SARP chapters, containing analysis results, require Quality Assurance (QA) documentation of the pedigree of the software version and platform utilized, as well as the Verification and Validation (V&V) of the computational models that support design analyses and regulatory test configuration analyses:

- Chapter 2: Structural Evaluation
- Chapter 3: Thermal Evaluation
- Chapter 4: Containment Evaluation
- Chapter 5: Shielding Evaluation
- Chapter 6: Nuclear Criticality Safety Evaluation.

The QA information documented in the above SARP chapters is to be summarized and indexed in Chapter 9 on Quality Assurance. It is recommended that an appendix be included in each of the five design/analysis chapters, as applicable, to provide objective evidence that the pedigree of in-house developed or commercially-available software has been documented, depending on the risk assessment of the packaging. For Safety Significant Components (see Q-list in Chapter 9), implementation of V&V activities for analyses and models used to design or analyze the packaging SSCs likewise must be documented.

D.1. Software Quality Assurance Plan and Implementation Summary

The following summary provides examples of key software quality assurance areas that should be documented in a SARP appendix, as applicable for software used in computation modelling of regulatory conditions:

- Scope/requirements definition
- Software version with revision date
- Applicable SSC risk categories A, B, or C for component application of design/analysis software
- Roles and responsibilities
- Software description: developed, acquired, legacy
- Software SQA Plan number
- Software Test Plan documentation
- Software lifecycle activities description (for developed software)
- Platforms, Operating Systems used
- Commercial grade dedication documentation/ vendor audit reports (for acquired software, as applicable)
• Reviews/ analyses/ verification and validation techniques
• Configuration management/ baseline control
• Problem reporting/ corrective actions
• Tools, techniques, methods, standards, practices
• Test cases and test results summary
• Training /qualification of personnel
• QA records and archival information of applicable files
• For Safety Software applications, DOE O 414.1D SSQA applicable work activity documentation (see the ten SSQA work activities listed in DOE O 414.1D, Attachment 4).

D.2 Software Test Plan Summary
For developed software, a summary of the software test documentation with a description of the test cases, test results with acceptance criteria. The following are major items that may be included in a software test summary report:

• Scope
• Software identification
• Reference documents (i.e., software quality assurance plans should reference IEEE Computer Society standards, etc. used in the software development)
• Resources, including personnel, special equipment, software operating environment, configuration management system, etc.
• Matrix of requirements and corresponding test cases
• Testing activities, including, test plans, test problem description with acceptance criteria, test logs/reports, testing personnel qualifications, limiting conditions including initial conditions, error handling, regression testing, etc.
• Description of established baselines
• Uncertainty analyses performed
• Conclusions and recommendations.

D.3 Summary Reports on Structural, Thermal, Containment, Shielding, and Nuclear Criticality Evaluations
For models and analyses, general documentation areas to be discussed in appendices should include the V&V of the computational model, with discussions of the results. Details may be included in the following areas, as applicable:
• After application of the risk-based graded approach for the SSCs, overview of the modelling/analysis process planning, documentation of the necessary pedigree of software, analyses and models used in support of the SARP.

• Identification of the consensus standards used, (i.e., ANSI/ASME NQA-1, IEEE Computer Society, the ASME Working Committee on V&V in Computational Solid Mechanics, ASME PTC-60, ASME B&PV Code material specifications/Code Cases used, etc.).

• Verification that the SARP clearly describes the analysis methods, models, and results, including assumptions and input data.

• Verification that the computation model geometry is consistent with the information provided in the SARP drawings (with justification of any deviations from the SARP drawings).

• Verification that the computer codes are correctly used by the applicant.

• Verification that the models and material properties are appropriate for the loading/thermal combinations described in the SARP and in the SARP drawings.

• Verifications of the applied boundary and initial conditions (e.g. possible forces, displacements, conduction, convection, radiation heat transfer paths, etc.).

• Verification that the computer codes are benchmarked, and maintained under the appropriate risk-based quality controls.

• Description of the benchmarking results with standard test problems.

• Verification that the modeling results compare with closed form solutions, as appropriate.

• Verification of the correct geometric/material modelling compared with the information on the SARP drawings.

• Uncertainty analysis of the overall computational results.

• Conclusions.
<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acquired Software</td>
<td>Commercial grade software, that may not be ASME NQA-1 compliant</td>
</tr>
<tr>
<td>ASME NQA-1 Compliant Software</td>
<td>Software that either has been developed in accordance with the requirements of ASME NQA-1, Parts I and II; or has been subjected to an SQA audit, by an ASME NQA-1 certified audit team.</td>
</tr>
<tr>
<td>Commercial Grade Dedication (CGD) of Software</td>
<td>For acquired software that is not ASME NQA-1 compliant, implementation of the requirements of ASME NQA-1, Part II, Subsection 2.14 (for software CGD).</td>
</tr>
<tr>
<td>Software Baseline</td>
<td>A product that has been formally reviewed and agreed upon by the developer, that thereafter serves as the basis for further development</td>
</tr>
<tr>
<td>Software Configuration Management (SCM)</td>
<td>The process of identifying and defining baselines associated with the software product, controlling changes of the baselines, recording the status of baselines, and verifying the correctness and completeness of baselines</td>
</tr>
<tr>
<td>Software Critical Characteristics</td>
<td>Important design/performance characteristics that once verified, will provide reasonable assurance that the item of service will perform its intended safety function.</td>
</tr>
<tr>
<td>Software Engineering Environment</td>
<td>The set of automated tools, firmware, and hardware necessary to perform the software engineering effort, including the software development library. The automated tools may include compliers, assemblers, linke operating systems, debuggers, test tools, documentation tools, and data base management systems.</td>
</tr>
<tr>
<td>Software Quality Assurance (SQA)</td>
<td>A process that ensures that developed computer software complies with defined QA specifications, dictated by regulatory and by referenced consensus standards, (i.e., ASME NQA-1, IEEE Computer Society, etc.).</td>
</tr>
<tr>
<td>Software Quality Assurance Plans (SQAPs)</td>
<td>Planning by the project team for implementation of QA/QC of the software development process, using Codes and consensus standards as applicable (i.e., ASME NQA-1, the IEEE Computer Society Standards, etc.) to ensure that the software product meets all quality requirements. The SQAP involves defining a complete set of quality requirements, documentation of the planned SQA development process with roles and responsibilities, and description of the proposed verification and validation (V&amp;V) testing program with acceptance criteria. The rigor of the SQA plan is dictated by the risk-based graded approach.</td>
</tr>
<tr>
<td>Software Release</td>
<td>A SCM action whereby a particular version of software is made available for a specific purpose</td>
</tr>
</tbody>
</table>
### Table D.1 Software Quality Assurance (SQA) Selected Terminology (continued)

<table>
<thead>
<tr>
<th>Software Requirements Traceability Matrix</th>
<th>A cross-walk of software test cases against the SQA requirements matrix. At least one test case should be associated with each safety-related requirement.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Software Validation</td>
<td>The objectives of software validation are to ensure that the as-built product correctly and adequately performs all of the intended functions and does not perform any unintended functions, either by itself or in combination with other interfaces that may degrade the system.</td>
</tr>
<tr>
<td>Software Verification</td>
<td>The process of evaluating the software to determine if it and its associated products conform to established requirements. Examples of verification activities include formal reviews and audits, peer reviews, and testing activities, from the unit level to the system level.</td>
</tr>
</tbody>
</table>
| Summary of the Safety Software QA (SSQA) Requirements of DOE O 414.1D | The SSQA requirements for safety software (SS), listed in DOE O 414.1D, Attachment 4, are summarized:  
  - SS shall be acquired, developed, and implemented in accordance with ASME NQA-1-2008/NQA-1a-2009, or other national/international equivalent QA consensus standard.  
  - The design authority shall be involved in key SSQA management activities such as the requirements specification, acquisition, design, development, V&V and SCM, and identification, documentation, control, and maintenance of the SS  
  - The design authority approves the SS grading levels  
  - Using the consensus standard selected and the approved grading levels, the applicable ten SSQA work activities listed in Attachment 4 shall be selected and implemented. |
APPENDIX E: TRANSFER FUNCTION METHOD FOR EVALUATION OF EXTERNAL RADIATION LIMITS

In order to potentially minimize the number of separate calculations involving very similar contents in a package, a transfer function (TF) method has been proposed (see Reference 5-2 in this document). Using this method, a set of functions could be defined for a specific energy group structure that could be used repeatedly for folding in a source spectrum and summing over the energy groups to obtain a desired quantity such as a dose rate at a specific location. The method involves starting a single source particle in each energy group and estimating its contribution to the dose rate at specified locations. This results in a set of Transfer Functions that are dose rates on a per source particle in each energy group. An identical energy group structure is used to obtain a source spectrum based on a specific mass, for example 1g, and multiplying the source term in each group by the corresponding transfer function and summing over all energies. This approach would give the dose rate at a specific location on the basis of 1g of source material. This quantity could then be scaled up to determine a mass that would be compliant with the external radiation limits prescribed by the regulations. A similar approach could also be used for spent fuel by performing similar calculations based on for example, a single fuel rod and scaling up to an entire assembly.

Contents made up of actinides in pure form or in combination with light elements are typical contents that need to be shipped in DOE packages. For these types of contents, the TF method fails in many cases by being non-conservative or in other cases, overly conservative, depending on whether the self-shielding provided by the neutron source is less dominant than subcritical multiplication, or self-shielding was more dominant than subcritical multiplication, respectively. The extensive study that was conducted into this method demonstrated that in cases where mass limits are to be estimated to comply with regulatory external radiation limits, the TF method is not appropriate for use and individual calculations are needed to produce optimal mass limits (see Reference 5-2 in this document). This turned out to be the case for gamma sources as well, where self-shielding, or the lack thereof, resulted in similar overly conservative or non-conservative estimates. An example of overestimation of shippable mass in a modern Type B package estimated using the TF method, is pure Cm-244. The TF method was non-conservative by 31%. On the overly conservative side, 4.34 times the amount of Am-243 estimated by the TF method could be shipped in the same Type B container. In the case of Cs-137, the TF method was non-conservative by 20% as an unshielded content but was overly conservative by 32% when it was placed in a tungsten shielded container. A complete set of data for actinides in pure form or combined with several light elements as well as common gamma sources, can be obtained by using this link:


In the case of spent fuel, the main characteristic of a spent fuel assembly is that the dose rates are dominated by gamma radiation that is being emitted by a fixed fuel matrix with a fixed high Z, high density material. There is a negligible contribution to the dose rates from neutrons resulting in the fact that the issue of subcritical multiplication is not important. If the goal here is to evaluate dose rates outside a set of spent fuel assemblies, this method could be successfully
employed. After a period of about 2 years, the main source of gamma radiation is Cs-137, a fission product with a long half-life of 30 years and a fission yield that is essentially the same (~6.5%) whether it is produced from U-235 or Pu-239 fissions. The gamma source term increases linearly with burnup and can be scaled up for a fixed cooling time. In addition, the gamma source per unit burnup decreases as power function of cooling time. Given these correlations, the TF method can be applicable to determine dose rates, dominated by gammas, outside spent fuel assemblies.

Extreme caution must be exercised when spent fuel is in a shipping container since shielding provided by the packaging can lead to the dose rates outside a shipping cask having contributions from neutrons and gammas that are comparable. If this is the case, the TF method will fail as the issue of subcritical multiplication will potentially be a factor. Thus, even if the dose rates are dominated by gammas outside an unshielded spent fuel assembly, this may not be the case outside a shipping cask designed to carry spent fuel. In addition, the contents in the cask may consist of spent fuel with widely varying burnups, cooling times and initial enrichment, all of which impact the neutron source term resulting in the failure of the TF method.

In summary, the TF method is not suitable to determine shippable quantities of radioisotopes or special nuclear materials in packages and detailed calculations are needed to determine optimal quantities. Even in the case of spent fuel in shipping containers, the TF method will mostly be inappropriate. Overall, like any other method, individual cases should be evaluated to ensure that, when employed, the TF method does not result in overestimating or underestimating the dose rates.