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UCID-21218 Rev. 3

Packaging Review Guide for Reviewing Safety Analysis Reports for Packagings

Revision 3

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Prepared by

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ABSTRACT

This Packaging Review Guide (PRG) provides guidance for Department of Energy (DOE) review and approval of packagings to transport fissile and Type B quantities of radioactive material. It fulfills, in part, the requirements of DOE Order 460.1B for the Headquarters Certifying Official to establish standards and to provide guidance for the preparation of Safety Analysis Reports for Packagings (SARPs).

This PRG is intended for use by the Headquarters Certifying Official and his or her review staff, DOE Secretarial offices, operations/field offices, and applicants for DOE packaging approval.

This PRG is generally organized at the section level in a format similar to that recommended in Regulatory Guide 7.9 (RG 7.9). One notable exception is the addition of Section 9 (Quality Assurance), which is not included as a separate chapter in RG 7.9. Within each section, 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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Revision 3 is a complete update of the 1999 edition of this document, whose authors deserve acknowledgment for the initial foundation from which this work was developed: M. K. Sheaffer, B. L. Anderson, L. E. Fischer, R. S. Hafner, J. Hovingh, S. C. Keeton, G. C. Mok, M. E. Mount, E. W. Russell, C. K. Syn, and M. C. Witte.

As noted in the Introduction, this document incorporates substantial guidance from various reports published by the U.S. Nuclear Regulatory Commission (NRC), including NUREG-1609, *Standard Review Plan for Transportation Packages for Radioactive Material*, and NUREG-1617, *Standard Review Plan for Transportation Packages for Spent Nuclear Fuel*. The authors would like to thank the NRC staff, with whom we have worked for almost two decades, for their support and assistance.

Appreciation should also be acknowledged to the packaging review staff at Argonne National Laboratory, and at Eagle Research Group, Inc., for their comments and suggestions on the draft of this document.

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ABBREVIATIONS AND ACRONYMS

ANL	Argonne National Laboratory
ANS	American Nuclear Society
ANSI	American National Standards Institute
ASME	American Society of Mechanical Engineers
AWS	American Welding Society
B&PV	Boiler and Pressure Vessel (ASME Code)
Bq	Becquerel
cc	cubic centimeter
CFR	Code of Federal Regulations
cg	center of gravity
Ci	curie
cm	centimeter
CoC	certificate of compliance
CSI	Criticality Safety Index
DOE	U.S. Department of Energy
DOE O	U.S. Department of Energy Order (used in designation of new-series orders)
DOT	U.S. Department of Transportation
ft	foot
g	acceleration due to gravity
h	hour
HAC	Hypothetical Accident Conditions
in.	inch
k_{eff}	effective multiplication factor
kPa	kilopascal
IAEA	International Atomic Energy Agency
ISG	Interim Staff Guidance
LLNL	Lawrence Livermore National Laboratory

m	meter
MNOP	Maximum Normal Operating Pressure
MPa	megapascal
mrem	millirem
mSv	millisievert
NCT	Normal Conditions of Transport
NRC	U.S. Nuclear Regulatory Commission
PBq	petabecquerel (10^{15} Bq)
PRG	Packaging Review Guide (this document)
psi	pounds (force) per square inch
QA	quality assurance
ref	reference
RG	Regulatory Guide
s	second
SARP	Safety Analysis Report for Packaging(s)*
SCO	surface contaminated object
SRNL	Savannah River National Laboratory
SSCs	structures, systems, and components (important to safety)
SER	Safety Evaluation Report
Sv	sievert
TBq	terabecquerel (10^{12} Bq)
TI	transport index
TRR	Technical Review Report

* The term "SARP" is commonly used by DOE and its contractors to denote the document that describes and evaluates the proposed package. NRC licensees typically use the term "Safety Analysis Report (SAR)." In addition to the SARP, the "application" typically includes a transmittal letter and other supplemental information docketed during the review process.

INTRODUCTION

Background

Department of Energy Order 460.1B (i.e., DOE O 460.1B)[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 must be in packagings approved by the Headquarters Certifying Official under conditions specified in the DOE Certificate of Compliance (CoC).

The authority for DOE to certify packagings is established by 49 CFR 173.7(d),[2] which states that packagings made by or under the direction of DOE may be used for the transportation of radioactive materials when evaluated, approved, and certified by DOE against standards equivalent to those specified in 10 CFR 71.[3] DOE O 460.1B explicitly states that such packages must comply with the standards of 10 CFR 71, and with any other requirements deemed applicable by the Headquarters Certifying Official.

Purpose

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

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

- Summarize the regulatory requirements for package approval
- 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.

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* Similar requirements were previously established by DOE Orders 1540.2 and 5480.3, which may still be applicable depending on specific contractual relationships.

This PRG was originally published in September 1987. Revision 1, issued in October 1988, added new review sections on quality assurance and penetrations through the containment boundary, along with a few other items. Revision 2 was published October 1999. Revision 3 of this PRG is a complete update, and supersedes Revision 2 in its entirety.

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 NRC. Such assurance can be provided by:

- Requiring that DOE package designs meet the standards of 10 CFR 71 or their equivalent
- Ensuring that the evaluation methods used to demonstrate compliance with these standards 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-1609, *Standard Review Plan for Transportation Packages for Radioactive Material*[4]
- NUREG-1617, *Standard Review Plan for Transportation Packages for Spent Nuclear Fuel*[5]
- Regulatory Guide 7.9, *Standard Format and Content of Part 71 Applications for Approval of Packaging for Radioactive Material*[6, 7]
- Regulatory Guide 7.10, *Establishing Quality Assurance Programs for Packaging Used in Transport of Radioactive Material*[8, 9]
- Other regulatory guides such as the Interim Staff Guidance (ISG) and NUREG reports that provide guidance on criteria for evaluating transportation packages.

Scope

Because of the large variety of packages and the many different approaches that can be taken to evaluate these packaging designs, no single guide can address in detail every situation that might be applicable to a review. This PRG is intended to provide a general description of the principles and procedures for evaluating packaging applications. DOE may therefore need to modify or expand the guidance in this PRG to adapt to specific packaging designs. This PRG does not relieve any DOE element or contractor from the requirements of DOE O 460.1B or other pertinent regulations, or imply that SARPs reviewed in accordance with this guide will necessarily be approved.

This PRG addresses shipment of fissile or Type B quantities of radioactive material in DOE certified packagings under the provision of DOE O 460.1B and 10 CFR 71. The following areas of DOE O 460.1B and 10 CFR 71 *are not* currently within the scope of this PRG:

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

Organization of PRG

The main body of this PRG is organized into nine sections 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 Section 9 (Quality Assurance), which is not included as a separate chapter in RG 7.9. Within each section, this 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 section follows the format below.

Introduction

The introduction succinctly states the objective of the review for each section, provides summary information as appropriate, and relates the review to information provided in other chapters of the SARP.

No chapter of a SARP can be reviewed independently from information presented in other 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 only 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 or with the specific format of the SARP.

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* For clarification, the major divisions of RG 7.9 (and a SARP) are referred to as “chapters.” The major divisions of this PRG are considered “sections.”

Subsection 1. Areas of Review

This subsection identifies the principal areas that are reviewed to demonstrate that the packaging design complies with regulatory requirements. In general, the Areas of Review correspond to the major subsections of RG 7.9, although in some cases they have been modified 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. This modification in wording is not intended to change or interpret the regulations. Furthermore, the reader is cautioned that the categorization of regulatory requirements by SARP section (or PRG chapter) is a subjective judgment, which may depend on the package design as well as the specific format in which the SARP is organized. 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 the review of a package. The Review Procedures are organized in parallel with the Areas of Review identified in Subsection 2 above. Because of the large number of different package designs, DOE may need to expand or modify these procedures to adapt to a specific package or to address the method of evaluation presented in the SARP.

The review of the evaluation presented in the SARP will often necessitate confirmatory analyses by the reviewers. The effort and level of detail of such analyses will depend on many factors, including the issues evaluated, the method of evaluation (e.g., test or analysis), the complexity of the evaluation, the experience of the reviewer, similarity to other approved packages, the margin between evaluated performance and regulatory requirements, importance to safety, and many other factors.

Subsection 4. Evaluation Findings

This subsection presents an example of the major findings of the review. The review staff will modify the wording as appropriate to address specific details of the SARP and methods of review. In addition, this subsection identifies typical limiting assumptions or conditions applicable to the evaluation that might not be specified in the General Information chapter of the SARP but that should be included as conditions of approval in the CoC.

Subsection 5. References

This subsection identifies references cited in the section. DOE orders are specified in this PRG by order number (e.g., DOE O 460.1B or DOE O 414.1C). Revision designations (e.g., A, B, C) are those in effect at the time of publication of this PRG.

Appendices of PRG

This PRG contains four appendices. Appendix A provides definitions of common package-related terms, many of which are also defined in 10 CFR 71 or 49 CFR Part 173. Appendix B presents a summary listing of 10 CFR 71 requirements and the SARP chapters to which they are generally applicable. The 2004 revision of 10 CFR 71 resulted in several changes and additional requirements, which are highlighted in Appendix C. A summary of issues relevant to materials and fabrication, which are typically addressed in several SARP chapters, is included in Appendix D.

Requirements and Guidance

Throughout this PRG, the word *must* 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 review of DOE SARPs is 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:

- Applicable regulatory requirements
- Methods 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 findings 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 to document DOE's review of the package for compliance with DOE O 460.1B and 10 CFR 71.

References

[1] U.S. Department of Energy, *Packaging and Transportation Safety*, DOE Order 460.1B, April 4, 2003.

[2] Department of Transportation, Research and Special Programs Administration, *49 CFR Parts 171, 172, et al., Hazardous Materials Regulations; Compatibility with the Regulations of the International Atomic Energy Agency; Final Rule*, 69 F.R. 3632, January 26, 2004, as amended.

[3] Nuclear Regulatory Commission, 10 CFR Part 71, *Compatibility with IAEA Transportation Standards (TS-R-1) and Other Transportation Safety Amendments; Final Rule*, 69 F.R. 3698, January 26, 2004, as amended.

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

[5] U.S. Nuclear Regulatory Commission, *Standard Review Plan for Transportation Packages for Spent Nuclear Fuel*, NUREG-1617, March 2000.

[6] U.S. Nuclear Regulatory Commission, Office of Nuclear Regulatory Research, Proposed Revision 2 to Regulatory Guide 7.9, *Standard Format and Content of Part 71 Applications for Approval of Packaging for Radioactive Material*, May 1986.

[7] U.S. Nuclear Regulatory Commission, Office of Nuclear Regulatory Research, *Standard Format and Content of Part 71 Applications for Approval of Packages for Radioactive Material*, Regulatory Guide 7.9, Revision 2, March 2005.

[8] U.S. Nuclear Regulatory Commission, Office of Nuclear Regulatory Research, *Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material*, Regulatory Guide 7.10, Revision 1, June 1986.

[9] U.S. Nuclear Regulatory Commission, Office of Nuclear Regulatory Research, *Establishing Quality Assurance Programs for Packaging Used in Transport of Radioactive Material*, Regulatory Guide 7.10, Revision 2, March 2005.

1.0 GENERAL INFORMATION REVIEW

This review verifies that the package design has been described in sufficient detail to provide an adequate basis for its evaluation.

The General Information chapter of the Safety Analysis Report for Packaging (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.

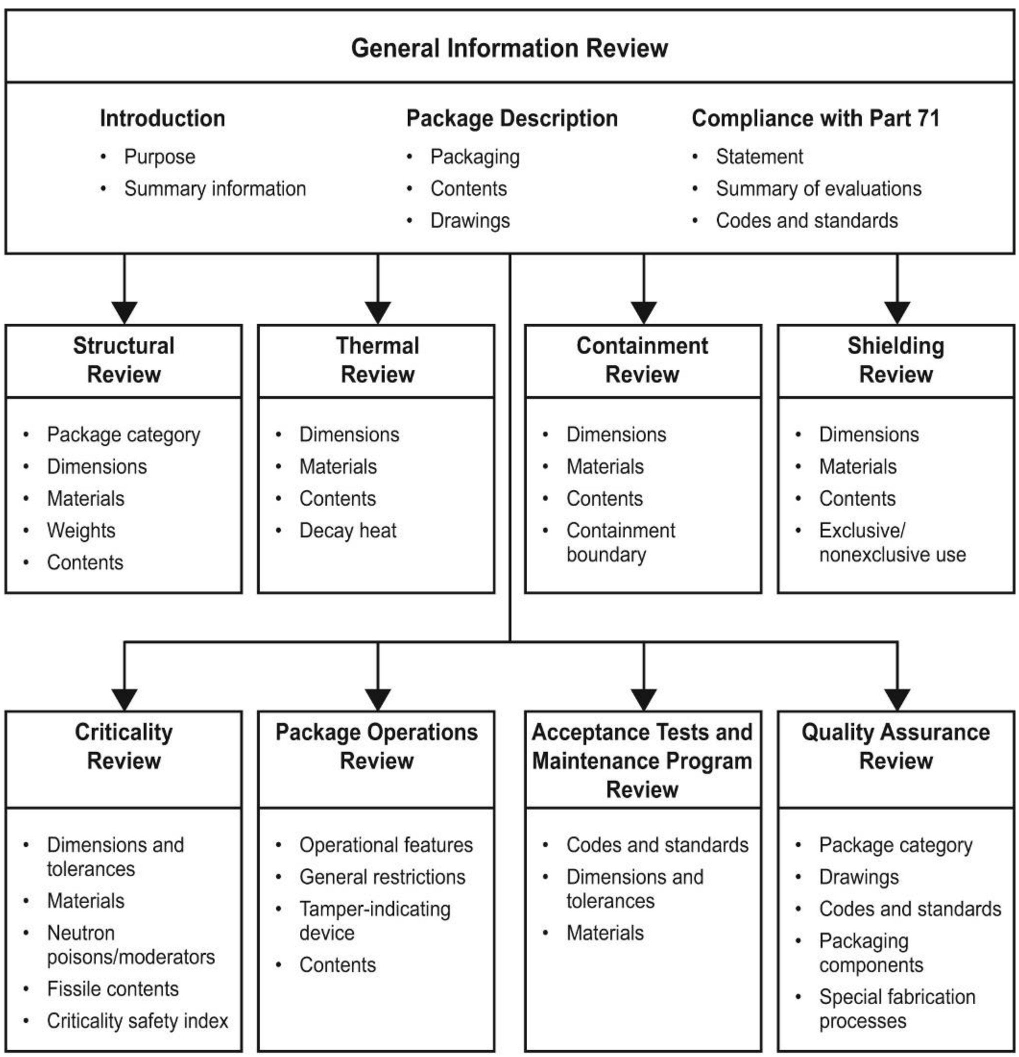

Figure 1.1 Example of Information Flow for the General Information Review

1.1 Areas of Review

The package description and engineering 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 must be submitted 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 must be approved. [§71.19, §71.31(b), §71.107(c)]
- The application must 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 must 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 must reference or describe the quality assurance program applicable to the package. [§71.31(a)(3), §71.37]
- The application must 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 must describe the basis and rationale used to formulate the quality assurance program. [§71.31I]

- An application for renewal of a previously approved package must 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 must not be less than 10 cm (4 in.). [§71.43(a)]
- The outside of the package must 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) must 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 must not exceed the A_1 or A_2 values listed in 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, 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 must meet the requirements of §71.55(f).
- A fissile material package must 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) must be shipped as a solid. [§71.63]
- The package must 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 Packaging Review Guide (PRG).

1.3.1 Introduction

1.3.1.1 Purpose of Application

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

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

Applications for modification of an approved design should clearly identify the changes being requested. Modifications may include design changes, changes in authorized contents, or changes in the conditions of the approval (including changes in the designation of the package identification number). Design changes should be clearly identified on revised engineering drawings. The application should include an 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(e). A summary of regulatory changes affecting the "-96" designation is provided in Appendix C of this PRG.

Applications for renewal of an existing approval should be made within 30 days of expiration of the approval to assure continued use. Expiration of approvals and applications for renewal are subject to the provisions of §71.38.

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.

Review the maximum activity and radionuclides of the contents. Ensure they are consistent with the designated package type. For a mixture of radionuclides, the maximum activity allowed in a Type A package must be determined in accordance with 10 CFR 71 Appendix A and §71.51(b). Packages for transporting fissile radionuclides should also be designated as fissile material packages (e.g., AF-96, B(U)F-96) 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. Review of packagings for plutonium air shipments is not addressed 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. Detailed justification, including calculation of an effective A_2 from the maximum activity of the contents, might be presented in the appendices to the General Information chapter or in another chapter of the SARP (e.g., Containment).

Table 1.1 Category Designations for Type B Packages[1-1]

Contents Form	Category I	Category II	Category III
Normal Form*	Greater than 3,000 A_2 or greater than 1.11 PBq (30,000 Ci)	Between 3,000 A_2 and 30 A_2, and not greater than 1.11 PBq (30,000 Ci)	Less than 30 A_2 and less than 1.11 PBq (30,000 Ci)

*Similar requirements apply to special form radioactive material, which is not explicitly addressed in this PRG.

The package category will determine which code[1-2] or other criteria[1-3, 1-4] 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 engineering 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 chapter of the SARP. Review designated codes and standards as appropriate.

Confirm that the SARP identifies the applicant's quality assurance (QA) program applicable to the package. Details of QA program requirements should be presented in the QA chapter of the SARP.

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*. Note that the CSI, used in shipment, depends on criticality safety and the Transport Index (TI) is based on external radiation levels. Unlike the CSI based on criticality, the TI based on radiation is determined by 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 based on criticality safety.

Determine if the shipment of the package is limited to exclusive use because of other regulatory requirements (e.g., external radiation levels or 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 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, §71.55, §71.59
- General requirements for all packages, §71.43
- Structural requirements for lifting and tie-down devices and for shipments containing more than 10^5 A_2, §71.45 and §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.

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, or other schematic diagrams should be provided as appropriate. Ensure that the description of the packaging presented in the text and figures is consistent with that depicted on the engineering drawings (see Section 1.3.3.1).

Verify that the following information, as applicable, is adequately discussed:

- General packaging description, including overall dimensions, maximum weight, and minimum weight, if appropriate
- Containment features, including a clear identification of the containment boundary
- Shielding features, including personnel barriers
- Criticality control features, including neutron poisons, moderators, and spacers
- Heat-transfer features, including 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, if applicable, 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.

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 the containment-system seal, should be clearly identified. A sketch of the containment system should be provided, and all components should be shown on the engineering drawings in the appendices. Additional information regarding the review of the containment boundary and special containment requirements for plutonium and for damaged reactor fuel are addressed in Section 4 of this PRG.

Based on the package description and engineering drawings, confirm that the package meets the following requirements of §71.43(a) and §71.43(b):

- The smallest overall dimension of the package is not less than 10 cm (4 in.)
- The outside of a package must 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.

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 and maximum quantity (radioactivity or mass) of the radioactive material
- Identification and maximum quantity of fissile material
- Chemical and physical form, including density and moisture content, and the presence of other moderating constituents
- Location and configuration of contents within the packaging, including secondary containers, wrapping, shoring, and other material not defined as part of the packaging
- Identification and quantity of nonfissile materials used as reflectors, neutron absorbers, or moderators
- Any material subject to chemical, galvanic, or other reaction, including the generation of combustible and reactive gases
- Maximum normal operating pressure
- Maximum weight (including shoring, canisters, secondary containers, etc.) and minimum weight if appropriate
- Maximum decay heat.

If the contents include reactor fuel rods or assemblies, the following additional information should be specified as appropriate:

- Type of fuel, maximum enrichment and density of fissile material prior to irradiation (including specifications of non-uniform enrichment, if applicable). If the reactivity (activity) of irradiated fuel is larger than fresh fuel, the isotopic composition of the irradiated fuel should also be presented.
- Burnup, minimum initial enrichment, specific power, cooling time, and heat load
- Fuel assembly specifications, including 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) 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.

1.3.2.4 Operational Features

Verify that appropriate operational features are discussed. A schematic diagram of any special operational feature should be included if applicable. Additional information on operational features may be presented in the Package Operations chapter of the SARP.

1.3.3 Appendices

1.3.3.1 Drawings

Verify that information on the engineering drawings is sufficiently detailed and consistent with the package description. The appendices should not include a full set of drawings for large, complex packages, nor should they 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.[1-5]

Department of Energy (DOE) orders (e.g., DOE O 460.1B and 1540.2) 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 engineering drawings in the SARP is to define the package design, approved by DOE, and compliance with these drawings is typically included in the certificate 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 packaging and contents, including dimensions
- Design features 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 should include, as appropriate:

- Identification of the design feature and its components
- Materials of construction, including applicable material specifications
- Codes, standards, or other similar specification documents for fabrication, assembly, and testing (including welding symbols), and inspection. As appropriate, such information may be included on a separate fabrication specification that can be referenced as a condition of approval in the certificate. Compliance with this specification should generally be noted on the drawings as applicable.
- Location, with respect to other package features
- Dimensions with appropriate tolerances
- Operational specifications (e.g., bolt torque, specifications of pressure-relief devices, etc.).

1.3.3.2 Other Information

Confirm that the appendices include a list of references and a copy of any applicable references not generally available to the reviewer, as appropriate. The appendices may also provide supporting information on special fabrication procedures (as noted on the drawings), determination of the package category, and other appropriate supplemental information deemed necessary by the applicant or reviewer.

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 finding 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 Section 5 of 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
- Minimum criticality safety index

- Restriction to exclusive-use shipment, if applicable
- Drawings that define the package design, and additional fabrication specifications as applicable
- Requirement to add serial numbers to previously approved packages, as applicable.

1.5 References

[1-1] U.S. Nuclear Regulatory Commission, *Fracture Toughness Criteria of Base Material for Ferritic Steel Shipping Cask Containment Vessels with a Maximum Wall Thickness of 4 Inches (0.1 m)*, Regulatory Guide 7.11., June 1991.

[1-2] American Society of Mechanical Engineers, *ASME Boiler and Pressure Vessel Code*, 2004, New York.

[1-3] U.S. Nuclear Regulatory Commission, *Recommended Welding Criteria for Use in the Fabrication of Shipping Containers for Radioactive Materials*, NUREG/CR-3019 (UCRL-53044), March 1984.

[1-4] U.S. Nuclear Regulatory Commission, *Fabrication Criteria for Shipping Containers*, NUREG/CR-3854 (UCRL-53544), March 1985.

[1-5] U.S. Nuclear Regulatory Commission, *Engineering Drawings for 10 CFR Part 71 Package Approvals*, NUREG/CR-5502 (UCRL-ID-130438), May 1998.

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.

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 Packaging (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 requirements of the regulation. 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 reviewed. The Structural review should include the following:

2.1.1 Description of Structural Design

- Design Features
- Codes and Standards

2.1.2 Materials of Construction

- Material Specifications and Properties
- Prevention of Chemical, Galvanic, or Other Reactions
- Effects of Radiation on Materials

2.1.3 Fabrication, Assembly, and Examination

- Fabrication and Assembly
- Examination

2.1.4 General Considerations for Structural Evaluations

- Evaluation by Test
- Evaluation by Analysis

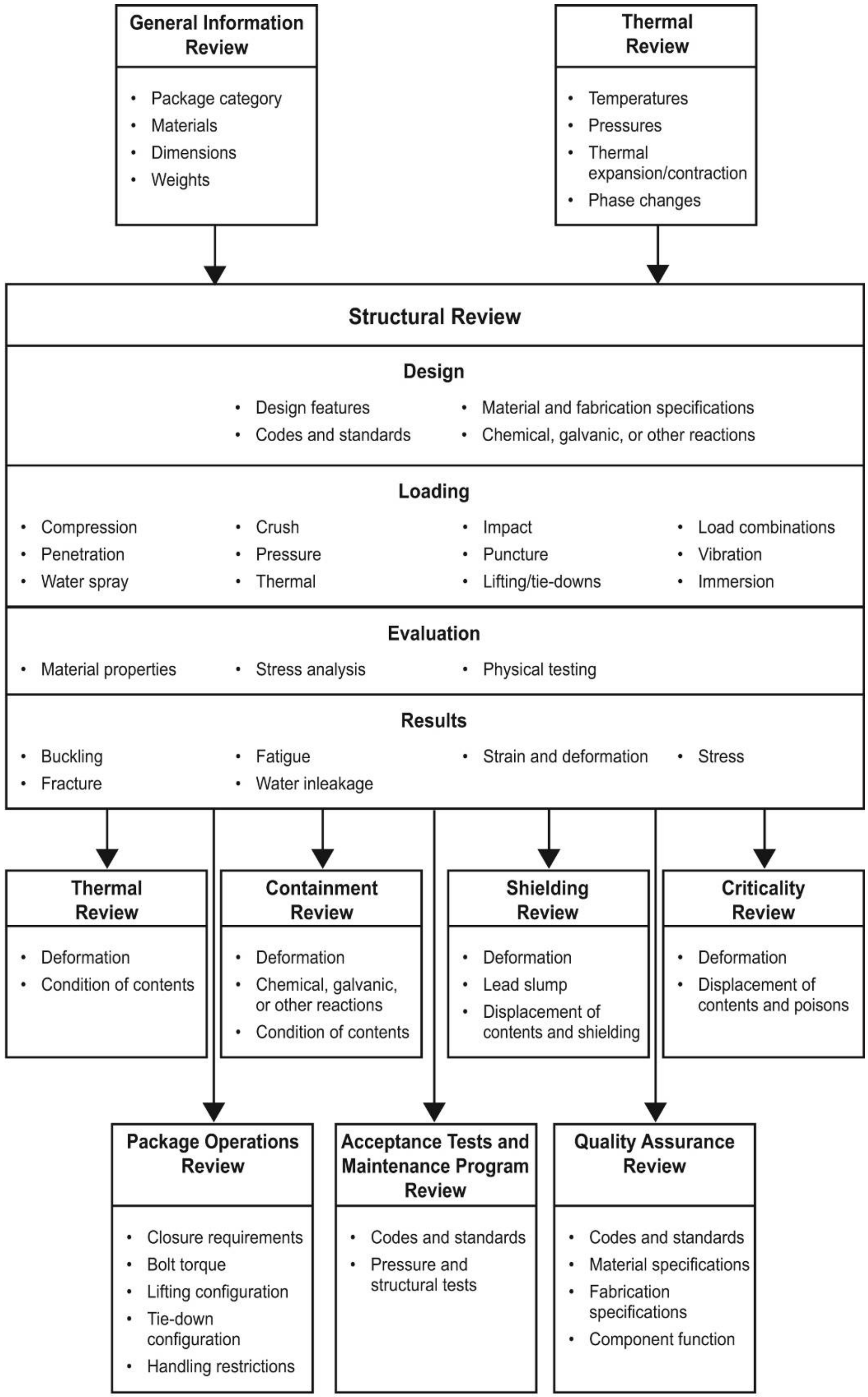

Figure 2.1 Example of Information Flow for the Structural Review

2.1.5 Structural Evaluation of Lifting and Tie-Down Devices

- Lifting Devices
- 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
- 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

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

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

- The application must 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 must describe the basis and rationale used to formulate the quality assurance program. [§71.31(c)]
- The package must 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 must be considered. [§71.43(d)]
- The package design must meet the lifting and tie-down requirements of §71.45.
- A fissile material packaging design to be transported by air must meet the requirements of §71.55(f).
- A Type B package, containing more than 10^5A_2, must 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 must be evaluated under the tests specified in §71.71 for normal conditions of transport. [§71.41(a)]
- The package must 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 must 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 must be evaluated under the tests specified in §71.73 for hypothetical accident conditions. [§71.41(a)]
- The package design must 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 Design Features

Review the structural design features presented in the General Information and Structural Evaluation chapters of the SARP. Design features important to the structural evaluation 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)
- Components that provide structural integrity to the contents (e.g., internal supporting structures).

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
- Description of closure systems
- Description of handling requirements.

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

2.3.1.2 Codes and Standards

Confirm that the SARP identifies established codes and standards applicable to the structural evaluation. The codes and standards should be appropriate for the intended purpose and be 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, codes, and standards documents provide guidance for package design. RG 7.8[2-1] identifies the load combinations to be used in package evaluations, and RG 7.6[2-2] provides design criteria for containment systems. The criteria of RG 7.6 are based on the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel (B&PV) Code,[2-3] Section III, Division 1, Subsection NB. In addition, ASME has recently published a new code section (Section III, Division 3), which is specifically intended for transportation packages. Although both RG 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, Vol. 6[2-4] and NUREG/CR-6322[2-5] discuss the buckling evaluation of containment vessels and baskets, respectively. In addition, ANSI N14.6[2-6] and NUREG-0612[2-7] have been used for the design of packaging trunnions.

Other NUREGs provide guidance on fabricating package components. NUREG/CR-3854[2-8] provides a list of industrial codes and standards for fabrication, and NUREG/CR-3019[2-9] presents criteria specifically for welding. These NUREGs also 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.

Table 2.1 summarizes those sections of the ASME B&PV Code that are generally acceptable for Type B packagings, 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. Specifications of Section III, Subsection NB, should be generally reviewed against those in Section III, Division 3, Subsections WA and WB.

Table 2.1 Sections of ASME B&PV Code Applicable to Type B Packages

Component Function	Category I	Category II	Category III
Containment	Section III, Division 1, Subsection NB or Section III, Division 3	Section III, Division 1, Subsection ND*	Section VIII, Division 1[§]
Criticality (structural support)	Section III, Division 1, Subsection NG (NF for Buckling)		
Shielding and Other Safety Features	Section VIII, Division 1 or Section III, Division 1, Subsection NF		

* 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 is presented in Appendix D 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 engineering 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 generally addressed in Section II.

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). 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. RG 7.11[2-10] and RG 7.12[2-11] 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.[2-12]

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. NRC Information Notice 96-34[2-13] 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, and examination is presented in Appendix D 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 should provide information on codes, standards, and the quality assurance program for fabrication and assembly. In terms of the 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 welding qualifications specified in Section IX. In SARP reviews, the term "fabrication" is often used to mean both fabrication and assembly (e.g., welding). As noted above, guidance on appropriate codes and standards is provided in NUREG/CR-3854 and NUREG/CR-3019.

If fabrication and assembly specifications are prescribed by an appropriate code or standard (e.g., ASME, American Welding Society [AWS]), the code or standard should be identified on the engineering 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 should identify the specifications on which the evaluation depends and describe the method of control to assure that these specifications are achieved. This description may reference a quality assurance or other appropriate specifications document. Such specifications should be included on the engineering drawings and separate fabrication specifications as appropriate. As noted in Section 1.3.3.1 of this PRG, the engineering drawings are generally specified as conditions of approval in the Certificate of Compliance (CoC).

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 B&PV Code, examination is addressed in the 5000-series articles of Section III, with additional details on nondestructive-evaluation methods specified in Section V.

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 should 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 should also be provided on the engineering 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 should 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 RG 7.8 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 should include the following:

- Verify that the test procedures and equipment are adequate. 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[2-14] 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 International Atomic Energy Agency (IAEA) TS.G-1.1(ST-2),[2-15] 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 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 evaluated and their implications interpreted, including interior and exterior damage of the test article. Unexpected or unexplainable test results indicating possible testing problems or non-reproducible specimen behavior should be discussed and evaluated.
- 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 video and photos of the tests as appropriate.
- Verify that the test results are reliable and 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 structural testing, the acceptance tests should be performed according to appropriate codes and standards.

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 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 (e.g., elastic, plastic) are consistent with the analysis methods. 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.[2-16]
- 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. At least one representative input and output file (or key section of the file) should generally be included in the SARP.
- 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 allowables.

2.3.5 Lifting and Tie-Down Standards for All Packages

2.3.5.1 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 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.

2.3.6 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 must 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 must 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 must be considered to be the maximum normal operating pressure, 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).

2.3.6.5 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, considering the combined stresses due to vibration, temperature changes, and pressure loads. If closure bolts are reused, verify that the bolt preload is included in the fatigue evaluation. NUREG/CR-6007[2-17] 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[2-18] and NUREG/CR-0128.[2-19]

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.

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.

2.3.7 Structural Evaluation for Hypothetical Accident Conditions

The evaluation under hypothetical accident conditions must 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 must consider the damage resulting from the preceding tests. In addition, as stated in Section 2.3.6, the tests under normal conditions of transport must 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 system 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 must 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 must 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 must 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, Vol. 3.

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 must 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. 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).

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, Vol. 7. Additional considerations for puncture testing are identified in Nuclear Regulatory Commission (NRC) Bulletin 97-02.[2-20]

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 must 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 must 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 water 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.[2-21] 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 must 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 list of references, copies of applicable references if not generally available to the reviewer, computer code descriptions, input and output files, test results, and other appropriate supplemental information.

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 finding 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 CoC. In addition to specifications of authorized contents and information specified on the engineering 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

[2-1] U.S. Nuclear Regulatory Commission, *Load Combinations for the Structural Analysis of Shipping Casks for Radioactive Material*, Regulatory Guide 7.8, Revision 1, March 1989.

[2-2] U.S. Nuclear Regulatory Commission, *Design Criteria for the Structural Analysis of Shipping Cask Containment Vessels,* Regulatory Guide 7.6, Revision 1 March 1978.

[2-3] American Society of Mechanical Engineers, ASME Boiler and Pressure Vessel Code, 2004.

[2-4] U.S. Nuclear Regulatory Commission, *SCANS (Shipping Cask Analysis System): A Microcomputer Based Analysis System for Shipping Cask Design Review*, NUREG/CR-4554 (UCID-20674), February 1990.

[2-5] U.S. Nuclear Regulatory Commission, *Buckling Analysis of Spent Fuel Basket*, NUREG/CR-6322 (UCRL-ID-119697), May 1995.

[2-6] Institute for Nuclear Materials Management, *American National Standard for Radioactive Materials—Special Lifting Devices for Shipping Containers Weighing 10,000 Pounds (4500 kg) or More*, ANSI N14.6, 1993.

[2-7] U.S. Nuclear Regulatory Commission, *Control of Heavy Loads at Power Plants*, NUREG-0612, June 1982.

[2-8] U.S. Nuclear Regulatory Commission, *Fabrication Criteria for Shipping Containers*, NUREG/CR-3854 (UCRL-53544), March 1985.

[2-9] U.S. Nuclear Regulatory Commission, *Recommended Welding Criteria for Use in the Fabrication of Shipping Containers for Radioactive Materials*, NUREG/CR-3019 (UCRL-53044), March 1985.

[2-10] U.S. Nuclear Regulatory Commission, *Fracture Toughness Criteria of Base Material for Ferritic Steel Shipping Cask Containment Vessels with a Maximum Wall Thickness of 4 Inches (0.1 m)*, Regulatory Guide 7.11, June 1991.

[2-11] U.S. Nuclear Regulatory Commission, *Fracture Toughness Criteria of Base Material for Ferritic Steel Shipping Cask Containment Vessels with a Wall Thickness Greater than 4 Inches (0.1 m),* Regulatory Guide 7.12, June 1991.

[2-12] U.S. Nuclear Regulatory Commission, *Materials Evaluation*, ISG-15, Spent Fuel Projects Office, January 10, 2001.

[2-13] U.S. Nuclear Regulatory Commission, *Hydrogen Gas Ignition during Closure Welding of a VSC-24 Multi-Assembly Sealed Basket*, NRC Information Notice 96-34, May 31, 1996.

[2-14] G. C. Mok, et al., *Guidelines for Conducting Impact Tests of Shipping Containers for Radioactive Material*, UCRL-ID-121673, Lawrence Livermore National Laboratory, September 1995.

[2-15] Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material, TS-G-1.1 (ST-2), International Atomic Energy Agency, Vienna, 2002.

[2-16] U.S. Nuclear Regulatory Commission, *Methods for Impact Analysis of Shipping Containers*, NUREG/CR-3966 (UCID-20639), November 1987.

[2-17] U.S. Nuclear Regulatory Commission, *Stress Analysis of Closure Bolts for Shipping Casks*, NUREG/CR-6007 (UCRL-ID-110637), January 1993.

[2-18] U.S. Nuclear Regulatory Commission, *Dynamic Analysis to Establish Normal Shock and Vibration of Radioactive Material Shipping Packages, Volume 3: Final Summary Report,* NUREG/CR-2146, Vol. 3, October 1983.

[2-19] U.S. Nuclear Regulatory Commission, *Shock and Vibration Environments for a Large Shipping Container During Truck Transport (Part II)*, NUREG/CR-0128, August 1978.

[2-20] U.S. Nuclear Regulatory Commission Bulletin 97-02, *Puncture Testing of Shipping Packages under 10 CFR Part 71*, September 23, 1997.

[2-21] U.S. Nuclear Regulatory Commission, *Compatibility with the International Atomic Energy Agency*, Federal Register, Volume 60, No. 188, September 28, 1995, p. 50257.

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3.0 THERMAL REVIEW

This review verifies that the thermal 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 thermal requirements of 10 CFR 71.

The Thermal review is based in part on the descriptions and evaluations presented in the General Information and Structural Evaluation chapters of the Safety Analysis Review for Packaging (SARP). Similarly, results of the Thermal review are considered in the Structural review and in the review 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), the thermal performance of the package under normal conditions of transport and hypothetical accident conditions must be addressed in the structural evaluation, and the combined structural/thermal performance of the package affects its ability to meet the containment, shielding, and subcriticality requirements of the regulation. Consequently, the Thermal review focuses on confirming the SARP evaluation of the effects of these tests and on coordinating these effects with the review of the Structural Evaluation, Containment, Shielding Evaluation, and Criticality Evaluation chapters.

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
- Decay Heat of Contents
- Codes and Standards
- Summary Tables of Temperatures
- Summary Table of Maximum Pressures

3.1.2 Material Properties, Thermal Limits, and Component Specifications

- Material Properties
- Temperature Limits
- Component Specifications

3.1.3 General Considerations for Thermal Evaluations

- Evaluation by Test
- Evaluation by Analysis

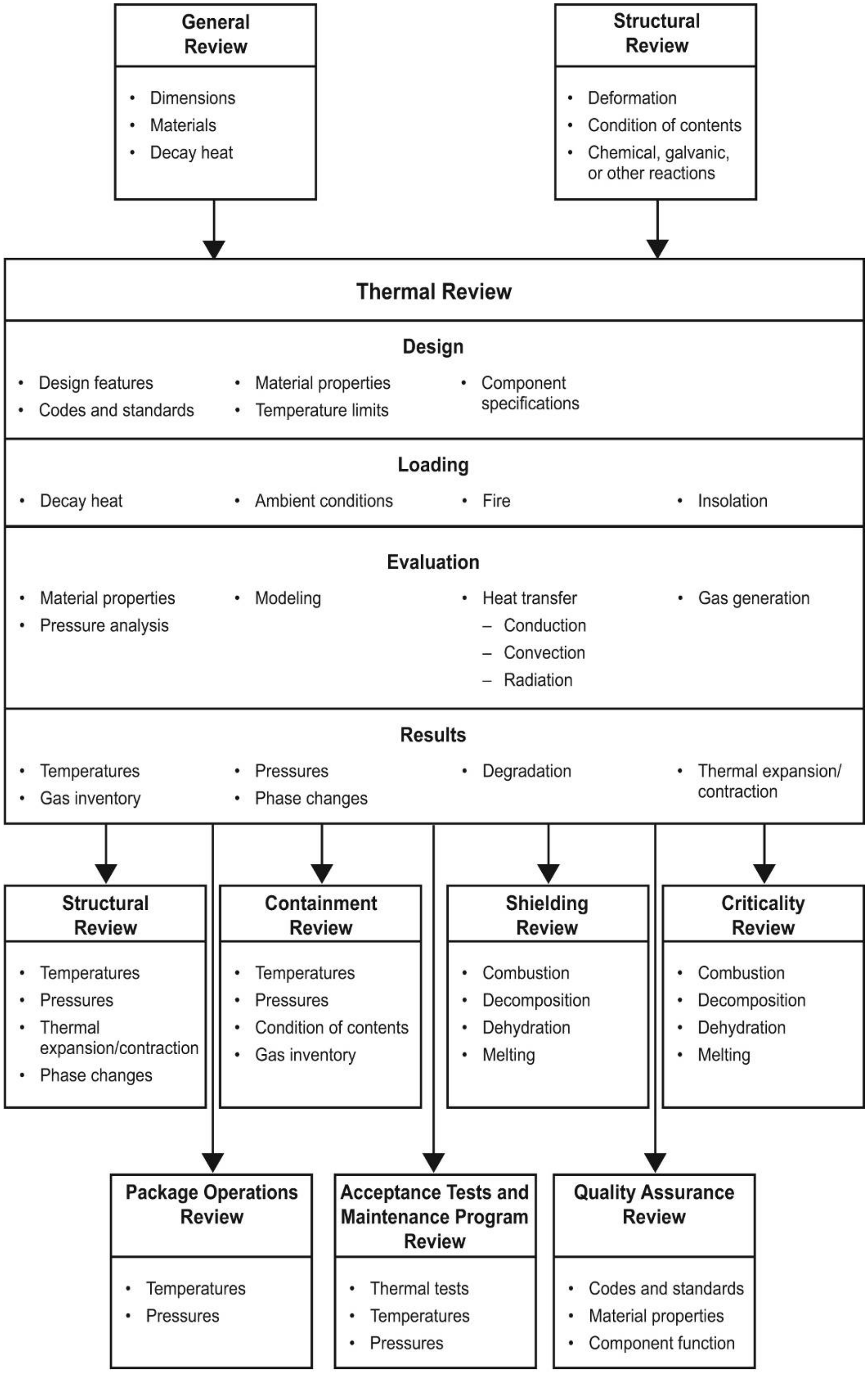

Figure 3.1 Example of Information Flow for the Thermal Review

3.1.4 Thermal Evaluation under Normal Conditions of Transport

- Initial Conditions
- Effects of Tests
- Maximum and Minimum Temperatures
- Maximum Normal Operating Pressure
- Maximum Thermal Stresses

3.1.5 Thermal Evaluation under Hypothetical Accident Conditions

- Initial Conditions
- Effects of Thermal Tests
- Maximum Temperatures and Pressures
- Maximum Thermal Stresses

3.1.6 Thermal Evaluation of Maximum Accessible Surface Temperature

3.1.7 Appendices

- Description of Test Facilities and Equipment
- Test Results
- Applicable Supporting Documents or Specifications
- Details of Analyses

3.2 Regulatory Requirements

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

- The package design must be described and evaluated to demonstrate that it satisfies the thermal requirements of 10 CFR 71. [§71.31(a)(1), §71.31(a)(2), §71.33, §71.35(a)]
- The application must 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 must describe the basis and rationale used to formulate the quality assurance program. [§71.31(c)]
- The package must 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 must be considered. [§71.43(d)]
- The package must 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 must not rely on mechanical cooling systems to meet containment requirements. [§71.51(c)]
- A fissile material packaging design to be transported by air must meet the requirements of §71.55(f).
- The performance of the package must be evaluated under the tests specified in §71.71 for normal conditions of transport. [§71.41(a)]
- The package must 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 must be evaluated under the tests specified in §71.73 for hypothetical accident conditions. [§71.41(a)]

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 mechanical means for the transfer of heat (e.g., fill gas, baskets or other internal supporting structures, physical contacts between components, coolant receptacles, type and volume of coolants, cooling fins, and surface conditions of the packaging components)
- Insulating features, including gaps and insulating materials
- Configuration and materials of the contents.

Information on 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 enginering 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.

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 and fabrication. Ensure that such codes and standards are consistent with those specified in the General Information and Structural Evaluation chapters of the SARP. Determine if these codes or standards specify temperature limits for materials.

3.3.1.4 Summary Tables of Temperatures

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

- The maximum temperatures under normal conditions of transport
- The maximum temperatures under hypothetical accident conditions, and the time after initiation of the fire at which they occur
- The maximum temperatures for the post-fire steady-state condition.

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

Minimum package temperatures are discussed in Section 3.3.2.2 below. In general, the minimum temperature of all materials and components will be -40°C (-40°F).

3.3.1.5 Summary Table of Maximum Pressures

Verify that a summary table includes the maximum normal operating pressure and the maximum pressure in the containment system(s) under hypothetical accident conditions. Determine if other confined volumes of the package are subject to maximum pressure limitations (e.g., outer shell, neutron shielding system, contents) and that such limitations are 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 appropriate properties are specified for materials that affect heat transfer through the package to (or from) the environment, pressures in the package, and thermal stresses. Material properties and the temperature range over which they are designated should be consistent with those used in the structural and thermal evaluations. If a property is specified as temperature independent, ensure that its value is conservative compared with a temperature-dependent specification. Note that a conservative value for heat removal under normal conditions of transport is not necessarily conservative for the thermal test under hypothetical accident conditions. The SARP should provide an authoritative reference for each material property. In general, textbooks are not acceptable references. If the applicant determines thermal properties experimentally, the experiments should be conducted under his/her quality assurance program, and the adequacy of the experiments should be reviewed.

Properties of package (packaging and contents) materials that may be applicable to the heat-transfer evaluation include density, thermal conductivity, specific heat, viscosity, emissivity, and absorptivity. Confirm that the absorptivities and emissivities are appropriate for the package surface conditions, geometries, and radiant spectra. If the SARP justifies an absorptivity less than unity for insolation based on external packaging surface conditions, ensure that controls and procedures are in place to maintain these conditions during service life. Coordinate with the Package Operations review as applicable.

Properties of package material that affect thermally induced pressures or stresses may include the coefficient of thermal expansion, modulus of elasticity, and Poisson’s ratio. Verify that these properties are consistent with those in the Structural Evaluation chapter, as applicable.

If materials undergo chemical or physical changes (e.g., phase transformation, decomposition, dehydration, or combustion), verify that the temperatures at which these conditions occur are presented and that the corresponding material properties (e.g., conductivity, specific heat, density) are appropriate prior to and following the change.

3.3.2.2 Temperature Limits

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

For spent fuel, the SARP should justify the allowable fuel/cladding temperatures. This justification should consider fuel/cladding materials, irradiation conditions, transport environment (including the package fill gas), temperature history of the fuel since removal from the reactor, and intended post-transport storage or disposition. Temperature limits should address creep, creep rupture, diffusion controlled cavity growth, eutectic melting, and other conditions as appropriate.

The minimum temperature of all materials and components will generally be that of the ambient environment, and the minimum allowable temperatures should not exceed -40°C (-40°F) for the conditions of §71.71(c)(2) and -29°C (-20°F) for the other tests of §71.71 and §71.73.

Ensure that the temperatures listed in the summary tables are within the allowable temperature limits.

3.3.2.3 Component Specifications

Ensure that technical specifications are provided for package components (e.g., pressure relief valves, fusible plugs, valves, seals), as appropriate. Confirm that temperature and pressure specifications are not exceeded. Verify that appropriate specifications (e.g., rupture pressure) are included on the engineering 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 initial regulatory conditions have been addressed. RG 7.8 provides guidance on selection of initial conditions. Note that the thermal evaluations should consider a package that has first been subjected to the structural tests under normal conditions of transport and hypothetical accident conditions, as appropriate. Coordinate with the Structural review.
- The most unfavorable orientations have been considered. The most unfavorable orientation for one component may not be the most unfavorable for another component.
- All regulatory test requirements have been included in the evaluation.
- The evaluation methods are appropriate for the thermal conditions considered and follow accepted practices and precepts.
- The time interval after the fire test is adequate to assure that maximum component temperatures and post-fire steady-state temperatures have been determined.
- The results are interpreted correctly.
- The thermal evaluations appropriately address pass/fail criteria and the design margins for package temperatures, pressures, and thermal stresses. Verify that these discussions include the effects of uncertainties in thermal properties, modeling, analytical methods, test conditions, and diagnostics, as appropriate.

3.3.3.1 Evaluation by Test

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

- Verify that the test facility and instrumentation are adequately described and that the test methods and equipment are sufficient for determining the thermal response of the package. Also verify whether the equipment has to be calibrated before the test, and consider if there are differences between the conditions of the test and calibration. Section 3.3.7.1 provides additional detail on the type of information appropriate.
- Verify that the test procedures, test conditions, and test results are adequately documented. Section 3.3.7.2 provides additional detail on test documentation.
- Verify that the test specimen has been fabricated using the materials, methods, and quality assurance specified for the package design. 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 the same weight, thermal properties, and interaction with the packaging as the actual contents. 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 or is otherwise included in post-test analysis of the results.
- Verify that all test results are 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.
- Verify that the interpretation of the test results addresses differences between test conditions and regulatory conditions. For example, decay heat and regulatory ambient temperature and insolation can result in package temperatures that differ from those of the tested package. Such test results may need to be extended to the regulatory conditions by detailed analysis.
- Review the video and photographs of the tests as appropriate.
- Verify that the test results are reliable and 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 UCRL-ID-110445.[3-1]

3.3.3.2 Evaluation by Analysis

If the package is evaluated by analysis, 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 initial and boundary conditions are appropriate.
- Verify that all assumptions, including those in modeling heat sources and heat transfer paths and modes, are clearly stated and justified.
- Verify that appropriate expressions are used for conductive, convective, and radiative heat transfer among package components and from the surfaces of the package to (and from) the environment.
- 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.

- Verify that the results are correctly interpreted and demonstrate adequate margin of safety based on uncertainties and assumptions of the analysis.
- Review the criteria for evaluating pass/fail for the analysis results. Compare these results with the criteria. The maximum temperatures should be compared to corresponding design-code allowables.

3.3.4 Thermal Evaluation under Normal Conditions of Transport

The package must be evaluated for the effects of the tests in §71.71 on the thermal performance of the package. A description of these tests is presented in Section 2.3.6 of this PRG.

3.3.4.1 Initial Conditions

Except as noted in the next paragraph, the initial conditions for tests under normal conditions of transport must be based on an ambient temperature preceding and following the tests remaining 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 pressure in the containment system must be considered to be the maximum normal operating pressure unless a lower internal pressure consistent with the ambient temperature is more unfavorable. Note that the determination of maximum normal operating pressure must assume that the package is subjected to the insolation specified in §71.71(c)(1).

As specified in §71.71(c)(2), the effects of low temperature (cold) on the package must consider an ambient temperature of -40°C (-40°F) in still air and shade (no insolation).

3.3.4.2 Effects of Tests

Confirm that the thermal evaluation demonstrates that the tests for normal conditions of transport 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 materials.
- Changes in material conditions or 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.
- Ability of the packaging to withstand the tests under hypothetical accident conditions. Coordinate also with the Structural review.

3.3.4.3 Maximum and Minimum Temperatures

Verify that the maximum and minimum temperatures of package components and materials under normal conditions of transport 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

Verify that the maximum normal operating pressure is properly evaluated and is consistent with that presented in the summary table discussed in Section 3.3.1.5 above. Maximum normal operating pressure is the maximum gauge pressure that would develop in the containment system in a period of one year under the heat condition of §71.71(c)(1), in the absence of venting, external cooling by an ancillary system, or operational controls during shipment. The evaluation should include the effects of the appropriate local 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 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 NUREG/CR-6487[3-2])
- Hydrogen or other gases resulting from thermal or radiolytic decomposition of materials (e.g., water, plastics) or other reactions as appropriate.

Ensure that the SARP demonstrates that hydrogen and other flammable gases comprise less than 5% by volume of the total gas inventory within any confined volume, or otherwise addresses concerns for deflagration of such gases. For spent fuel, the release of fill gas from the fuel rods should not be considered for diluting the hydrogen concentration. Ensure that any operational controls (e.g., reduced shipment time), used to limit hydrogen production, are adequate and are appropriately addressed in the Package Operations chapter. Note that operational controls during shipment may not be used to limit the maximum normal operating pressure.

If other confined volumes of the package are subject to pressure limitations (e.g., secondary containment, outer shell, neutron shielding system, contents), confirm that pressures within these volumes are appropriately evaluated.

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

3.3.4.5 Maximum Thermal Stresses

Ensure that the evaluation determines thermal stresses caused by geometric constraints, temperature gradients, and other differential thermal expansions. The evaluation should include the maximum stresses as well as cyclic stresses during the service life of the package. Coordinate with the Structural review.

3.3.5 Thermal Evaluation under Hypothetical Accident Conditions

The package must be evaluated for the effects of the tests in §71.73 on the thermal performance of the package.

3.3.5.1 Initial Conditions

Prior to the fire test, the package design must be evaluated for the effects of the drop, crush (if applicable), and puncture tests. Ensure that the initial physical condition of the package design used in the thermal evaluations considers the most unfavorable effects of these 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 thermal test, supplemental information[3-3] published with the 1996 rule stated that insolation may be neglected prior to and during the thermal test but should be considered in subsequent package evaluation after the fire. Neglecting insolation prior to the fire will result in an initial temperature in the containment system that is inconsistent with that corresponding to 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. Consequently, for simplicity and conservatism, the SARP evaluation may frequently include insolation as an initial condition for the fire test.

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 that temperature, heat-transfer boundary conditions (including fire-enhanced convection), and an appropriate supply of oxygen are maintained for at least 30 minutes.

Confirm that 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 is provided in UCRL-ID-110445.

Ensure that the physical condition of the package is clearly identified and appropriately considered in the Containment, Shielding Evaluation, and Criticality Evaluation chapters of the SARP. Coordinate with those reviews as appropriate. In addition, if the package is subjected to the water immersion test of §71.73(c)(5), coordinate with the Structural review to ensure that the post-fire condition of the package has been appropriately addressed.

3.3.5.3 Maximum Temperatures and Pressures

Verify that the evaluation appropriately determines the peak transient temperatures of package components as a function of time after the fire and the maximum temperatures from the post-fire steady-state condition. Ensure that temperatures are corrected for differences between regulatory and test conditions, if applicable. Confirm that these temperatures do not exceed their maximum allowable values. 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 is based on the maximum normal operating pressure (Section 3.3.4.4) as it is affected by fire-caused increases in package component temperatures. 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 pressure determination.

Ensure that the SARP demonstrates that hydrogen and other flammable gases comprise less than 5% by volume of the total gas inventory within any confined volume, or otherwise addresses concerns for deflagration of such gases, as discussed in Section 3.3.4.4.

If other confined volumes of the package are subject to maximum pressure limitations (e.g., secondary containment, outer shell, neutron shielding system, contents), confirm that pressures in these volumes are appropriately evaluated and are acceptable.

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

3.3.5.4 Maximum Thermal Stresses

Ensure that the evaluation determines the thermal stresses caused by geometric constraints from temperature gradients and differential thermal expansions. Verify that the maximum thermal stresses, which can occur either during or after the fire, are consistent with those in the Structural Evaluation chapter.

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 subjected to the heat conditions of §71.43(g). For packages with a significant heat load, coordinate with the Package Operations review to ensure that the requirements of §71.87(k) are satisfied.

3.3.7 Appendices

3.3.7.1 Description of 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, and test package component temperatures and pressures

- The post-fire environment for a time period adequate to attain the post-fire, steady-state condition
- 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 Test Results

Verify that appropriate test reports are included in the appendices. These reports should include:

- Test procedures
- Test package description
- 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 conditions) 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. In addition to the documents noted in Sections 3.3.7.1 and 3.3.7.2, 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

Supplemental calculations may be required to support evaluations presented in the Thermal Evaluation chapter. Verify that all such special analyses are prepared in a manner consistent with Section 3.3.3.2.

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 finding 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 engineering 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

[3-1] VanSant, J. H., R. W. Carlson, L. E. Fischer, and J. Hovingh, *A Guide for Thermal Testing Transport Packages for Radioactive Material—Hypothetical Accident Conditions*, UCRL-ID-110445, Lawrence Livermore National Laboratory, February 9, 1993.

[3-2] U.S. Nuclear Regulatory Commission, *Containment Analysis for Type B Packages Used to Transport Various Contents,* NUREG/CR-6487, UCRL-ID-124822, November 1996.

[3-3] U.S. Nuclear Regulatory Commission, *Compatibility with the International Atomic Energy Agency*, Federal Register, Volume 60, No. 188, September 28, 1995, p. 50257.

4.0 CONTAINMENT REVIEW

This review verifies that the package design satisfies the containment requirements of 10 CFR 71 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 Packaging (SARP). Similarly, results of the Containment review are considered in the review of Package Operations, Acceptance Tests and Maintenance Program, and Quality Assurance. An example of the information flow for the Containment review is shown in Figure 4.1.

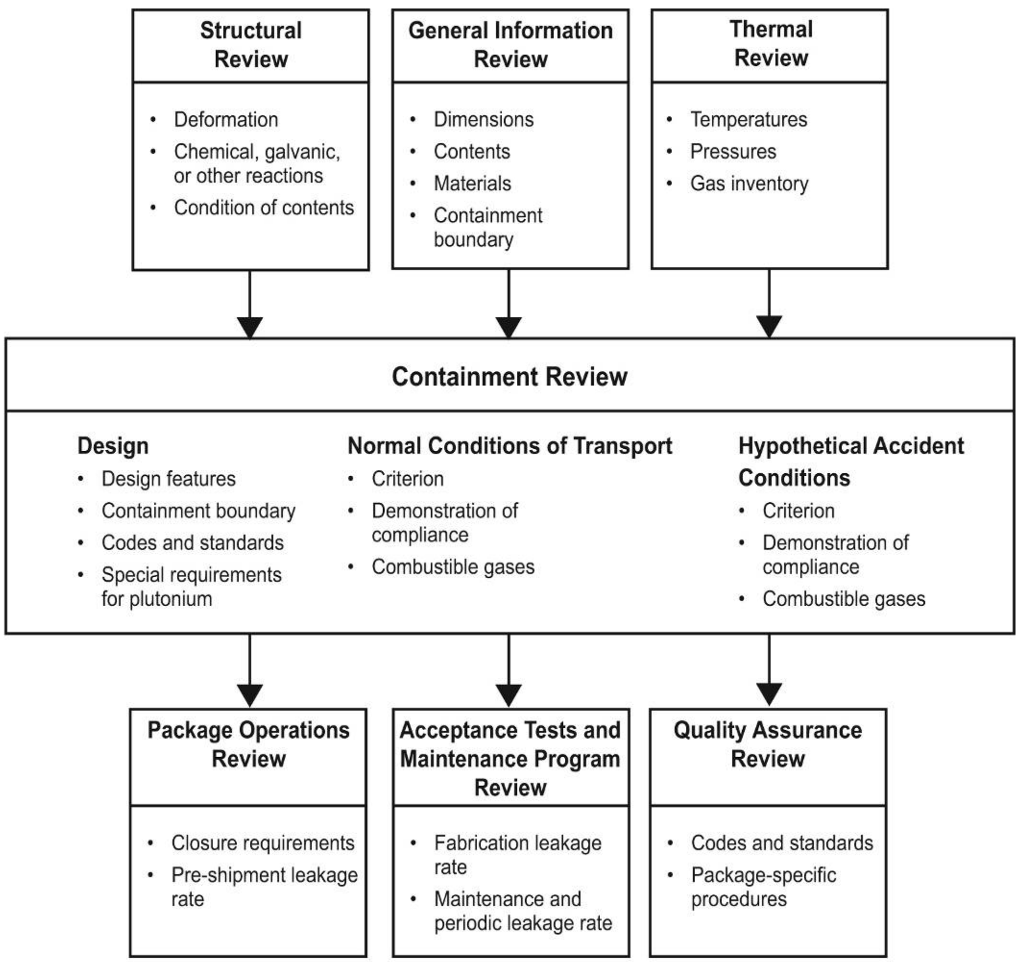

Figure 4.1 Example of Information Flow for the Containment Review

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
  - Fissile Type A 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 must 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 must 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 must describe the basis and rationale used to formulate the quality assurance program. [§71.31(c)]
- The package must 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 must 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 must be considered. [§71.43(d)]
- Any valve or similar device on the package must be protected against unauthorized operation and, except for a pressure relief valve, must be provided with an enclosure to retain any leakage. [§71.43(e)]
- The package must 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 must meet the containment requirements of §71.51(a)(1) under the tests specified in §71.71 for Normal Conditions of Transport.
- A Type B package must meet the containment requirements of §71.51(a)(2) under the tests specified in §71.73 for Hypothetical Accident Conditions.
- The maximum activity of radionuclides in a Type A package must 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 A_2 equal to $10A_2$ 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 10^5A_2, the requirements of §71.61 must be met. [§71.51(d)]
- A Type B package containing more than 10^5A_2 must 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) must 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.

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 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 (as it does for Type B packages), the containment must be adequate to ensure subcriticality. Coordinate with the Criticality review as appropriate.

4.3.1.1.2 Type B Packages

Type B packages must satisfy the quantitative *release* rates of §71.51(a)(1) and (a)(2). As is noted in Reg. Guide 7.4, the guidance contained in American National Standards Institute (ANSI) N14.5[4-1] 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., L_N and L_A, respectively). These two volumetric leakage rates should be converted to maximum allowable *air* leakage rates under reference conditions (temperature, pressures) in accordance with ANSI N14.5. The smaller of L_N and L_A (when converted to reference conditions) is defined as the reference air leakage rate, L_R.

In general, the normal condition leakage rate is the most restrictive. Hence, L_N, when converted to reference conditions, is generally equal to L_R. 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 L_R is determined by L_A, 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 A_2, which must be determined according to the provisions of §71.51(b).

Representative analyses for determining simplified containment criteria are provided in NUREG/CR-6487[4-2] for Type B packages that contain powders, liquids, irradiated fuel rods, gases, or solids. If the SARP uses these analyses, ensure that the assumptions of that document are applicable to the package under consideration. Guidance on containment analyses for aluminum-based spent fuel is provided by WSRC-TR-98-00317.[4-3]

4.3.1.1.3 Combustible-Gas Generation

Confirm that the SARP demonstrates that any combustible gases generated in the package during a period of one year do not exceed 5% (by volume) of the free gas volume in any confined region of the package, or otherwise addresses concerns related to deflagration of such gases. Additional guidance on issues concerning combustible-gas generation can be found in

NUREG-1609,[4-4] NUREG-1617,[4-4] and the NRC's Interim Staff Guidance (ISG) Document, ISG-15.[4-5] All reviews on combustible-gas generation issues should be coordinated with the Structural and Thermal 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
- 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. Confirm that all containment boundary penetrations and their method of closure are adequately described. Verify that the containment system 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 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. Coordinate with the Thermal review as appropriate.

Any valve or similar device on the package must be protected against unauthorized operation and, except for a pressure relief valve, must 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 any codes or standards applicable to the containment 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.

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

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 packagings in service, and 3) it is expected that these double-containment plutonium packagings 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 must 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,[4-6] 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, as 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. 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., ref·cc/s, or 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., $\leq 1 \times 10^{-7}$ ref·cm^3/s, for their containment criterion for normal conditions of transport, then the applicant need not supply any calculations to further justify their position.

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 ($ref{\cdot}cc^3/s$, or $ref{\cdot}cm^3/s$) in accordance with ANSI N14.5.

Note: If the applicant has elected to adopt the ANSI N14.5 definition of *leaktight*, i.e., $\leq 1 \times 10^{-7}$ $ref{\cdot}cm^3/s$, 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 must 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 any additional supplemental information 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 finding 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 engineering 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 References

[4-1] American National Standards Institute, *American National Standard for Radioactive Materials—Leakage Tests on Packages for Shipment*, ANSI N14.5-1997, New York, New York, 10036.

[4-2] U.S. Nuclear Regulatory Commission, *Containment Analysis for Type B Packages Used to Transport Various Contents*, NUREG/CR-6487, UCRL-ID-124822, November 1996.

[4-3] Westinghouse Savannah River Company, *Bases for Containment Analyses for Transportation of Aluminum-Based Spent Nuclear Fuel*, WSRC-TR-98-00317, Aiken, SC, October 1998.

[4-4] U.S. Nuclear Regulatory Commission, *Standard Review Plan for Transportation Packages for Radioactive Material*, NUREG-1609, Washington, DC, March 31, 1999.

[4-4] U.S. Nuclear Regulatory Commission, *Standard Review Plan for Transportation Packages for Spent Nuclear Fuel*, NUREG-1617, Washington, DC, March 2000.

[4-5] U.S. Nuclear Regulatory Commission, Spent Fuel Project Office, *Interim Staff Guidance 15, Materials Evaluation*, Washington, DC, January 10, 2001.

[4-6] U.S. Nuclear Regulatory Commission, Spent Fuel Project Office, *Interim Staff Guidance 1, Damaged Fuel*, Washington, DC, October 25, 2002.

5.0 SHIELDING REVIEW

This review verifies that the package design meets the external radiation requirements of 10 CFR 71 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 Packaging (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.

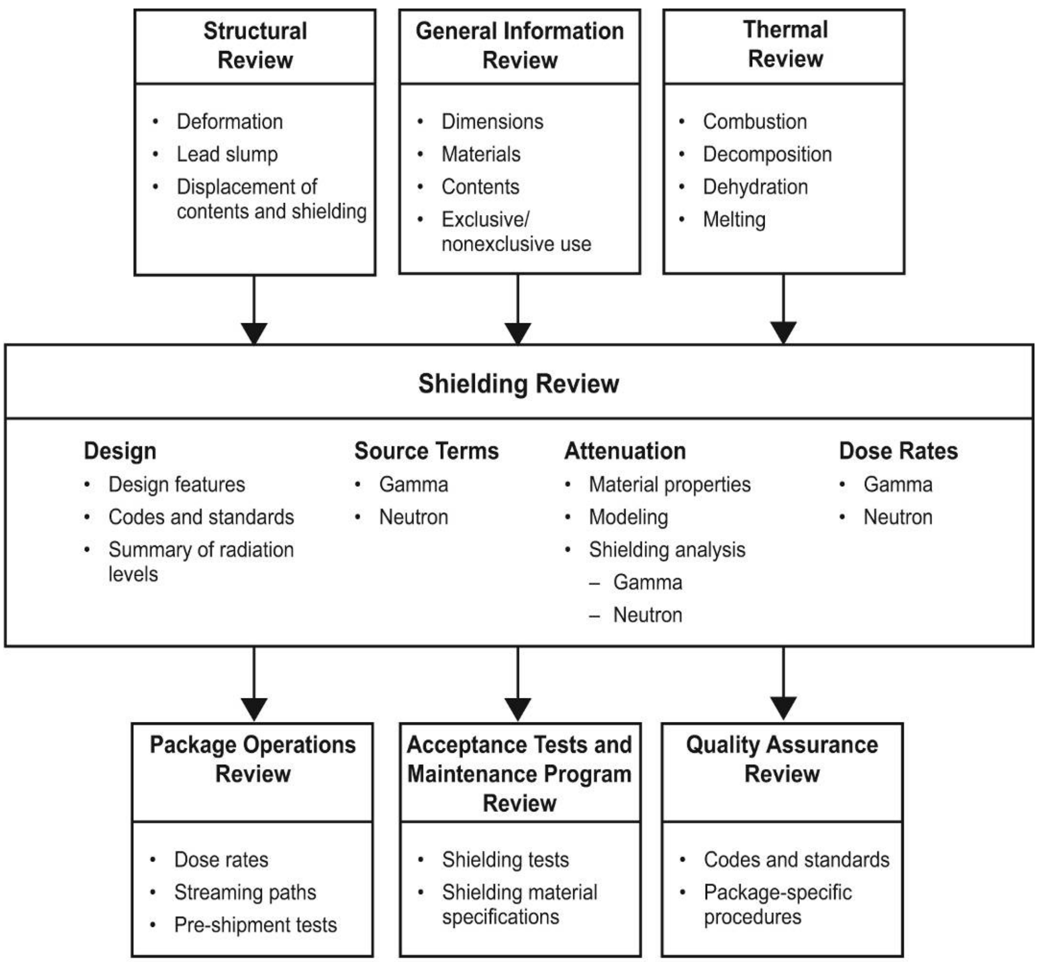

Figure 5.1 Example of Information Flow for the Shielding Review

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 must be described and evaluated to demonstrate that it meets the shielding requirements of 10 CFR 71. [§71.31(a)(1), §71.31(a)(2), §71.33, §71.35(a)]
- The application must 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 must 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 must meet the requirements of §71.47(a) for nonexclusive-use or §71.47(b) for exclusive-use shipments. [§71.47]
- The package must 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 must 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, including those packaging components considered in the shielding evaluation
- 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.

Confirm that the text and sketches describing the shielding design features are consistent with the engineering drawings and the 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.

Flux-to-dose-rate conversion factors should be consistent with American National Standards Institute (ANSI)/ANS6.1.1-1977,[5-1] 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 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. Review the variation of dose rates at different package locations for general consistency. For example, confirm that dose rates decrease as either the distance from the source or as the shielding effectiveness (e.g., thickness) increases.

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

Normal Conditions of Transport	Package Surface mSv/h (mrem/h)			1 Meter from Package Surface mSv/h (mrem/h)		
Radiation	**Top**	**Side**	**Bottom**	**Top**	**Side**	**Bottom**
Gamma						
Neutron						
Total						
10 CFR 71.47(a) Limit	2 (200)	2 (200)	2 (200)	0.1 (10)*	0.1 (10)*	0.1 (10)*

* Transport index may not exceed 10 for nonexclusive-use shipment.

Hypothetical Accident Conditions*	1 Meter from Package Surface mSv/h (mrem/h)		
Radiation	**Top**	**Side**	**Bottom**
Gamma			
Neutron			
Total			
10 CFR 71.51(a)(2) Limit*	10 (1000)	10 (1000)	10 (1000)

* Applicable to Type B packages only.

Table 5.2 Package and Vehicle Radiation Level Limits[a]

Transport Vehicle Use:	**Nonexclusive**	**Exclusive**		
Transport Vehicle Type:	Open or closed	Open (flat-bed)	Open w/enclosure[b]	Closed
Package (or Freight Container) Limits, mSv/h (mrem/h):				
External surface	2 (200)	2 (200)	10 (1000)	10 (1000)[c]
1 m from external surface	0.1 (10) [d]	No limit		
Roadway or Railway Vehicle (or Freight Container) Limits, mSv/h (mrem/h):				
Any point on the outer surface		N/A	N/A	2 (200)
Vertical planes projected from outer edges	N/A	2 (200)	2 (200)	N/A
Top of . . .		load: 2 (200))	enclosure: 2 (200)	vehicle: 2 (200)
2 m from . . .		vertical planes: 0.1 (10)	vertical planes: 0.1 (10)	outer lateral surfaces: 0.1 (10)
Underside		2 (200)		
Occupied position	N/A[e]	0.02 (2)[f]		

a. 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. The limits in this table do not apply to excepted packages—see 49 CFR 173.421-426.

b. Securely attached (to vehicle), access-limiting enclosure; package personnel barriers are considered as enclosures.

c. Package secured within vehicle so that its position remains fixed during transportation; no loading or unloading operations between beginning and end of transportation. Otherwise limit is 2 mSv/h (200 mrem/h).

d. Transport index may not exceed 10 for nonexclusive-use shipment.

e. No dose limit is specified, but separation distances apply to packages with Radioactive Yellow-II or Radioactive Yellow-III labels–see 49 CFR 177.842(b).

f. 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

Confirm that the contents, 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.

If the contents include spent fuel, verify that limitations on burnup, enrichment, and cooling time have been properly addressed. Although the maximum fuel enrichment is important for criticality analysis, the neutron source term for shielding evaluations can increase significantly with decreasing initial enrichment (for constant burnup and cooling time). Ensure that the SARP specifies a minimum initial enrichment for the fuel as appropriate. Verify that the cross sections used to calculate the source terms are applicable for the burnup indicated; some cross-section libraries are not valid for higher burnup.

In addition to increasing with decreasing enrichment, in the case of spent fuel, the source terms can be a strong function (usually the neutron source term) of the burnup. In the event that the relationship between burnup and the source term is non-linear, the average source term, $\overline{S}$, is not the same as the source at average burnup, $S(\overline{B})$. In cases where the source term has been determined at an average burnup, a multiplication factor, r, to obtain the average source from the spent fuel with axially varying burnup can be derived as

$$r = \frac{\overline{S}}{S(\overline{B})} = \frac{\frac{1}{H}\int_0^H f(B(z))dz}{f(\overline{B})}$$

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. The application of the factor r to the source at average burnup, $S(\overline{B})$, will give the correct average source term for the spent fuel. If this is applicable, verify that the proper factor to account for axial variability in burnup has been applied to obtain the bounding source term. In addition to the factor, r, verify that any other applicable peaking factors (radial and axial) have been applied to the source term for spent fuel.

5.3.2.1 Gamma Source

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 contents without decay. If the radioactive nuclides and gamma spectra are calculated with a computer code, review the key parameters described in the SARP or listed in the input file. 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 or shrouds, ensure that the source terms from these components are also included if applicable. 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 factors as discussed in Section 5.3.2 have been accounted for in determining the source term.

Confirm that the results of the source term determination are presented as a listing of gammas per second, or MeV per second, as a function of energy. The activity (or mass) of each nuclide that contributes significantly to the source term should also be provided as supporting information.

5.3.2.2 Neutron Source

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. If the SARP assumes that either of these source contributions is negligible, ensure that an appropriate justification is provided. 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. In the case of spent fuel where the source term is not calculated at the peak burnup, ensure that all applicable factors as discussed in Section 5.3.2 have been accounted for in determining the source term.

Confirm that the results of the source term calculation, if applicable, are presented as a listing of neutrons per second as a function of energy. The contributions from spontaneous fission and (α,n) should be separately identified. The activity (or mass) of each nuclide that contributes significantly to the source terms should also be provided as supporting information.

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 engineering 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. If contents can be positioned at varying locations or with varying densities, ensure that the location and physical properties of the contents used in the evaluation are those resulting in the maximum external radiation levels. For example, 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. 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.

For 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. Verify that flux peaking, both radially and axially within the fuel, has been treated appropriately if they have not already been accounted for in the source term (see Section 5.3.2).

In general, the shielding model and evaluation need 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 must also address criticality-safety restrictions, as discussed in Section 6 of this PRG.)

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, as well as positioning of the packages, become 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.

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. 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.

5.3.3.2 Material Properties

Verify the appropriate material properties (e.g., mass densities and atom densities) 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 should be referenced. Material specifications should be consistent with those in the engineering 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).

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 that sometimes 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.

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

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, including streaming paths, if applicable.

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).

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, 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 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.[5-2] 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).

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. Verify that the radiation levels presented in the shielding evaluation section are consistent with those in the summary table 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.

5.3.5 Appendices

Confirm that the appendices include a list of references, copies of applicable references if not generally available to the reviewer, computer code descriptions, input and output files, test results, flux-to-dose-rate conversion factors, and other appropriate supplemental information.

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 finding 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 engineering 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

[5-1] American Nuclear Society, *American National Standard for Neutron and Gamma-Ray Flux to Dose Rate Factors,* ANSI/ANS 6.1.1-1977, LaGrange Park, Illinois.

[5-2] U.S. Nuclear Regulatory Commission, *Averaging of Radiation Levels Over the Detector Probe Area*, HPPOS-13, in *Health Physics Positions Data Base*, NUREG/CR-5569, Rev. 1, 1992.

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6.0 CRITICALITY REVIEW

This review verifies that the package design meets the criticality safety requirements of 10 CFR 71 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 Packaging (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.

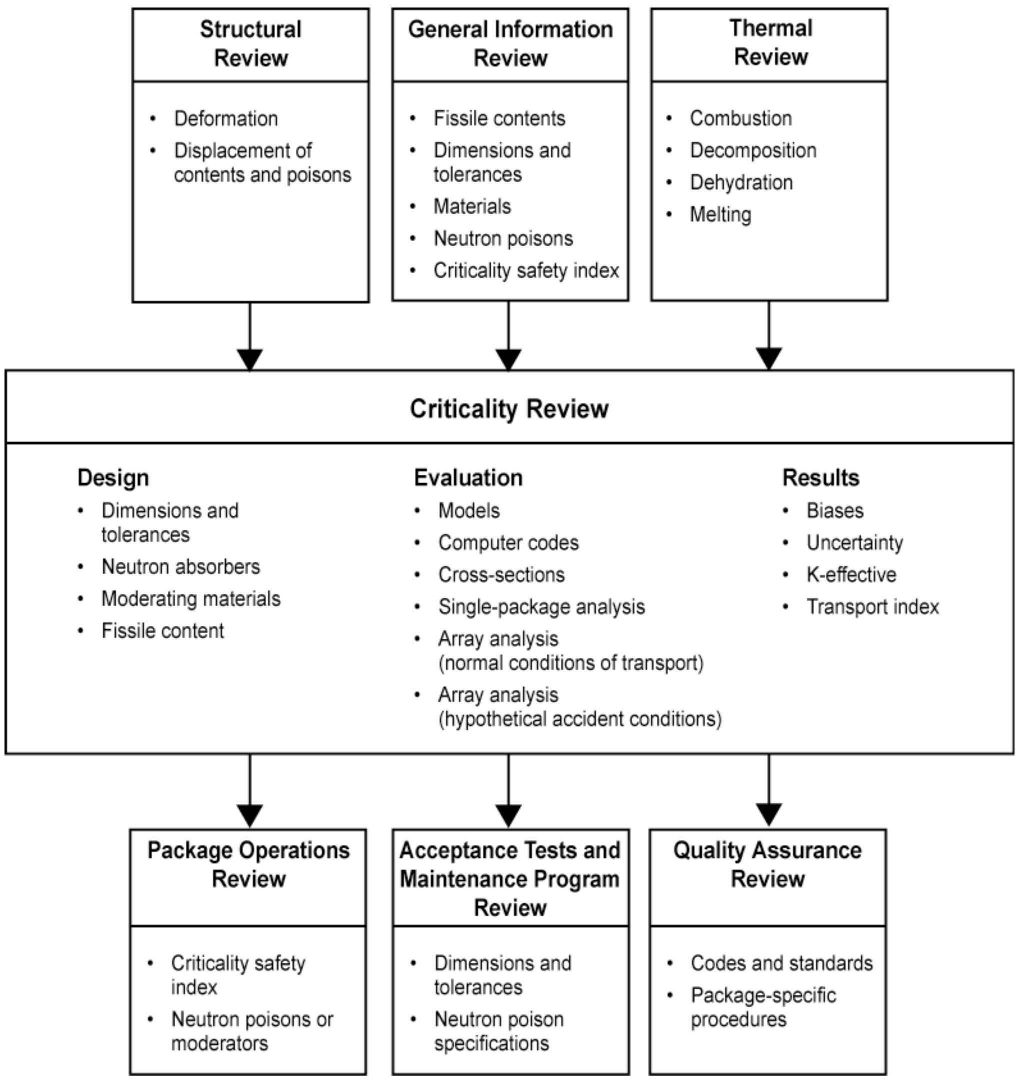

Figure 6.1 Example of Information Flow for the Criticality Review

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
- Codes and Standards
- Summary Table of Criticality Evaluations

6.1.2 Fissile Material and Other Contents

6.1.3 General Considerations for Criticality Evaluations

- Model Configuration
- Material Properties
- Demonstration of Maximum Reactivity
- Computer Codes and Cross-Section Libraries

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 Criticality Safety Index for Nuclear Criticality Control

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 must 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 must 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 must describe the basis and rationale used to formulate the quality assurance program. [§71.31(c)]
- A single package must be subcritical under the conditions of §71.55(b), §71.55(d), and §71.55(e).
- A fissile material packaging design to be transported by air must meet the requirements of §71.55(f).
- An array of undamaged packages must be subcritical under the conditions of §71.59(a)(1).
- An array of damaged packages must be subcritical under the conditions of §71.59(a)(2).
- A fissile material package must 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 must 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 must 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
- Structural components that maintain the fissile material or neutron poisons in a fixed position within the package or in a fixed position relative to each other

- Locations, dimensions, and densities (concentration) of neutron absorbing materials and moderating materials, including neutron poisons and shielding
- Dimensions and tolerances of floodable voids and flux traps 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 engineering drawings and the models used in the criticality evaluation.

6.3.1.2 Codes and Standards

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 (see Tables D.1 and D.2). 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.

6.3.1.3 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).

Verify that the 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 uncertainties and bias in Table 6.1 is consistent with that in NUREG/CR-5661[6-1] and NUREG/CR-6361.[6-2] Because variations in the details of bias determination have been used over the years, the reviewer should ensure that the approach is adequately described. 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 6.3.7 below.

Table 6.1 Example of Summary Table for Criticality Evaluations

Type of evaluation/ package condition	Number of packages*	$k + 2\sigma$ (package or array)	Bias (β)	Uncertainty in bias ($\Delta\beta$)	$k + 2\sigma - \beta^{\S} + \Delta\beta$
Single Package (Description of package condition)	1				
Undamaged Array (Description of package condition, array configuration)					
Damaged Array (Description of package condition, array configuration)					

* Criticality Safety Index for Nuclear Criticality Control = _______.

§ Positive biases are not subtracted.

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, nonfissile materials, used as moderators, absorbers and impurities must be specified if they are to be included as authorized contents in the Certificate of Compliance (CoC).

Specifications for 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 poisons (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.

To date, burnup credit (to account for depletion of fissile material or increase in fission product poisons due to irradiation) has been accepted only on a very limited basis,[6-3] which is generally not applicable to material shipped by DOE. Consequently, the enrichment for spent fuel should be that of the unirradiated fuel, except in rare cases where irradiated material has a higher reactivity. If assemblies contain fuel with several enrichments, the evaluation should either assume the maximum enrichment or demonstrate that another approach (e.g., average enrichment) is bounding. Section 6.3.3.2 discusses consideration of poison densities and the depletion of burnable poisons.

Any differences in the contents specifications from those in the General Information chapter should be clearly identified and justified.

Because 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. 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.

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.

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.

6.3.3.1 Model Configuration

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 engineering drawings. Coordinate with the Structural and Thermal reviews as appropriate.

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 and densities. The relative location and physical properties of the contents within the packaging should be justified as those that result in the maximum 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 poison 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.

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_{eff} of heterogeneous and homogeneous models and by consistently evaluating benchmark experiments).

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 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., poisons, 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 poison concentration in packaging components or in unirradiated contents should generally be considered in the criticality evaluation. No credit should be taken for burnable poisons in irradiated contents (e.g., spent fuel).

Unknown properties of fissile material must be assumed to be those that will credibly result in the highest neutron multiplication, §71.83.

6.3.3.3 Demonstration of Maximum Reactivity

Verify that the analyses evaluate the most reactive configuration of each case listed in Section 6.3.1.3 (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. Confirm that preferential flooding of different regions within the package, including the fuel-cladding gap, is considered as appropriate. As noted in Section 6.3.2, the maximum allowable fissile material is not necessarily the most reactive contents.

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.

6.3.3.4 Computer Codes and Cross-Section Libraries

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[6-4] and NUREG/CR-6686.[6-5]

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.

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.

6.3.4 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
- Full water reflection on all sides of the package, including close reflection of the containment system or reflection by the package materials, whichever is more reactive.

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[6-6] 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.
- 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 on all sides of a finite array.

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)
- 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.

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.[6-7]
- 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 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 must be the smaller value that assures subcriticality for both 5N packages under normal conditions of transport and 2N packages under hypothetical accident conditions. 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.

Ensure that the criticality safety index is consistent with that reported in the summary table of Section 6.3.3 above and in the General Information chapter of the SARP. This criticality safety index is typically specified in the CoC as the minimum criticality safety index.

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_{eff} values for the package.

Additional guidance on benchmarking of nuclear criticality codes is provided in NUREG/CR-6361. Numerous well-documented benchmark experiments have been published by the Nuclear Energy Agency, Organization for Economic Co-Operation and Development.[6-8]

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, poison, 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 indicated in Table 6.1, positive biases should not be used to reduce the calculational uncertainty. Additional information on determining biases and their range of applicability is provided in NUREG/CR-5661, NUREG/CR-6361, and NUREG/CR-6698.[6-9]

6.3.9 Appendices

Confirm that the appendices include a list of references, copies of applicable references if not generally available to the reviewer, 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 finding 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.

6.5 References

[6-1] U.S. Nuclear Regulatory Commission, *Recommendations for Preparing the Criticality Safety Evaluation of Transportation Packages*, NUREG/CR-5661, ORNL/TM-11936, April 1997.

[6-2] U.S. Nuclear Regulatory Commission, *Criticality Benchmark Guide for Light-Water-Reactor Fuel in Transportation and Storage Packages*, NUREG/CR-6361, ORNL/TM-13211, January 1997.

[6-3] U.S. Nuclear Regulatory Commission, *Burnup Credit in the Criticality Safety Analysis of PWR Spent Fuel in Transport and Storage Casks*, ISG-8, Rev. 2, Spent Fuel Project Office, September 27, 2002.

[6-4] *The Radioactive Materials Packaging Handbook:, Design, Operations, and Maintenance*, ORNL/M-5003, 1998, prepared by Oak Ridge National Laboratory, Oak Ridge, Tennessee.

[6-5] S. M. Bowman et. Al., *Experience the SCALE Criticality Safety Cross-Section Libraries*, NUREG/CR-6686, ORNL/TM-1999/322, 2000, prepared by Oak Ridge National Laboratory, Oak Ridge, Tennessee.

[6-6] American Nuclear Society, *American National Standard for Nuclear Criticality Safety in Operations with Fissionable Material Outside Reactors*, ANSI/ANS 8.1-1983 (R1988), LaGrange Park, Illinois.

[6-7] American National Standards Institute, ANSI N14.5-1997, *American National Standard for Radioactive Materials—Leakage Tests on Packages for Shipment*, New York.

[6-8] Organization for Economic Co-Operation and Development, *International Handbook of Evaluated Criticality Safety Benchmark Experiments*, NEA/NSC/Doc(95)03, Nuclear Energy Agency, September 2006.

[6-9] *Guide for Validation of Nuclear Criticality Safety Calculational Methodology*, NUREG/CR-6698, 2000, prepared for Fuel Cycle Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC.

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7.0 PACKAGE OPERATIONS REVIEW

This review verifies that the operating controls and procedures for the package 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.

The Package Operations chapter of the Safety Analysis Report for Packaging (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 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 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

7.1.3 Preparation of Empty Package for Transport

7.1.4 Other Operations

7.1.5 Appendices

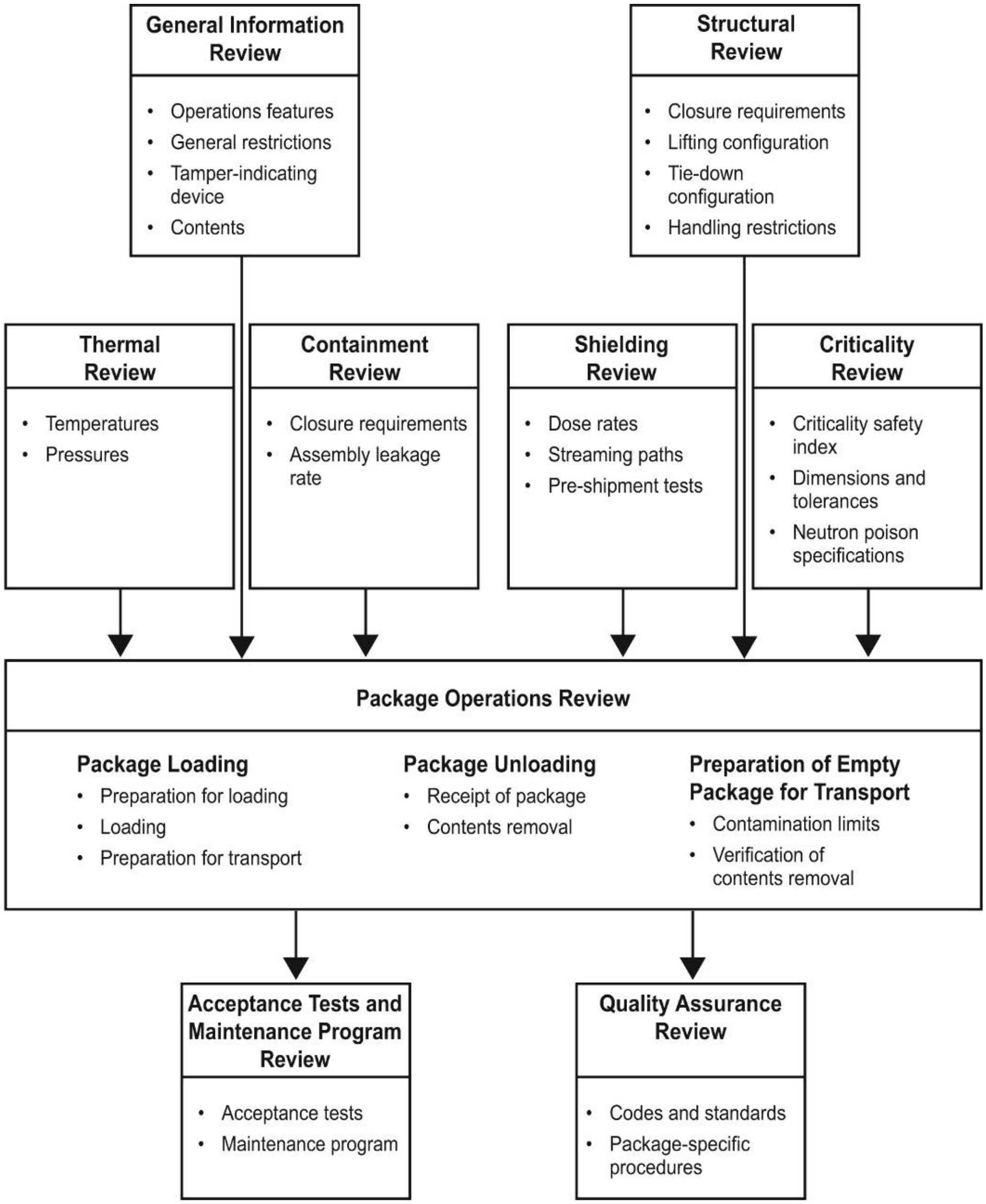

Figure 7.1 Example of Information Flow for the Package Operations Review

7.2 Regulatory Requirements

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

- The application must 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 must describe the basis and rationale used to formulate the quality assurance program. [§71.31(c)]

- The application must 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 must not exceed 10, and the sum of the Criticality Safety Indices (CSI) of all packages in the shipment must not exceed 50. [§71.47(a), §71.59(c)(1)]
- Packages that require exclusive-use shipment because of increased radiation levels must 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 must not exceed 100. [§71.59(c)(2)]
- The application must 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 must be assumed to be those that will credibly result in the highest neutron multiplication. [§71.83]
- A package must 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 must 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 must 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.[7-1]

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
- 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[7-2]
- 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 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 a maximum allowable shipping duration due to potential generation of hydrogen gas.

7.3.5 Appendices

Confirm that the appendices include a list of references, copies of applicable references, if not generally available to the reviewer, test results, and any additional supplemental information, 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 finding 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 References

[7-1] U.S. Nuclear Regulatory Commission, *Guide for Preparing Operating Procedures for Shipping Packages,* NUREG/CR-4775, UCID-20820, Washington, DC, July 1988.

[7-2] American National Standards Institute, *American National Standard for Radioactive Materials—Leakage Tests on Packages for Shipment*, ANSI N14.5-1997, New York, New York, 10036.

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8.0 ACCEPTANCE TESTS AND MAINTENANCE PROGRAM REVIEW

This review verifies 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.

The Acceptance Tests and Maintenance Program chapter of the Safety Analysis Report for Packaging (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. 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 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 Examinations
- Structural and Pressure Tests
- Leakage Tests
- Component and Material Tests
- Shielding Tests
- Thermal Tests
- Miscellaneous Tests

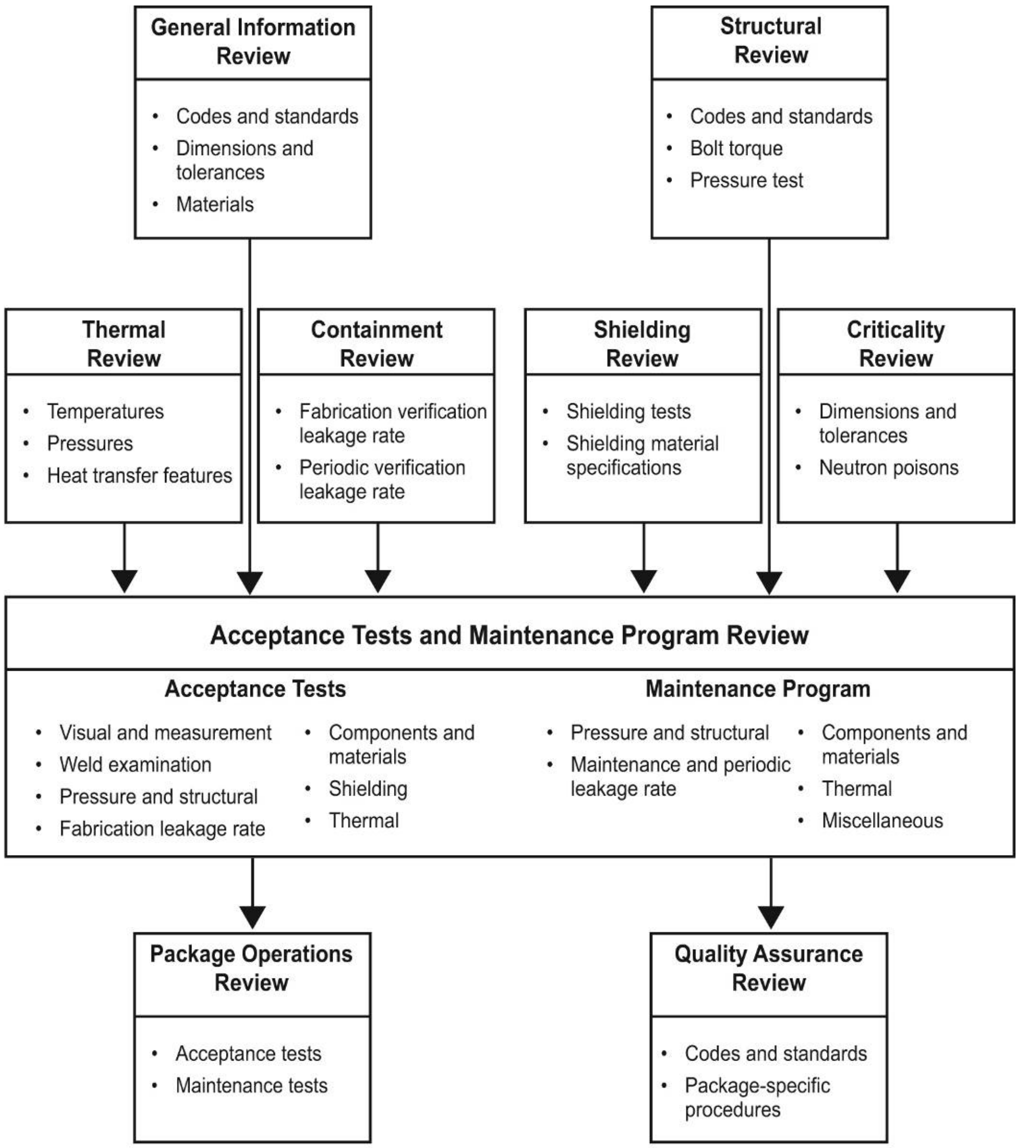

Figure 8.1 Example of Information Flow for the Acceptance Tests and Maintenance Program Review

8.1.2 Maintenance Program

- Structural and Pressure Tests
- Leakage Tests
- Component and Material Tests
- 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 must 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 must 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, … 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 must 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 must 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 must 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 must be verified to be in accordance with the approved design. [§71.85(c)]
- The applicant must perform any tests deemed appropriate by the certifying authority. [§71.93(b)]

8.2.2 Maintenance Program

- The application must 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 must 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 … testing, maintenance, repair, modification, and use of the proposed package. [§71.37(a)]
- The packaging must 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 must be verified prior to each shipment. [§71.87(g)]
- The applicant must perform any tests deemed appropriate by the certifying authority. [§71.93(b)]
- Each type B(U) or Type B(M) package design must 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 must be fabricated in accordance with the engineering drawings listed in the CoC.

Additional guidance on acceptance tests is provided in NUREG/CR-3854.[8-1]

8.3.1.1 Visual Inspections and Measurement

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

8.3.1.2 Weld Examinations

Verify that welding examinations and acceptance criteria are specified to verify fabrication in accordance with the codes and standards cited in the SARP. Location, type, and size of the welds should be confirmed by visual examination. For weld surface and volumetric integrity, nondestructive examination and acceptance criteria should be verified as appropriate. Additional guidance on welding criteria is provided in NUREG/CR-3019.[8-2]

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.[8-3] 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 engineering 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 engineering drawing of the package. Ensure that material examinations are performed in accordance with the codes and standards specified. Confirm that appropriate tests and acceptance criteria are specified 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 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, 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. Maintenance tests and inspections should be described with schedules for each test 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. 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 that could result in deterioration of packaging materials, including loss of neutron absorbers, reduction in hydrogen content of shields, and density changes of insulating materials. 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.

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

[8-1] U.S. Nuclear Regulatory Commission, *Fabrication Criteria for Shipping Containers*, NUREG/CR-3854, UCRL-53544, March 1985.

[8-2] U.S. Nuclear Regulatory Commission, *Recommended Welding Criteria for Use in the Fabrication of Radioactive Material Shipping Containers*, NUREG/CR-3019, UCRL-53044, March 1984.

[8-3] American National Standards Institute, *American National Standard for Radioactive Material—Leakage Tests on Packages for Shipment*, ANSI N14.5-1997, New York, New York, 10036.

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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 and that specific QA requirements for the package are adequate to assure that it is designed, fabricated, assembled, tested, used, maintained, modified, and repaired in a manner consistent with its evaluation in the Safety Analysis Report for Packaging (SARP).

The QA chapter of the SARP should 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 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.

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 drawings in the General Information chapter include dimensions and tolerances and codes or standards for fabrication and material specifications, and 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 QA-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.

Because 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
- Cross-Referencing Matrix

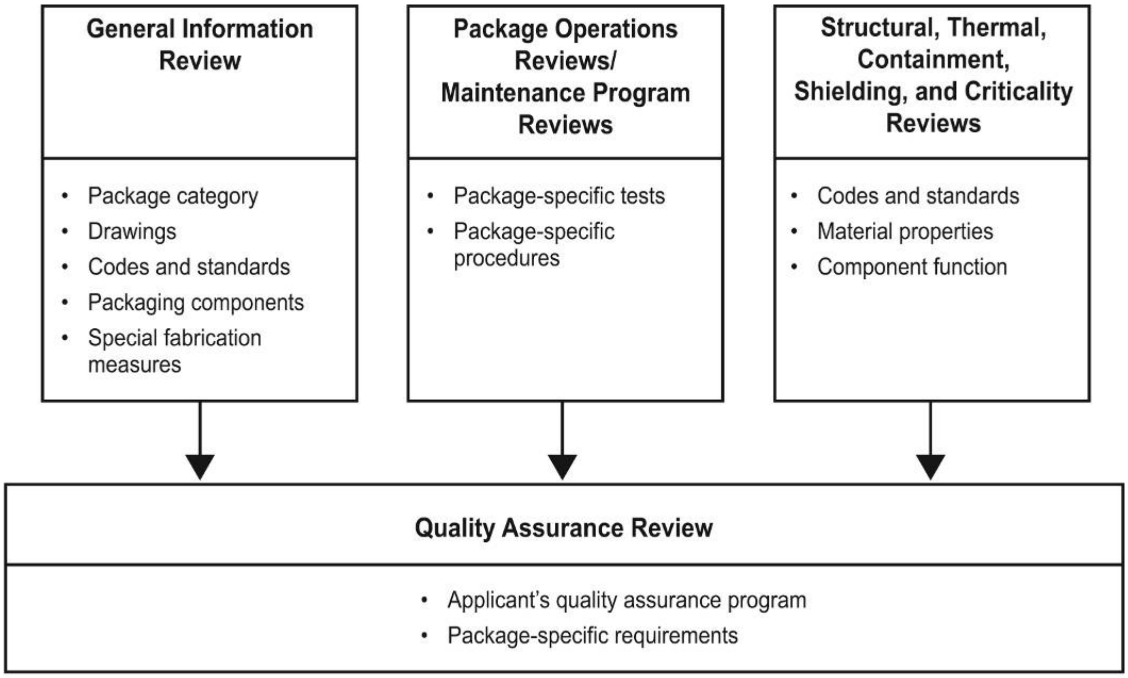

Figure 9.1 Example of Information Flow for the Quality Assurance Review

9.1.2 Package-Specific QA Requirements

- Graded Approach for Structures, Systems, and Components Important to Safety
- Package-Specific Quality 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 must 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 must 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 must describe the basis and rationale used to formulate the package quality assurance program. [§71.31(c)]
- Package activities must 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 must 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 must be retained for three years after the life of the packaging. [§71.91(b)]

- Records identified in §71.91(a) must be retained for three years after shipment of radioactive material. [§71.91(a)]
- Records must 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 must 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, must 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 must 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 package activities for which the applicant has QA-responsibility. These activities may include design, procurement, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification. Applicants should be considered responsible if they perform, contract, or otherwise oversee the activity. Although applicants are typically responsible for packaging design, responsibility for other activities may be assigned to other DOE organizations. For example, the applicant may design, fabricate, assemble, and perform acceptance testing of a packaging, 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 also likely supplement the applicant's overall site QA program. 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.

Confirm that the SARP specifies on which QA-requirements document (e.g., DOE O 414.1C,[9-1] Subpart H of 10 CFR 71) the QA program and its approval are based. Although DOE organizations are generally required to comply with DOE O 414.1C* and 10 CFR 830 Subpart A, QA programs for packages must also comply with Subpart H (and other applicable

* Earlier versions of DOE O 414.1x may still be applicable because of contractual relationships.

subparts) of 10 CFR 71. 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, QA program for packages approved under American Society of Mechanical Engineers (ASME) NQA-1[9-2] or Appendix B, 10 CFR Part 50, will meet the requirements of Subpart H.

In addition to his umbrella QA program, the applicant will generally 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 and identify those that are intended to be prepared in the future. As a minimum, detailed procedures for all activities performed during SARP preparation should be completed as described in Regulatory Guide (RG) 7.10.

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 414.1C 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 RG 7.10.[9-3]

If the applicant's QA program for packaging augments a site program based on DOE O 414.1C 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).

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 written procedures. An example of such a matrix is presented in Table 1 of RG 7.10. 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, an organizational change, or renumbering of the 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.

9.3.2 Package-Specific QA Requirements

The SARP should describe QA requirements for the proposed package. Requirements should be based on a graded approach, considering the importance to safety of package structures, systems, components, and activities. The review should address controls necessary for design, fabrication, testing, 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 graded approach should 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
- Degree to which functional compliance can be demonstrated by inspection or test
- Quality history and degree of standardization of the item.

9.3.2.1 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 packaging drawings. Justification should be provided for any item identified on the drawings but not defined as important to safety in the Q-list.

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 RG 7.10 provides guidance on defining quality categories and QA requirements. Definitions of typical categories and representative safety classifications for SSCs of transportation packagings are also presented in Table 2 and Table 5, respectively, of NUREG/CR-6407.[9-4]

In some cases, commercial grade items and services are used for quality category A and B SSCs. The commercial grade item and service dedication process should be described in the SARP. Refer to ASME NQA-1 for further guidance.

9.3.2.2 Package-Specific Quality 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 effort for package activities based on their importance to safety. Guidance on QA requirements applicable to each category is provided in Appendix A of RG 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.

Table 9.1 Typical Level of QA Effort by Quality Category

QA Element/Level of Effort	Category A	Category B	Category C
1. QA Organization			
Responsibility established	X	X	X
Authority and duties written	X	X	X
QA functions executed	X	X	X
Reporting levels clearly defined	X	X	X
Independence from cost and schedule assured	X	X	X
2. QA Program			
Procedures written	X	X	X
Activities affecting quality controlled	X	X	X
Graded approach established	X	X	X
Indoctrination and training provided	X	X	X
3. Package Design Control			
Most stringent codes and standards	X		
Codes and standards		X	
Prototype test and/or analysis	X	X	
Formal design review	X	X	
Internal peer review	X	X	
Software QA	X	X	
Off-the-shelf items			X
Conditions of approval controlled	X	X	X
4. Procurement Document Control			
Traceabililty	X		
Qualified vendor lists	X		
Suppliers required to meet Subpart H	X	X	
Off-the-shelf items			X

Table 9.1 Typical Level of QA Effort by Quality Category (cont.)

QA Element/Level of Effort	Category A	Category B	Category C
5. Instructions, Procedures, and Drawings			
Written and documented	X	X	
Qualitative or quantitative acceptance criteria	X	X	
Changes to conditions of approval listed in certificate controlled	X	X	X
6. Document Control			
Controlled issue	X	X	
Controlled changes	X	X	
7. Control of Purchased Material, Equipment, and Services			
Source evaluation and selection	X		
Inspection at contractor	X		
Formal receiving inspection	X	X	
Audits or surveillance at vendor plants	X		
Evidence of QA at contractor	X	X	
Objective proof that all specifications are met	X	X	
Commercial grade item/services dedication	X	X	
Incoming inspection for damage only			X
8. Identification and Control of Materials, Parts, and Components			
Positive identification and traceability	X		
Identification and traceability to heats, lots, or other groupings	X	X	
Identification to end use drawings			X
9. Control of Special Processes			
Welding, heat treating, and NDE performed with qualified/certified personnel and procedures	X		
Qualification records and training of personnel	X		
Only specified critical operations by qualified personnel		X	
No special processes			X

Table 9.1 Typical Level of QA Effort by Quality Category (cont.)

QA Element/Level of Effort	Category A	Category B	Category C
10. Internal Inspection			
Documented inspection of all specifications	X		
Process monitoring if required by quality	X		
Examination, measurement, or test of material or processed product to assure quality	X	X	
Inspectors independent of those performing operations	X	X	
Qualified inspectors only	X	X	
Visual receiving inspection only			X
11. Test Control			
Written test program	X	X	
Written test procedures	X	X	
Documentation of testing and evaluation	X	X	
Observation of supplier acceptance tests as appropriate	X		
12. Control of Measuring and Test Equipment			
Tools, gauges, and instruments in formal calibration program	X	X	
13. Handling, Storage, and Shipping Control			
Written plans and procedures	X	X	
Routine handling			X
14. Inspection, Test, and Operating Status			
Individual items identified as to status or condition	X	X	
Status indicated by stamps, tags, labels, etc.	X	X	
Visual examination only			X
15. Nonconforming Materials, Parts, or Components			
Written procedures to prevent inadvertent use	X	X	X
Nonconformance documented and closed	X	X	X
Disposal (scrap) without records			X

Table 9.1 Typical Level of QA Effort by Quality Category (cont.)

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

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, heat treating, and nondestructive examination) are often included in the code or standard used for design and fabrication (and specified on the drawing), and special processes (e.g., pouring lead and resin shielding, applying special coatings, and injecting foam) are generally specified by more detailed procedures 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 poisons, 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 generally be subject to the quality assurance requirements of Subpart H, including (but not limited to) written procedures, training of personnel, verification, documentation, nonconformance control, record retention, and audit. 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. Additional guidance on types of records that should be retained for each quality category is provided in Chapter 4 of NUREG/CR-6407. 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.

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, and other appropriate supplemental information. Detailed QA procedures should not be provided in the SARP but 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 finding 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 package 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 packaging activities. Conditions of approval should not include site-specific requirements or procedures.

9.5 References

[9-1] Department of Energy, *Quality Assurance*, DOE O 414.1C, June 17, 2005.

[9-2] American Society of Mechanical Engineers, *Quality Assurance Requirements for Nuclear Facility Applications,* ASME NQA-1-2004 Edition, December 22, 2004, New York, New York.

[9-3] U.S. Nuclear Regulatory Commission, *Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material*, Regulatory Guide 7.10, Rev. 2, March 2005.

[9-4] U.S. Nuclear Regulatory Commission, *Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety*, NUREG/CR-6407 (INEL-95/0551), February 1996.

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APPENDICES

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APPENDIX A
DEFINITIONS

The majority of package terms are defined in 10 CFR 71.4 or 49 CFR 173.403, and are repeated in Table A.1 for convenience. Where applicable, the source of each definition is indicated. In many cases, terms defined in 10 CFR 71.4 are also defined in 49 CFR 173.403.

Table A.1 Definitions

A_1	The maximum activity of special form radioactive material permitted in a Type A package. [10 CFR 71.4]
A_2	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]
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 (CoC)	A certificate issued by DOE approving for use, with specified limitations, a specific packaging. 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 must limit access from the top, sides, and bottom. [49 CFR 173.403]
Confirmatory analysis	Use of alternate calculations/methods to verify correctness of the original calculations or analyses.
Containment system	The assembly of components of the packaging intended to retain the radioactive material during transport. [10 CFR 71.4]

Table A.1 Definitions (cont.)

Conveyance	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]
Criticality Safety Index (CSI)	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].
Damaged fuel	Fuel with known or suspected cladding defects greater than a hairline crack or a pinhole leak.
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 must ensure that any loading or unloading is performed by personnel having radiological training and resources appropriate for safe handling of the consignment. The consignor must issue specific instructions, in writing, for maintenance of exclusive use shipment controls, and include them with the shipping paper information provided to the carrier by the consignor. [10 CFR 71.4]
Fissile material	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]
Fissile material package	A fissile material packaging together with its fissile material contents. [10 CFR 71.4]
Low specific activity (LSA) material	Radioactive material with limited specific activity that satisfies the descriptions and limits specified in 10 CFR 71.4.
Maximum normal operating pressure (MNOP)	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]
Natural thorium	Thorium with the naturally occurring distribution of thorium isotopes (essentially 100 weight percent thorium 232). [10 CFR 71.4]

Table A.1 Definitions (cont.)

Normal form radioactive material	Radioactive material that has not been demonstrated to qualify as "special form radioactive material." [10 CFR 71.4]
Optimum interspersed hydrogenous moderation	The presence of hydrogenous material between packages to such an extent that the maximum nuclear reactivity results. [10 CFR 71.4]
Package	The packaging together with its radioactive contents as presented for transport. [10 CFR 71.4]
Packaging	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]
Quality assurance	All planned and systematic actions necessary to provide adequate confidence that a system or component will perform satisfactorily in service. [10 CFR 71.101]
Radiation level	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]
Radioactive contents	A Class 7 (radioactive) material together with any contaminated liquids or gases within the package. [49 CFR 173.403]
Radioactive material	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
Reference air leakage rate	The allowable leakage rate converted to reference cubic centimeters per second. [ANSI N14.5]
Reference cubic centimeter per second (ref·cm^3/s)	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]
Safety Evaluation Report (SER)	A report issued by the DOE Headquarters Certifying Official that documents DOE's review of the package for compliance with DOE O 460.1B and 10 CFR 71.
Special form radioactive material	Radioactive material that satisfies the conditions specified in 10 CFR 71.4.

Table A.1 Definitions (cont.)

Specific activity of a radionuclide	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]
Spent nuclear fuel or spent fuel	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.
Surface contaminated object (SCO)	A solid object that is not itself classed as radioactive material, but which has radioactive material distributed on any of its surfaces. SCO must be in one of two groups with surface activity not exceeding the limits specified in 10 CFR 71.4.
Technical Review Report (TRR)	A report prepared by the DOE review staff that documents the technical review of the package for compliance with DOE O 460.1B and 10 CFR 71. The TRR provides the justification for the technical information included in the SER.
Transport index (TI)	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)).
Type A quantity	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]
Type A packaging	A packaging approved to transport a Type A quantity of radioactive contents.

Table A.1 Definitions (cont.)

Type B package	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 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]
Type B packaging	A packaging approved to transport a Type B quantity of radioactive contents.
Type B quantity	A quantity of radioactive material greater than a Type A quantity. [10 CFR 71.4]
Uranium–natural	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]
Uranium–depleted	Uranium containing less uranium-235 than the naturally occurring distribution of uranium isotopes. [10 CFR 71.4]
Uranium–enriched	Uranium containing more uranium-235 than the naturally occurring distribution of uranium isotopes. [10 CFR 71.4]

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APPENDIX B
SUMMARY LISTING OF 10 CFR 71 REQUIREMENTS

This appendix provides a summary listing of the sections in 10 CFR 71 and the primary sections of this PRG to which they apply. In several cases, the applicability is a subjective judgment, which may depend on the package design as well as on the specific format in which the Safety Analysis Report for Packaging is organized. The user is cautioned accordingly.

Table B.1 Summary Listing of 10 CFR 71 Requirements

Section/ Chapter	General Information	Structural	Thermal	Containment	Shielding	Criticality	Package Ops.	Acc. Tests & Maint.	Quality Assurance	Comments
71.0(d)(2)	X									Application for package approval
71.15	X									Exemption from classification as fissile material
71.19	X						X			Previously approved package
71.19(a)(2)							X			Serial number
71.19(b)(3)							X			Serial number
71.19(e)	X									-96 packages
71.22(a)				X						General license
71.31(a)(1)	X	X	X	X	X	X				Package description
71.31(a)(2)		X		X	X	X				Package evaluation
71.31(a)(3)	X								X	Description of QA program
71.31(b)	X									See also 71.13 for grandfathering
71.31(c)	X	X	X	X	X	X	X	X	X	Identification of codes and standards. Primary interest is ASME B&PV Code but applicable to ANSI N14.5 and perhaps others
71.33	X	X	X	X	X	X				Packaging and content description
71.33(a)	X									Description must include with respect to the packaging
71.33(b)	X									Description must include with respect to the contents of the package

Table B.1 Summary Listing of 10 CFR 71 Requirements (cont.)

Section/ Chapter	General Information	Structural	Thermal	Containment	Shielding	Criticality	Package Ops.	Acc. Tests & Maint.	Quality Assurance	Comments
71.35(a)		X	X	X	X	X				Package evaluation
71.35(b)	X					X				Max. packages/shipment based on criticality
71.35(c)							X			Special fissile material controls
71.37	X	X							X	QA
71.37(a)		X								QA-applicant
71.38	X									Renewal of certificate or QA program approval
71.38(b)	X									Application for renewal
71.39										Any additional information may be required.
71.41(a)		X	X							Demonstration of compliance
71.41(b)										Vehicle may be considered in evaluation.
71.41(c)										Variations in §§71.71 and 71.73 may be approved by NRC.
71.43	X									General standards
71.43(a)	X									Size
71.43(b)	X									Tamper-indicating device
71.43(c)				X						Positive closure
71.43(d)		X	X	X						Chemical or galvanic reactions
71.43(e)				X						Valves
71.43(f)		X	X	X	X	X				Package effectiveness
71.43(g)	X		X				X			Temperature limits
71.43(h)				X						Venting

Table B.1 Summary Listing of 10 CFR 71 Requirements (cont.)

Section/ Chapter	General Information	Structural	Thermal	Containment	Shielding	Criticality	Package Ops.	Acc. Tests & Maint.	Quality Assurance	Comments
71.45	X	X					X			Lifting and tie-down
71.45(a)		X								Lifting attachments
71.45(b)		X								Tie-down devices
71.47	X	X			X		X			External radiation standards
71.47(a)	X				X		X			Dose rates, nonexclusive use
71.47(b)	X				X		X			Dose rates, exclusive use
71.47(b)(1)							X			200 mreh/hr limit on external surface of package
71.47(b)(2)							X			200 mrem/hr limit on outer surface of vehicle
71.47(b)(3)							X			10 mrem/hr limit at 2 meters from lateral surfaces of vehicle
71.47(b)(4)							X			2 mrem/hr limit for normally occupied space in vehicle
71.47(c)										Instructions for exclusive use shipments
71.47(d)										Instructions for exclusive use shipments
71.51	X									Additional requirements
71.51(a)(1)		X	X	X	X	X				NCT leakage, shielding, package effectiveness
71.51(a)(2)				X	X					HAC leakage and shielding
71.51(b)	X			X						A_2 for mixture
71.51(c)			X	X						Filters and mechanical cooling
71.55	X	X								General requirements
71.55(a)										Criticality, general
71.55(b)						X				Water inleakage analysis

Table B.1 Summary Listing of 10 CFR 71 Requirements (cont.)

Section/ Chapter	General Information	Structural	Thermal	Containment	Shielding	Criticality	Package Ops.	Acc. Tests & Maint.	Quality Assurance	Comments
71.55(c)										Exemption from water inleakage
71.55(d)		X				X				NCT criticality
71.55(d)(2)		X				X				Geometric form of package
71.55(d)(3)		X				X				No leakage of water
71.55(d)(4)		X				X				No substantial reduction in effectiveness of package
71.55(e)						X				HAC criticality
71.55(f)	X	X	X			X				Fissile shipments by air
71.59	X					X				Criticality, arrays, CSI
71.59(a)(1)		X				X				Five times “N” packages
71.59(a)(2)						X				Two times “N” packages
71.59(b)						X				Determination of CSI
71.59(c)	X					X				CSI values
71.59(c)(1)							X			CSI less than 50
71.59(c)(2)							X			CSI sum less than 100
71.61	X	X								Deep water immersion for spent fuel only
71.63	X			X						Special requirements for Pu
71.64	X									Pu air shipment
71.65										Any other requirements may be imposed to protect public health or minimize danger to life or property.
71.71	X	X	X	X	X	X				NCT tests
71.71(c)(1)			X							NCT heat
71.71(c)(2)			X							NCT cold

Table B.1 Summary Listing of 10 CFR 71 Requirements (cont.)

Section/ Chapter	General Information	Structural	Thermal	Containment	Shielding	Criticality	Package Ops.	Acc. Tests & Maint.	Quality Assurance	Comments
71.73	X	X	X	X	X	X				HAC tests
71.73(b)			X							Test conditions
71.73(c)(2)		X								Crush test
71.73(c)(3)		X								Puncture test
71.73(c)(4)		X	X							Thermal test
71.73(c)(5)	X		X			X				Immersion-fissile material
71.73(c)(6)						X				Immersion-all packages
71.74										HAC tests for Pu air shipments
71.75										Special form
71.77										LSA-III
71.81							X		X	Operating controls
71.83						X	X			Assumptions for unknown properties
71.85									X	Preliminary determinations
71.85(a)					X			X		Cracks, voids
71.85(b)		X						X		Pressure test
71.85(c)	X						X	X		Data plate
71.87							X			Routine determinations
71.87(a)										Proper contents
71.87(b)								X		Undamaged packaging

Table B.1 Summary Listing of 10 CFR 71 Requirements (cont.)

Section/ Chapter	General Information	Structural	Thermal	Containment	Shielding	Criticality	Package Ops.	Acc. Tests & Maint.	Quality Assurance	Comments
71.87(c)										Closure devices
71.87(d)										Liquid systems
71.87(e)										Pressure relief devices
71.87(f)										Loaded by procedures
71.87(g)								X		Moderator/absorber present
71.87(h)										Tie-down devices
71.87(i)										Non-fixed contamination
71.87(j)					X					External radiation levels
71.87(k)			X							Accessible package surface temperature limits
71.88	X									Pu air shipment
71.89							X			Opening instructions
71.91									X	Records
71.91(a)									X	Maintenance of shipping records
71.91(b)									X	Maintenance of packaging records
71.91(c)									X	Records availability for Commission
71.91(d)									X	Records of packaging quality
71.93										Inspection and tests
71.93(b)								X		Tests
71.95									X	Reports of problems
71.95(a)(1)									X	Reduction in effectiveness of package
71.95(a)(2)									X	Defects in safety significance

Table B.1 Summary Listing of 10 CFR 71 Requirements (cont.)

Section/ Chapter	General Information	Structural	Thermal	Containment	Shielding	Criticality	Package Ops.	Acc. Tests & Maint.	Quality Assurance	Comments
71.95(a)(3)									X	Conditions of approval not observed
71.95(c)(4)									X	Description of corrective actions
71.97										Advance notification of spent fuel and HLW shipments
71.99										Violations
71.101(b)									X	Establishment of QA program
71.103									X	QA (Subpart H)
71.105(c)									X	Considerations for QA program
71.107(c)	X								X	Design Changes
71.135									X	Quality Assurance records
71.137									X	Audits

APPENDIX C
SUMMARY OF CHANGES RESULTING FROM THE 2004 (AS AMENDED) 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 must 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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* Safety Requirements No. TS-R-1, *Regulations for the Safe Transport of Radioactive Material*, 1996 Edition (As Amended 2000), International Atomic Energy Agency, Vienna, 2000.

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

New section number	Existing section number
§ 71.8 ……………	§ 71.11
§ 71.9 ……………	New Section
§ 71.10 ……………	New Section
§ 71.11 (Reserved) ...	NA
§ 71.12 ……………	§ 71.8
§ 71.13 ……………	§ 71.9
§ 71.14 ……………	§ 71.10
§ 71.15 ……………	§ 71.53
§ 71.16 (Reserved) ...	NA
§ 71.17 ……………	§ 71.12
§ 71.18 (Reserved)…………	New Section
§ 71.19 ……………	§ 71.13
§ 71.20 ……………	§ 71.14
§ 71.21 ……………	§ 71.16
§ 71.22 ……………	§ 71.18
§ 71.23 ……………	§ 71.20
§ 71.24 (Reserved) ...	§ 71.22 (Section removed)
§ 71.25 (Reserved) ...	§ 71.24 (Section removed)
§ 71.53 (Reserved) ...	§ 71.53 (Section re-designated)

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 must 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 A_1 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, must 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 H_2O) 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 H_2O.”

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 must 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 10^5A_2 of any radionuclide must 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 must 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 UF_6 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 10^5A_2

This section has been revised to require an enhanced water immersion test for packages used for radioactive contents with activity greater than 10^5A_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/in^2) 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.

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APPENDIX D
MATERIALS AND FABRICATION

Issues related to package materials and fabrication are interlaced among all chapters in the Safety Analysis Report for Packaging (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 nine chapters of the SARP format. Consequently, the review of material and fabrication should address all SARP chapters to ensure that these areas have been properly evaluated.

Tables D.1 and D.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 engineering drawings may be described in additional detail in a separate fabrication specification.

Table D.1 Review of Materials

Identification of Packaging Components	• Is each packaging component depicted on the drawings and identified in the parts list or by other appropriate means? • Is each packaging component not identified on the drawings properly justified as not important to safety?
Material Specifications of Packaging Components	• Is the material of construction of each packaging component specified on the drawings? • Is a material specification (e.g., ASME, ASTM, commercial equivalent) designated on the drawings for each material? Is the material specification appropriate for the code or standard applicable to the packaging? • For materials without an applicable specification, are 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? • Are appropriate examination requirements for each material specified on the drawings?
Material Properties	• Are material properties relevant to the SARP evaluation specified where appropriate? • Are the material properties appropriate for the temperatures and pressures under normal conditions of transport and hypothetical accident conditions? • Have appropriate test requirements for materials been established?
Brittle Fracture	• Is any packaging material subject to brittle fracture by cold or other mechanisms (e.g., hydrogen embrittlement)? • Are the criteria of RG 7.11 or 7.12 satisfied? • Has embrittlement by other mechanisms (e.g., fabrication processes) been properly addressed?
Chemical, Galvanic, and Other Reactions	• Is any material subject to chemical, galvanic, or other reaction (e.g., radiolysis) with each other 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?

Table D.1 Review of Materials (cont.)

Package Operations	• Should any material or component be inspected and/or replaced prior to fabrication or each use? • Are appropriate types of inspections and acceptance criteria specified?
Acceptance Testing and Maintenance Program	• Should any material or component be subject to acceptance testing prior to first use? • 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? • Are the requirements for acceptance testing and maintenance specified?
Quality Assurance	• Has each component been properly categorized as to its importance to safety? • Have appropriate controls been established in the Quality Assurance chapter to assure that quality requirements are met? • Has appropriate documentation been specified to document that quality requirements are met?

Table D.2 Review of Fabrication

Identification of Packaging Components	• Is each packaging component depicted on the drawings and identified in the parts list or by other appropriate means? • Is each packaging component not identified on the drawings properly justified as not important to safety? • Have all safety-related fabrication features been well-characterized on the drawings, with regard to the appropriate code requirements?
Welds	• Is the location, type, size, thermal cycle/metallurgy (if applicable), and method of examination (with acceptance criteria) for each weld specified on the drawings or in the text? • Is a code or standard requirement for each weld, welding procedure, and welder qualification specified on the drawings? Is all of the weld information consistent with this code or standard? • Is the code or standard for the weld appropriate (see NUREG/CR-3019 and -3854)?
Codes and Standards for Other Fabrication Processes	• Is an appropriate code or standard for fabrication of each packaging component specified on the drawings? • For components without an applicable specification (e.g., lead shielding), is the fabrication process sufficiently described, controlled, and specified on the drawings? • Are appropriate examination requirements for each fabrication process specified on the drawings? • Is the package evaluation consistent with its fabrication specifications?
Package Operations	• Should components or features be inspected prior to each fabrication or use? • Are appropriate types of inspections and acceptance criteria specified?
Acceptance Testing and Maintenance Program	• Are appropriate acceptance tests and documentation specified to address fabrication issues (e.g., uniformity of lead, nondestructive evaluation of materials prior to fabrication, etc.)? • Should any component or feature 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? • Are the requirements for acceptance testing and maintenance specified?

Table D.2 Review of Fabrication (cont.)

Quality Assurance	• Has each component been properly categorized as to its importance to safety? • Are training and qualification requirements for fabrication personnel properly specified? • Have appropriate controls been established in the Quality Assurance chapter to assure that quality requirements are met? • Has appropriate documentation been specified to document that quality requirements are met?

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