



## **Service Center**

## **Safety Guide**

*Defense Programs  
Package Certification  
and  
Offsite Transportation  
Authorization  
Guide*

**SG-500**

Revision 3

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### **FOREWORD**

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The purpose of this safety guide is to establish and disseminate standardized Department of Energy (DOE)/National Nuclear Security Administration (NNSA) processes for establishing and maintaining packaging programs that ensure that off-site shipments of nuclear weapon components, Category I and II special nuclear materials (SNM), nuclear weapon program special assemblies (SAs), and other materials of national security interest are safe, comply with the applicable federal regulatory and DOE Order 461.1A requirements, and present no undue risk to the public, worker safety and health, or the environment.

Comments (recommendations, proposed additions or deletions, or any other suggested improvements) should be sent to:

U.S. Department of Energy/ National Nuclear Security Administration  
Service Center  
Packaging Certification Division  
Attention: Manager  
P.O. Box 5400  
Albuquerque, NM 87185-5400

## SECTION 1.0 GENERAL OVERVIEW

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The United States Government in cooperation with other countries, regulates the design and certification of packaging used in the transport of hazardous materials with a special emphasis on radioactive material (RAM). The U.S. Department of Transportation (DOT), in *Title 49 Code of Federal Regulations (CFR) Part 173* (49 CFR 173) grants the U.S. Department of Energy the authority to certify packagings used for transporting Class 7 materials. More specifically, 49 CFR 73(d) states the following: “Notwithstanding the requirements of §§ 173.416 and 173.417 of this subchapter, packagings made by or under the direction of the U.S. Department of Energy may be used for the transportation of Class 7 materials when evaluated, approved and certified by the Department of Energy against packaging standards equivalent to those specified in 10 CFR part 71. Packages shipped in accordance with this paragraph shall be marked and otherwise prepared for shipment in a manner equivalent to that required by this subchapter for packagings approved by the Nuclear Regulatory Commission.”

Neither 49 CFR nor 10 CFR 71 impose specific requirements on structural components in terms of allowable stress or limits on permissible deformation. Nevertheless, it is well understood that a packaging’s containment boundary may be compromised if the structure components are overstressed or grossly distorted, and could negatively impact the packaging’s ability to remain within regulatory limits for containment of hazards, radiation protection and protection from criticality events. Therefore, it is essential that structural components be designed in accordance with a well-established design standard.

The Nuclear Regulatory Commission (NRC), in order to meet its regulatory responsibilities, adopted the philosophy of applying strict requirements and high margins of safety to packages used to transport significant quantities of RAM, and has therefore developed numerous regulatory guides to establish guidance for the design criteria for shipping casks used to package and ship radioactive materials. NRC Regulatory Guides 7.6, *Design Criteria for the Structural Analysis of Shipping Casks Containment Vessels* and 7.11, *Fracture Toughness Criteria of Ease Material for Ferritic Steel Shipping Cask Containment Vessels with a Maximum Wall Thickness of 4 Inches (0.1 m)* are two of those guides.

Regulatory Guide 7.6 recommends that structural components be designed in accordance with the American Society of Mechanical Engineers (ASME) Code. Regulatory Guide 7.6 also describes the design criteria for the structural analysis of shipping cask containment vessels and explains the use of the “design-analysis” approach for Class I components from Section III of the ASME Code as a design criteria for the containment vessels. Other codes and standards can be used as design criteria provided that they can be justified to be as conservative as the ASME Code.

Regulatory Guide 7.11 Section 2.2 recommends that the structural design of all shielding structures be in accordance with the criteria contained in the ASME Boiler and Pressure Vessel Code. Regulatory Guide 7.11 also defines three categories of Type B packages based on the activity levels of the contents. For a specific radio-isotope or combination of radio-isotopes, Category I includes the highest levels of hazards and therefore requires packaging designs with the highest margin of safety, whereas Categories II and III include the medium to low activity levels and therefore require packaging designs with lower margins of safety.

The DOE/NNSA has assigned the DOE/NNSA Service Center's Certifying Official and Packaging Certification Division (PCD) the overall responsibility for certifying Type B packages, and assessing the safety, and when appropriate, authorizing shipments of nuclear weapon program special assemblies or other materials of national security interest transported in the Transportation Safeguards System (TSS), or other vehicles approved by the Assistant Deputy Administrator for Secure Transport. The TSS is managed and operated by the Office of Secure Transportation (OST). Refer to DOE Order 461.1A for additional information on this subject.

The DOE/NNSA PCD maintains a program and corresponding management system for certifying Type B packages and for reviewing applications and associated Transportation System Risk Assessments (TSRAs)/Hazards Assessment Reports (HARs) for authorizations to ship special assemblies and other materials of national security interest off-site. The DOE/NNSA PCD's program and management system is based on the requirements contained in 10 CFR 71, 49 CFR 100-185, DOE Order 461.1A, and applicable ASME, American National Standards Institute (ANSI) and American Society for Testing and Materials (ASTM) national standards, and the guidance contained in the NRC Regulatory Guides. The processes and responsibilities delineated in this guide are based on these regulatory requirements and guides, and industry standards, and their effectiveness has been proven through years of successful implementation.

Applicants/users who choose to deviate from the responsibilities and processes provided in this guide do so at the risk of not having a certified package, and/or offsite shipment authorization in time to support their needs, or not being authorized to use a currently certified package.

Requests for authorizations for off-site shipments that meet the 10 CFR 71 and 49 CFR 100-185 requirements must be supported by a safety analysis report for packaging (SARP) that is prepared and submitted by the applicant to the DOE/NNSA PCD for review and approval via the appropriate contractor and DOE/NNSA line management chain. The safety of the associated operations shall be documented in a safety evaluation report (SER) that is prepared by the PCD,

and the authorization, if approved by the DOE/NNSA Certifying Official, is granted via an Offsite Transportation Certificate (OTC).

Requests for authorizations for off-site shipments of packages that contain Type B quantity of RAM, but which cannot be shown to meet all of the 10 CFR 71 performance requirements must be supported by SARPs and TSRAs.

Requests for authorizations for off-site shipments of packages that contain Type B quantity of RAM, but cannot be shown to meet the 49 CFR and/or 10 CFR and/or DOE Order 461.1A requirements must be supported by SARPs and TSRAs, and must include requests, that are addressed to the DOE/NNSA Deputy Administrator for Defense Programs (NA-10), for an exemption from the requirements of DOE Order 461.1A.

Requests for authorization for off-site shipments of nuclear weapon special assemblies that contain a Type B quantity of RAM, but cannot be shown to meet the 49 CFR and/or 10 CFR requirements must be supported by TSRAs. Requests for authorizations for off-site shipment of nuclear weapon special assemblies that contain a Type A quantity of RAM, or contain no RAM but contain other hazardous material; or contain no hazardous material but must be shipped in the TSS due to security reasons, must be supported by hazards assessment reports (HARs). The TSRA/HAR must be prepared by the applicant and must be submitted to PCD for review and approval via the appropriate contractor and DOE/NNSA line management chain. The safety of the associated operations shall be documented in a SER that is prepared by PCD, and the authorization, if approved by the DOE/NNSA Certifying Official, is granted via an Offsite Transportation Authorization (OTA).

The safety guide is intended to serve those subject to DOE Order 461.1A. The safety guide is also intended as an operations manual that is consistent with both DOT 49 CFR 173 and NRC 10 CFR 71 requirements, and to emphasize the DOE/NNSA PCD requirement for contractors to develop and maintain a formal approved Quality Assurance Program Plan (QAPP) for packaging RAM.

Appendix G of this guide satisfies the 10 CFR 71 Subpart H and 10 CFR 830.120 requirements for a DOE/NNSA PCD QAPP. This guide fully complies with the requirements of a DOE Integrated Safety Management System as required in DOE Policy P 450.4.

The safety guide is a living document and will continue to be updated as new processes and/or technologies are developed and as management systems change. This safety guide does not address on-site transfers of RAM, which are covered by DOE M 461.1A-1. In addition, this safety guide does not address accident response activities covered by 10 CFR 830.

The provisions of this safety guide should not be construed as contractual requirements in any audit or appraisal for compliance with DOE Order 461.1A unless such provisions are specified by laws, federal regulations (10 CFR 71, 10 CFR 830, and 49 CFR 100-185), or other “requirements” documents such as DOE Directives, Orders, etc.

## **RESPONSIBILITIES**

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### **2.1 Introduction**

The DOE/NNSA PCD management retains the primary responsibility for the scope and implementation of the DOE/NNSA Service Center's Package Certification and Offsite Transportation Authorization Program including quality assurance related activities. The sites and organizations that use the products and/or services of this program are responsible for complying with the requirements of this program and with achieving quality in the activities for which they are responsible.

### **2.2 Responsibilities**

This section delineates the responsibilities of each of the principals involved in the DOE/NNSA package certification, and offsite transportation authorization use and associated processes. The responsibilities are based on the requirements contained in 10 CFR 71, 49 CFR 100-185, DOE Order 461.1A, and ASME, ANSI, and ASTM national standards, and the guidance contained in NRC Regulatory Guides.

Applicants/users who choose to deviate from the responsibilities delineated below do so at the peril of not having a certified package, and/or offsite transportation authorization in time to support their needs, or not being authorized to use a currently certified package.

#### **2.2.1 DOE/NNSA Headquarters**

Refer to DOE Order 461.1A.

#### **2.2.2 DOE/NNSA Certifying Official**

##### **A. Budget**

1. Ensures that the DOE/NNSA PCD has the staff and resources to continue to perform assigned Type B package certification and off-site transportation authorization functions.
2. Works with funding sources to ensure that the PCD is allocated the resources needed to fund the SARP and TSRA reviews, maintain program guides, conduct staff training, and perform official travel.

##### **B. Package Certification and Shipment Authorization**

1. Certifies Type B Package by approving an OTC and returning the signed OTC and the SER to the PCD Manager for distribution.
2. Authorizes off-site shipment of special assembly or other material of national security interest by approving the OTA and returning the signed OTA and SER to the PCD Manager for distribution.

3. Forwards requests for exemptions to DOE Order 461.1A to the DOE/NNSA Deputy Administrator for Defense Programs (NA-10) with recommendations for approval/disapproval via management chain.
4. Approves/disapproves a OTC/OTA, SER and distribution memorandum associated with a NA-10 exemption by signing the OTC/OTA and distribution memorandum.
5. If OTC, OTA, SER and/or distribution memorandum are disapproved, identifies the reason(s) for the disapproval and instructs the PCD on how to proceed.
6. Reviews the PCD Manager's recommendations to decertify a currently certified package and take action as needed. For example:
  - Option 1: approve PCD's recommendation, brief/notify senior DOE/NNSA management of planned action, and sign a letter that is prepared by the PCD staff to notify the Nuclear Weapons Complex that the package has been decertified and must not be used under the specified SARP(s), SER(s), OTC(s) and/or OTA(s) until further notice. The letter should also specify that the applicable Packaging Line Manager should submit a recovery plan, via the Packaging Line Manager's management chain, to the Certifying Official for review and approval prior to proceeding with proposed corrective actions.
  - Option 2: disapprove PCD Manager's recommendation and instruct the PCD to re-review package and recommendations and revise proposed recommendations as needed and resubmit for reconsideration, if required.
7. Reviews documentation and recommendations provided by the PCD to terminate a user's use of a specified OTC/OTA based on the user's noncompliance and/or violations of the SARP, and/or OTC/OTA, and take action as needed. For example: approve the PCD's recommendation, brief/notify upper management of planned action, and sign a letter that is prepared by the PCD staff to notify the subject user, DOE/NNSA management, DOE/NNSA Site Manager, and the applicable Packaging Line Manager/Weapon System Program Manager that the subject user is prohibited from using the authority granted in the specified OTC/OTA until further notice. The letter should also specify that a recovery plan must be submitted, via the user's management chain, to the Certifying Official for review and approval prior to proceeding with proposed corrective actions.

### **2.2.3 PCD Manager**

#### **A. Budget**

1. Works with Certifying Official and funding sources to ensure that the PCD is allocated the resources needed to fund the SARP and TSRA reviews, maintain program guides, conduct staff training, and perform official travel.
2. Develops, maintains, and submits budget projections to DOE/NNSA Headquarters via applicable management chain.
3. Manages PCD budget.
4. Maintains records of allocations and expenditures.

## **B. Program Management**

1. Establishes and maintains PCD position descriptions and team composition to ensure that the staff can perform all of the program's assigned functions.
2. Makes PCD team member candidate selection, when applicable.
3. Establishes work assignment priorities, assigns resources, monitors work and makes adjustments as required based on schedule demands, funding availability, and other considerations as appropriate.
4. Appoints PCD Web Page Master and Alternate.
5. Establishes and maintains a viable Lessons Learned Workshop program. Conduct periodic workshops to review the Program status, improve the working relations between the Transportation Safety Review Panel (TSRP) members and applicant's staff, incorporate lessons learned, improve the processes, increase efficiency, and ensure that the Program requirements and processes are appropriate and do not become unnecessarily cumbersome.
6. Appoints an Acting Manager during his/her absence of one day or more, and notifies management and customers of his/her absence by providing the name of the Acting Manager, the period for the appointment, and information on how he/she can be contacted.
7. Implements and complies with the guidance specified in [Section 3.0](#), *Programs and Processes*.

## **C. Training**

1. Completes and maintains qualification through the PCD Manager's Technical-Qualification Standard (TQS).
2. Establishes and maintains PCD Manager's and Package Certification Engineer's (CE's) TQS and oversees/manages team members' TQS training and qualifications.
3. Ensures that the CEs are trained on the TSS's capacity, restraint hardware and general systems limitations.

## **D. Support of Others**

1. Provides technical assistance/advice to DOE/NNSA Headquarters, DOE/NNSA Certifying Official, Site management, Package Line Managers, Weapon System Program Managers and OST when required.
2. Assigns CEs that have undergone training on the TSS's capacity, restraint hardware and general systems limitations as liaisons between OST and PCD staffs, if the need arises.
3. Works with Package Line Managers, Site managers and Weapon System Program Managers to ensure that they understand their responsibilities, and why their roles in the success of the package certification and off-site transportation authorization program are critical to the success of their programs.

## **E. Package Certification and Shipment Authorizations**

1. Assigns TSRP Chairman to lead SARP and TSRA reviews, and Packaging Project Lead Certification Engineer to lead HAR reviews and/or other projects.
2. Appoints Technical Advisor to support SARP and/or TSRA development team, if resources allow.
3. Assigns/allocates resources to TSRP Chairman, HAR review leader, and TSRA technical advisor.
4. Reviews and approves comments (Qs) developed during SARP and TSRA reviews and forward them to the applicant via applicable DOE/NNSA line management (Site management, Package Line Managers or Weapon System Program Manager, as applicable).
5. Reviews TSRP Chairman's and HAR review leader's recommendation for approving SARP, TSRA or HAR or for terminating the review and informing the applicant and the DOE/NNSA line management (Site's management, Package Line Managers and/or Weapon System Program Manager, as applicable).
6. Reviews SER, OTC or OTA, and associated distribution for completeness and correctness.
7. Returns SER, OTA or OTC and associated distribution memorandum to the TSRP Chairman or HAR review leader for rework, or forwards to the DOE/NNSA Certifying Official with recommendation for approval.
8. Forwards signed OTAs/OTCs and SER to the CEs for distribution.
9. Forwards requests for exemptions to DOE Order 461.1A to the DOE/NNSA Certifying Official with recommendations for the DOE/NNSA Deputy Administrator for Defense Programs to approve/disapprove.
10. Reviews information on OTA/OTC user's noncompliance with SARP, and/or OTA/OTC requirements and takes appropriate action. See PCD Manager Oversight Section for additional information. The following are examples of actions that could be taken:
  - a. Review documentation of the OTA/OTC user's acts of noncompliance. Review, and if applicable approve, CE developed recommended action(s) and present to the DOE/NNSA Certifying Official. Review and if appropriate forward the letter that is prepared by the CE for the DOE/NNSA Certifying Official's signature. The letter shall notify the subject user, DOE/NNSA management, DOE/NNSA Site Manager, and the applicable Packaging Line Manager/Weapon System Program Manager that the subject user is prohibited from using the authority granted in the specified OTA/OTC until further notice. The letter should also specify that a recovery plan must be submitted, via the user's management chain, to the DOE/NNSA Certifying Official for review and approval prior to proceeding with proposed corrective actions.
  - b. Staff a surveillance team and conduct a surveillance visit of the OTA/OTC user and tasks the team to develop a recommended course of action. Present the surveillance team's recommended course of action to the DOE/NNSA Certifying Official and take action(s) as directed by the

DOE/NNSA Certifying Official. Refer to Appendix D for guidance on surveillance process.

11. Reviews all reports or evidence concerning any currently certified Type-B package that may indicate that the package may not meet the applicable regulatory requirements (i.e., the regulatory requirements that were applicable when the package was first designed and certified and new regulatory requirements that have been specified for the package type since its original certification) and take the appropriate action. For example:
  - a. Develop recommended package certification course of action (continue the package's certification or decertify the package) and provide to the DOE/NNSA Certifying Official for his/her approval. Review and if applicable forward the CE prepared letter to the DOE/NNSA Certifying Official.
  - b. Recommend that Packaging Line Manager task the SARP and package owners to perform a review of the issues and to develop a recommended course of action.
  - c. Task a CE or TSRP to conduct a review and provide a recommended package certification course of action (continue the package's certification or decertify the package).
  - d. For proposed actions that involve the termination/suspension of a currently certified package' certification, task the CE to prepare a letter for the DOE/NNSA Certifying Official's signature. The letter shall notify the Nuclear Weapons Complex that the package has been decertified and must not be used under the specified SARP, OTC and/or OTA until further notice. The letter should also specify that the applicable Packaging Line Manager should submit a recovery plan, via the Packaging Line Manager's management chain, to the Certifying Official for review and approval prior to proceeding with proposed corrective actions.

#### **F. Management of Technical Support Contractor**

1. Tasks, provides oversight and manage Technical Support Contractor(s).
2. Funds Technical Support Contractor(s) activities.
3. Develops work plan and work scope and budget as a "Work For Others" work transfer for on-call technical support. Refer to Appendix F for guidance on developing a Scope of Work.
4. Develops Work Scope for Package Certification support (Work For Others) technical subject matter experts (SMEs) that perform SARP/TSRA reviews and associated confirmatory analysis (Structural, Thermal, Shielding, Criticality, quality assurance (QA), etc. – NRC NUREG-1609/Regulatory Guide 7.9) and selects providers using the following criteria:
  - a. Availability and affordability of national laboratory and contractor resource for providing technical support.
  - b. Record of leadership and performance.
  - c. Qualifications of prospective technical SMEs and their compatibility with TSRP needs. The TSRP must be composed of members that are technically competent to review the adequacy and correctness of each of

- the SARP sections recommended in NRC NUREG-1609/Regulatory Guide 7.9 and that are technically competent to review the adequacy and correctness of TSRAs. Refer to Appendix A for information on SARP and TSRA reviews.
- d. Ability to develop and implement work plans and procedures for performing SARP/TSRA reviews and confirmatory analysis, and maintaining prescribed schedule. Refer to Appendix A for additional information on performing confirmatory analysis.
  - e. Ability to demonstrate that there is no conflict of interest. The technical support contractor must provide assurance to DOE/NNSA PCD that they can staff the team leader and SMEs positions with qualified staff members that have not provided direction or technical input nor participated in any procurement and/or development activities for the package to be evaluated prior to initiating any SARP/TSRA review activities.
  - f. Ability to document and clearly communicate the results of the SARP/TSRA review.
  - g. Ability to manage a program to ensure that it stays on schedule and within budget.
  - h. Ability to develop and provide monthly expenditure and activity reports for each of the assigned tasks to DOE/NNSA PCD.
  - i. Ability for maintaining auditable records of the work performed in support of the DOE/NNSA package certification and offsite authorization program.
5. Periodically reviews the capabilities and affordability of the technical support contractor(s) used to supplement SARP and/or TSRA reviews and to perform confirmatory analysis and other available contractor sources available for these tasks to ensure that the contractor used is technically competent and cost effective. One of the principal goals of this process is to ensure the availability of technically competent and affordable on-call technical support that can provide technically correct and timely products in response to tasks.

## **G. Oversight**

1. Provides appropriate oversight of OTA/OTC user activities.
2. Supports DOE/NNSA Headquarters in their appraisal/oversight function by providing members for appraisal/oversight teams.
3. Appoints surveillance team and team leader to conduct surveillance of OTA/OTC user activities, as required. Refer to Appendix D for information on surveillance process.
4. Provides the surveillance team's findings and recommendations to the DOE/NNSA Certifying Official.

### **2.2.3.1 PCD Certification Engineers (CEs)**

#### **A. Program Management**

1. Perform the functions of Acting PCD Manager, when assigned.
2. Implement and comply with the guidance specified in [Section 3.0](#), *Programs and Processes*.

## **B. Package Certification and Shipment Authorizations**

1. Lead and manage SARP, TSRA and HAR reviews, and/or other tasks as assigned.
2. Review all reports or evidence, concerning currently certified Type-B packages under their cognizance and/or other packages as assigned, that may indicate that the package may not meet the applicable regulatory requirements (i.e., the regulatory requirements that were applicable when the package was first designed and certified and new regulatory requirements that have been specified for the package type since its original certification). Develop action plan that is commensurate with the level of the review, lead and/or perform the review, and prepare the resultant documents and recommendations and provide them to the PCD Manager on a predetermined schedule. Prepare a letter for the DOE/NNSA Certifying Official's signature that shall notify the Nuclear Weapons Complex that the package has been decertified and must not be used under the specified SARP(s), OTC(s) and/or OTA(s) until further notice. The letter should also specify that the applicable Packaging Line Manager should submit a recovery plan, via the Packaging Line Manager's management chain, to the DOE/NNSA Certifying Official for review and approval prior to proceeding with proposed corrective actions.
3. Review information on OTA/OTC user's noncompliance with SARP, and/or OTA/OTC requirements and prepare a brief/document that addresses the issues and provides a proposed recommended course of action, and provide it to the PCD Manager. Prepare a letter, for the DOE/NNSA Certifying Official's signature, that notifies the subject user, DOE/NNSA management, DOE/NNSA Site Manager, and the applicable Packaging Line Manager/Weapon System Program Manager that the subject user is prohibited from using the authority granted in the specified OTA/OTA until further notice. The letter should also specify that a recovery plan must be submitted, via the user's management chain, to the DOE/NNSA Certifying Official for review and approval prior to proceeding with proposed corrective actions.
4. Perform the following SARP, TSRA and HAR functions:
  - a. TSRP Chairman must:
    - (1) Assist the PCD Manager in developing documents for tasking the Technical Support Contractor that will perform the SARP and/or TSRA review and associated confirmatory analysis, and/or other technical reviews.
    - (2) Lead the TSRP's review of the SARP/TSRA.
    - (3) Provide distribution list for draft SARP and/or TSRA to applicant.
    - (4) Convene the TSRP to evaluate the SARP/TSRA upon receipt of the SARP/TSRA from the PCD Manager.
    - (5) Chair TSRP-applicant comment review meeting.
    - (6) Document Qs developed during the review and submit the Qs and distribution memorandum to the PCD Manager.
    - (7) Review applicant's responses to the Qs and:

- (a) Recommend closure of Qs to the PCD Manager, if applicable.
  - (b) Develop and submit Qs that address issues that remain open or new Qs in response to applicant's responses, if applicable.
  - (c) Submit open/new Qs and associated distribution memorandum to PCD Manager.
- (8) Recommend approval of SARP/TSRA after all Qs have been resolved satisfactorily, or recommend termination of review if Qs cannot be resolved.
- b. CEs who lead HAR reviews must:
- (1) Review HAR and document Qs developed during the review and provide to the applicant and the applicable Weapon System Program Manager.
  - (2) Approve applicant's responses to Qs, or if unable to come to closure on the Qs, recommend termination of the review to the PCD Manager.
  - (3) Prepare correspondence, for the PCD Manager's signature, to officially advise the applicant and the Weapon System Program Manager of the decision to terminate the review, when required.
- c. CEs that chair TSRPs or lead HAR reviews must:
- (1) Review and approve or disapprove and provide review comments for resolution to the prospective package users on their draft package-specific packaging procedures for items packaged and shipped in certified containers, and the associated Site quality assurance plan. If unable to approve a prospective user's packaging procedures and/or Site quality assurance plan, due to irresolvable deficiencies, the issue will be briefed to the DOE/NNSA Certifying Official and the DOE/NNSA Service Center's management. The prospective user shall not be designated an authorized user of the package and the prospective user will be prohibited from using the package until the packaging procedures and Site quality assurance plan have been approved. If the prospective user disagrees with the DOE/NNSA Service Center's decision to not approve the prospective user's draft packaging procedures, the prospective user is free to appeal this decision, with appropriate technical justification, to upper DOE/NNSA management.
  - (2) Ensure that the documentation submitted for items shipped in handling gear lists the approved handling gear for that item.
  - (3) Develop SER in accordance with the format provide in Appendix C.
  - (4) Provide SER and associated OTC/OTA and distribution memorandum to PCD Manager. If applicable, lead the effort to resolve the issues that led to the DOE/NNSA Certifying Official disapprove the OTC/OTA, SER or distribution memorandum, and if necessary rewrite and resubmit the documents for approval. The probability of this occurring in not very high since the PCD will have kept the DOE/NNSA Certifying Official informed of all possible problems as the project progressed.

- (5) Ensure that copies of approved OTAs/OTCs and SERs are distributed to the applicant and other NNSA-approved users, and the Office of Secure Transportation.
  - (6) Maintain OTA/OTC, SARP, TSRA, HARs and associated records.
  - (7) Provide timely and accurate information to update PCD Web Page to the Web Page Master. Refer to [Appendix E](#) for information on Web Page content.
- d. SARP/TSRA Technical Advisor must:
- (1) Provide technical advice to applicable line manager/Weapon System Manager responsible for overseeing SARP/TSRA development.
  - (2) Attend, support and participate in SARP and TSRA related meeting, as needed.
  - (3) Attend, support and participate in TSRA kick-off meeting, as required.
  - (4) Keep PCD Manager advised of SARP/TSRA support activities.
  - (5) Maintain SARP/TSRA Technical Advisor records.

### **C. Assistance to OST Staff**

1. Assist OST planning staff to properly interpret OTAs, OTCs, NRC and EM-5 Certificates of Compliance (CofCs), and other regulatory approval documents.
2. Screen all OTC and OTA requests to determine if Technical Publication (TP) 45-51 and/or the DOE/NNSA tiedown manuals contain the tiedown procedures needed to secure the package and/or handling gear and associated configuration proposed for shipment. Remind the applicant that they must submit draft tiedown procedures to the OST Engineering/Assurance Staff for those package/handling gear/configurations not covered in the TP 45-51 or DOE tiedown manuals and notify the OST Engineering/Assurance Staff of the situation. Consult with OST Engineering/Assurance Staff when there is uncertainty as to whether the TSS hardware can accommodate a specified cargo configuration.
3. Supplement OST staff efforts to advise potential OST customers of the general limits on TSS hardware application and practical hazardous material (HAZMAT) and particularly radiological emission guidelines.
4. In consultation with OST, mirror maximum HAZMAT limits on mixed hazards and radiological exposure hazards into OTCs and OTAs.
5. Function as liaisons between OST and PCD staffs if the need arises.

### **D. Training**

1. Complete and maintain Package Certification Engineer qualification under the Package Certification Engineer's TQS.
2. Establish and maintain familiarity with operation of the TSS trailer hardware and restraint systems, and TSS capabilities and limitations.

### **E. Oversight**

1. Perform oversight of OTA/OTC activities as directed.

2. Notify the PCD Manager of all noncompliance issues/concerns and/or OTA/OTC violations and provide recommended course of action.
3. Perform surveillance visit of OTA/OTC users when directed.
  - a. Refer to [Appendix D](#) for guidance on surveillance process.
  - b. Prepare surveillance report with associated recommendations, and submit the report to the PCD Manager.
4. Participate on DOE/NNSA Headquarters appraisal/oversight teams when directed.

#### **F. Web Page Management**

1. Assist OTA/OTC Web Page Master in maintaining the Web Page by providing timely updates.
2. Perform the functions of the PCD Web Page Master and/or Alternate Web Page Master when assigned by updating the Web Page information to reflect the current status of all items addressed in the Web Page. See [Appendix E](#) for information on PCD Web Page.

### **2.2.4 OST**

#### **2.2.4.1 OST Planning Staff**

- A. Validate that the requirements outlined in OTA(s) and OTC(s) are consistent with the stipulations of the transportation service request (TSR).
- B. Address inquiries about a particular OTA or OTC to the cognizant CE. The cognizant CE is identified in the OTA/OTC transmittal memorandum.
- C. Maintain current copies of SERs, OTCs, CofCs and OTAs.
- D. Advise PCD through the cognizant CE of any notable anomalies with the application of the OTC or OTA during a shipment, including any incompatibility with TSS hardware issues.
- E. Notify the PCD when any transportation requests indicate that the proposed shipment does not concur with the authorized content specified in the applicable OTA or OTC.

#### **2.2.4.2 Engineering/Assurance Staff**

- A. Provide general training to all CEs on the TSS vehicles and restraint equipment, as needed.
- B. Address CE inquiries concerning use of TSS vehicles and restraint equipment for proposed shipment applications.
- C. Review applicant developed restraint tiedown procedures and approve or disapprove, as applicable, and notify the applicant and PCD in writing.
- D. Provide technical assistance to CEs on TSS safety and risk bases documents in support of transportation risk assessment activities performed in support of OTA requests/renewals.

## 2.2.5 Federal DOE/NNSA Site Line Managers

- A. Determine Site needs for OTCs and/or OTAs and communicate the need to supporting organizations and PCD.
- B. Ensure that the consignor and consignee sites are authorized users of the Type B packages that they need to support their mission. If they are not authorized users, the sites must submit the applicable packaging procedures for review and approval by DOE/NNSA PCD, and be designated an approved user of the package before they can be allowed to use the package.
- C. Ensure that contractor(s) comply with OTA/OTC requirements, and report all noncompliances to the DOE/NNSA Certifying Official and the PCD Manager.
- D. Review recovery plans that are developed by OTA/OTC users that have been prohibited to use specified OTA(s)/OTC(s) by the DOE/NNSA Certifying Official and provide comments, as applicable.
- E. Oversee the contractor assigned to develop the SARP, TSRA and/or HAR and ensure that the SARP, TSRA and/or HAR are submitted in the time schedule prescribed.
- F. Review SARP and completed current version of the Safety Guide (SG) 200 *SARP Completeness Review Checklist of DOE/NNSA Defense Programs Packages*, TSRA and/or HAR and associated OTC/OTA request to ensure that they are correct, complete, and accurate.
- G. Participate in TSRP-applicant SARP and/or TSRA comment review meeting(s), when requested by PCD.
- H. Review the Qs developed by the TSRP during the SARP/TSRA review and the applicant's responses to the Qs to ensure that they are correct and timely.
- I. Assist in issue resolution, if required.
- J. Review the Site's exemption requests to the DOE/NNSA Deputy Administrator for Defense Programs and provide recommendation for approval/disapproval to the DOE/NNSA Deputy Administrator for Defense Programs. If the DOE/NNSA Deputy Administrator for Defense Programs grants the exemption, perform the functions directed in the DOE/NNSA Deputy Administrator for Defense Programs correspondence that grants the exemption, and determine if and when the packaging and transportation activities addressed in the DOE/NNSA Deputy Administrator for Defense Programs exemption may begin.
- K. Review package specific packaging procedures to ensure that they are correct, complete, and accurate.
- L. Ensure Site's compliance with DOE Order 461.1A, and OTA/OTC requirements.
- M. Establish and maintain, and ensure that the applicable site contractor(s) establishes and maintains a packaging program QAPP that meets 10 CFR 71, Subpart H requirements.
- N. Maintain file of current OTAs and OTCs applicable to the site.
- O. Support DOE/NNSA Headquarters in their appraisal/oversight function by providing members for appraisal/oversight teams.

- P. Verify that that there are no outstanding appraisal findings that might affect a packaging/shipment operation.
- Q. Perform oversight of packaging and off-site transportation activities.
- R. Implement and comply with the guidance specified in [Section 3.0](#), *Programs and Processes*.

### **2.2.6 DOE/NNSA Package Line Managers**

- A. Oversee the contractor assigned to develop the SARP and/or TSRA and ensure that the SARP and/or TSRA are submitted at least nine months prior to the OTC/OTA need date. Refer to [Section 3.0](#), [Appendix A](#) and [Appendix B](#) for additional information on the associated processes.
- B. Review SARP and completed SG 200 *SARP Completeness Review Checklist of DOE/NNSA Defense Programs Packages* and/or TSRA and associated OTC/OTA request to ensure that they are correct, adequate, and accurate.
- C. Participate in and support TSRP-applicant SARP and/or TSRA comment review meeting(s).
- D. Review the Qs developed by the TSRP during the SARP/TSRA review and the applicant's responses to the Qs to ensure that the responses are correct and timely.
- E. Assist in issue resolution, if required.
- F. Review package specific packaging procedures to ensure that they are correct, adequate, and accurate.
- G. Support DOE/NNSA Headquarters in their appraisal/oversight function by providing members for appraisal/oversight teams.
- H. Verify that that there are no outstanding appraisal findings that might affect a packaging/shipment operation.
- I. Review all reports or evidence concerning any currently certified Type-B package that may indicate that the package may not meet the applicable regulatory requirements (i.e., the regulatory requirements that were applicable when the package was first designed and certified and new regulatory requirements that have been specified for the package type since its original certification) and task the SARP and package owners to perform a review of the issues and to develop a recommended course of action. Submit the results of the review and recommended course of action to the DOE/NNSA Certifying Official and PCD Manager. When applicable, develop recovery plan for packages that have been decertified by the DOE/NNSA Certifying Official and submit the draft recovery plan to the DOE/NNSA Certifying Official and the PCD Manager for review and approval via the appropriate management chain.
- J. Implement and comply with the guidance specified in [Section 3.0](#), *Programs and Processes*, of this guide.

### **2.2.7 Weapon System Program Manager**

- A. Determine special assembly needs.

- B. Get written authorization from the senior DOE/NNSA Headquarters nuclear weapons program line manager who has responsibility for granting approval to build and test special assemblies that contain Type B quantity RAM prior to scheduling a build or test of a special assembly that contains fissile material.
- C. Determine program needs for OTAs and communicate the need to supporting organizations and PCD.
- D. Select, task, fund and oversee the contractor assigned to develop the TSRA and/or HAR.
- E. Ensure that the TSRA is submitted not less than nine months prior to the OTA need date, and the HAR is submitted not later than 60 days prior to the OTA need date. Refer to [Section 3.0](#), [Appendix A](#) and [Appendix B](#) for additional information on the associated processes.
- F. Review TSRA and/or HAR and associated OTC/OTA request to ensure that they are correct, complete and accurate.
- G. Review the Qs developed by the TSRP during the TSRA review and the applicant's and/or TSRA development organization's responses to Qs to ensure that the applicant and/or TSRA development organization provides correct and timely responses.
- H. Assist in issue resolution, if required.
- I. Review recovery plans that are developed by OTA/OTC users that have been prohibited to use specified OTA(s)/OTC(s) by the DOE/NNSA Certifying Official and provide comments, as applicable.
- J. Perform the functions associated with the responsibilities assigned in DOE Order 461.1A.
- K. Support DOE/NNSA Headquarters in their appraisal/oversight function by providing members for appraisal/oversight teams.
- L. Implement and comply with the guidance specified in [Section 3](#), *Programs and Processes*, of this guide.

### **2.2.8 SARP Owner**

- A. Maintain contact with DOE/NNSA PCD for requirements and guidance relating to packaging and transportation.
- B. Manage and maintain SARP and supporting documents.
  1. Develop or manage (See SARP/TSRA Development Organization Section) the development of the SARP/SARP addendum.
  2. Attend, support and participate in applicable SARP/SARP addendum related meetings, as needed.
  3. Attend, support and participate in applicable SARP/SARP addendum kick-off meetings, as required.
  4. Ensure that the SARP/SARP addendum is prepared using the formats and contents specified in [Appendix B](#). Refer to [Section 3.0](#) and [Appendix A](#) for additional information on the associated processes.
  5. Ensure that at least nine months prior to the OTC need date, copies of the draft SARP/SARP addendum are provided to the Package Line Manager and to the individuals on the list provided by PCD.

6. Participate in TSRP-applicant SARP/SARP addendum comment review meetings.
7. Review the Qs developed by the TSRP during the SARP/SARP addendum /TSRA review, and ensure that responses are developed and submitted on time, and are correct and appropriate to the Qs. Proposed changes to SARP/SARP addendum/TSRA and/or supporting documents must be submitted to PCD verbatim for review and approval before the SARP/SARP addendum /TSRA and/or supporting documents is changed.
8. Ensure that the final SARP/SARP addendum /TSRA and/or supporting documents are published and distributed after the changes have been approved by PCD.
- C. Work with applicant to determine whether previously performed tests, analysis and documentation support their needs, as needed/requested.
- D. Review proposed changes to authorized contents and provide recommendations to PCD.
- E. Review all reports or evidence concerning any currently certified Type-B package that may indicate that the package may not meet the applicable regulatory requirements (i.e., the regulatory requirements that were applicable when the package was first designed and certified and new regulatory requirements that have been specified for the package type since its original certification) and develop a recommended course of action, and provide to PCD and the Package Line Manager.
- F. Review operational occurrence reports associated with the certified package(s) under their cognizance, and work in consonance with PCD to develop and implement changes/actions to prevent their recurrence, as needed.
- H. Implement and comply with the guidance specified in [Section 3.0](#), *Programs and Processes*.

### **2.2.9 Package Owner**

- A. Ensure that all required operating/refurbishment actions are completed and that all nonconformances identified are documented, evaluated, and reported to PCD.
- B. Work in consonance with PCD to resolve all nonconformances.
- C. Review all reports or evidence concerning any currently certified Type-B package that may indicate that the package may not meet the applicable regulatory requirements (i.e., the regulatory requirements that were applicable when the package was first designed and certified and new regulatory requirements that have been specified for the package type since its original certification) and develop a recommended course of action, and provide to PCD and the Package Line Manager.
- D. Receive package user complaints and provide responses to users and PCD.
- E. Ensure that the packaging's configuration is controlled and maintained.
- F. Implement and comply with the guidance specified in [Section 3.0](#), *Programs and Processes*.

## **2.2.10 Site Approved to Perform Maintenance on DOE/NNSA Certified Packages**

- A.** Perform authorized maintenance actions on certified packagings.
- B.** Perform specified acceptance tests and all other specified acceptance requirements on certified packagings under their cognizance.
- C.** Maintain fixtures for authorized contents of packagings under their cognizance.
- D.** Warehouse spare packagings and provide packagings to users as needed.
- E.** Track use, condition and location of packagings.
- F.** Submit proposed package design and/or SARP improvements to the package/SARP owner, as necessary. This site should also work collaboratively with the package/SARP owner, and support the 5-year package re-certification activities by performing non-destructive analysis on selected packagings as directed by the package owner, updating applicable documents, and performing other functions, as needed.
- G.** Implement and comply with the guidance specified in [Section 3.0](#), *Programs and Processes*.

## **2.2.11 Site Approved to Provide Packaging Supplies**

- A.** Provide authorized packagings, and packaging components/consumables to package authorized users and sites authorized to perform maintenance, as applicable.
- B.** Procure and perform quality acceptance of packagings and packaging supplies (i.e., spare parts such as O-rings, bolts, etc.).
- C.** Comply with the applicable requirements of [Section 3.0](#) of this Guide. The requirements that are of particular interest to this function are contained in [Sections 3.10](#), *Control of Engineered Items*, [3.11](#), *Control of Commercially Procured Items*, [3.14](#), *Procurement*, and [3.15](#), *Inspection and Acceptance Testing* of this Guide.
- D.** Maintain a DOE-auditable quality system that complies with the requirements of 10 CRF 71, Subparts G and H. The site shall maintain a qualified supplier list, use a graded approach for supplier qualification, periodically audit suppliers, track supplier performance, and require supplier corrective action, as necessary. The quality requirements for the item procured must be specified in the purchase order.
- E.** This site may also be used for maintenance and storage of packagings until needed by a using site. This activity includes performing periodic re-certification of the packagings. Refer to [Section 2.2.10](#), *Site Approved to Perform Maintenance on DOE/NNSA Certified Packages* for additional information on this responsibility.
- F.** Submit proposed package design and/or SARP improvements to the package/SARP owner, as necessary. This site should also work collaboratively with the package/SARP owner, and support the 5-year package re-certification activities by performing non-destructive analysis on

selected packagings only as directed by the package owner, updating applicable documents, and performing other functions, as needed.

#### **2.2.12 SARP/TSRA Development Organization**

- A.** Attend, support, and participate in SARP/TSRA kick-off meeting, TSRP-applicant SARP and/or TSRA comment review meeting and other applicable SARP and TSRA related meetings, as needed.
- B.** Ensure that the SARP and TSRA are prepared using the formats and contents specified in [Appendix B](#). Refer to [Section 3.0](#) and [Appendix A](#) for additional information on the associated processes.
- C.** Distribute one copy of draft SARP and/or TSRA to Site Management/Package Line Manager/Weapon System Program Manager and four copies to the recipients identified by PCD. The draft SARP/TSRA must be submitted not later than nine months prior to the OTC/OTA need date.
- D.** Review the Qs developed by the TSRP during the SARP/TSRA review, and develop and submit timely, correct and appropriate responses to Qs. Proposed changes to SARPs and/or TSRAs and/or supporting documents must be submitted to PCD verbatim for review and approval before the SARPs and/or TSRAs and/or supporting documents are changed.
- E.** Publish final SARP and/or TSRA and/or supporting documents after the changes have been approved by PCD.
- F.** Implement and comply with the guidance specified in [Section 3.0](#), *Programs and Processes*.

#### **2.2.13 OTA/OTC Applicant**

- A.** Determine the program needs for OTCs and/or OTAs and communicate the need to Site Management and/or Package Line Manager/Weapon System Program Manager and PCD.
- B.** Implement and comply with the guidance specified in [Section 3.0](#), *Programs and Processes*.
- C.** Use guidance in [Section 3.5.3](#) for determining whether the new content(s) can be added to the list of approved content(s) for a DOE/NNSA currently certified package or whether a new package must be designed, developed, certified and procured to need the need.
- D.** If the OTA/OTC Applicant and the SARP/TSRA Development Organization are the same organization, the organization must:
  - 1. Select staff and assign resources to develop the SARP/SARP addendum and/or TSRA.
  - 2. Attend, support and participate in SARP/SARP addendum, TSRA and HAR related meetings, as needed.
  - 3. Attend, support and participate in SARP/SARP addendum/TSRA kick-off meetings, as required.

4. Ensure that the SARP/SARP addendum, TSRA and/or HAR are prepared using the formats and contents specified in [Appendix B](#). Refer to [Section 3.0](#) and [Appendix A](#) for additional information on the associated processes.
5. Distribute one copy of draft SARP/SARP addendum and/or TSRA to Site Management/ Package Line Manager/Weapon System Program Manager and four copies to recipients identified by PCD not later than nine months prior to the OTC/OTA need date.
6. Submit copy of draft HAR to Weapon System Program Manager and PCD not later than 60 days prior to the OTA need date.
7. Review the Qs developed by the TSRP during the SARP/SARP addendum /TSRA review, and develop and submit timely, correct and appropriate responses to Qs. Proposed changes to SARPs/SARP addendums and/or TSRAs and/or supporting documents must be submitted to PCD verbatim for review and approval before the SARPs/SARP addendums and/or TSRAs and/or supporting documents are changed.
8. Publish final SARP/SARP addendum and/or TSRA and/or supporting documents after the changes have been approved by PCD.
- E. If the organization selected to develop the SARP and/or TSRA is not the same organization as the OTC/OTA applicant, the applicant must:
  1. Support and work closely with the SARP/TSRA Development Organization to ensure that it receives all of the data and information needed to develop the SARP/TSRA.
  2. Ensure that the SARP/TSRA Development Organization understands the applicant's needs.
- F. Select staff and assign resources to develop the HAR.

#### **2.2.14            OTA/OTC Users (consignors and consignees)**

- A. Establish and maintain packaging staff that is qualified to perform packaging functions.
- B. Establish, maintain and implement a packaging program QAPP that meets the requirements of 10 CFR 830.120, 10 CFR 71 Subpart H, and QC-1, and that is approved by the Federal Site Manager.
- C. Establish and maintain open communications with DOE/NNSA PCD.
- D. Maintain file of current OTAs, OTCs, and SARPs and supporting documents and/or TSRAs, and SERs applicable to the site.
- E. Perform oversight of program operations.
- F. Perform annual self-assessment of their activities that support the DOE/NNSA packaging program, document the results and implement and maintain a corresponding corrective actions program.
- G. Support DOE/NNSA Headquarters in their appraisal/oversight function by providing members for appraisal/oversight teams.
- H. Verify that there are no outstanding appraisal findings that might affect a packaging/shipment operation.
- I. Implement and comply with the guidance specified in [Section 3.0](#), *Programs and Processes*.

- J. Ensure compliance with the guidance provided in [Applicant's Checklist](#) or [Other Perspective Package Users' Checklist](#), as applicable, prior to using packaging that is authorized under a DOE/NNSA Deputy Administrator for Defense Programs exemption.
- K. Prepare a recovery plan in response to the DOE/NNSA Certifying Official's actions to prohibit the OTA/OTC user from using a specified OTA/OTC as a result of the user's noncompliance with SARPs, and/or OTC/OTA requirements, and submit the recovery plan to the DOE/NNSA Certifying Official and the PCD Manager for review and approval via the applicable management chain.
- L. Once all of the documents and processes listed above are in place and/or implemented, the following processes and requirements specific to the proposed operation must be followed:
  - 1. Ensure that the site is an authorized user for the container prior to use by verifying that the DOE/NNSA OTA/OTC Web Page lists the Site as an authorized user of the package.
  - 2. Ensure that site-specific operating, handling, loading, tiedown, and maintenance (if applicable) procedures applicable to the packaging/shipment are written, approved and implemented, and that personnel have been trained and subsequently qualified in the performance of these activities.
  - 3. Ensure that draft packaging procedures, associated packaging quality assurance plan that complies with the requirements of 10 CFR 71 Subpart H, and Site quality assurance plan are developed and submitted to DOE/NNSA for approval. Provide responses, to PCD review comments, that include prospective verbatim changes to the draft packaging procedures, associated packaging quality assurance plan that complies with the requirements of 10 CFR 71 Subpart H, and Site quality assurance plan until all review comments are resolved and the packaging procedures and Site quality assurance plan are approved. If the DOE/NNSA Service Center, due to irresolvable deficiencies, is unable to approve a prospective user's packaging procedures, associated packaging quality assurance plan that complies with the requirements of 10 CFR 71 Subpart H, and/or Site quality assurance plan, the DOE/NNSA Service Center will not designate the prospective user an authorized user of the package and the prospective user will be prohibited from using the package. If the prospective user disagrees with the DOE/NNSA Service Center's decision to not approve the prospective user as an authorized user, the prospective user is free to appeal this decision, with appropriate technical justification, to upper DOE/NNSA management. Approved package users shall publish, disseminate, maintain and use the approved packaging procedures, associated packaging quality assurance plan that complies with the requirements of 10 CFR 71 Subpart H, and Site quality assurance plan.
  - 4. Comply with the requirements and restrictions specified in the applicable OTC, SER, and SARP and supporting documents, and OTA and SER, as applicable. Report noncompliance occurrences, and or concerns and issues to PCD.

5. Package and ship nuclear weapon components, Category I and II special nuclear materials, nuclear weapon program special assemblies, and other materials of national security interest in certified packages, handling gear or other packaging authorized specified in the applicable OTA or OTC.

#### **2.2.15 Technical Support Contractor**

- A.** Ensure that the technical support team leader has a proven record for managing and leading a team of highly competent technical SMEs. The team leader must be capable of taking inputs provided by the SMEs and consolidating them into an accurate and timely report that documents the results of a comprehensive SARP/TSRA review and associated confirmatory analysis.
- B.** Submit monthly report that documents the status of SARP/TSRA review tasks and associated expenditures not later than the 15<sup>th</sup> of each month to DOE/NNSA PCD. Refer to Appendix F for monthly report outline.
- C.** Each SME must be an expert in his/her respective engineering and/or physical science field(s) and be knowledgeable of the NRC and DOT federal regulations, national standards and DOE Orders applicable to the packaging and shipment of RAM. Each SME must have successfully completed the two-week DOE sponsored SARP review training course provided by the Lawrence Livermore National Laboratory or undergo training specified by the PCD Manager (e.g., attend/participate in two SARP/TSRA reviews while undergoing on-the-job training, etc.). The SME's working relations must be conducive to functioning as an integral part of the TSRP team that must speak with a unified voice and work with the SARP/TSRA applicant's staff to resolve issues identified during the review. In case of a minority opinion on a specific topic or action, the SME is free to communicate his/her position to the federal TSRP Chairman.
- D.** Develop and implement work plans that comply with the tasking provided by DOE/NNSA PCD to meet the SARP/TSRA review and confirmatory analysis needs.
- E.** Attend, support and participate in SARP/TSRA kick-off meetings and other SARP and TSRA related meetings, as required.
- F.** Document and communicate the technical review comments and questions developed during the SARP/TSRA reviews and associated confirmatory analysis and provide them to DOE/NNSA PCD. Refer to Appendix A for additional information on SARP/TSRA review scope and associated report requirements.
- G.** Prepare and approve official confirmatory review correspondences and report, and ensure that records for confirmatory reviews are established and maintained.
- H.** Submit official confirmatory review correspondence and report to DOE/NNSA PCD.
- I.** Implement and comply with the guidance specified in [Section 3, Programs and Processes](#).

## **2.3 Graded Approach**

The DOT regulations are so structured that materials representing a greater hazard are subject to greater containment, communication, and control requirements. 10 CFR 830.3 states that a graded approach means the process of ensuring that the level of analysis, documentation, and actions used to comply with a requirement in this part are commensurate with the: relative importance to safety, safeguards, and security; magnitude of any hazard involved; life cycle stage of an activity; programmatic mission of an activity; particular characteristics of an activity; relative importance of radiological and non-radiological hazards; and any other relevant factor.

10 CFR 830.7 also states that where appropriate, a contractor must use a graded approach to implement the requirements of this part, document the basis of the graded approach used, and submit that documentation to DOE.

The contractor management's application of the requirements to the activities associated with Offsite Packaging and Transportation activities should be graded to provide the flexibility to design controls that best suit the facility or activity after satisfying all requirements mandated by law (Reference: 10 CFR 71.101(b).)

The graded approach process determines the appropriate level of effort necessary to satisfy a requirement and then documents the level of effort.

Factors to be considered in the graded approach include: level of risk (consequences of failure/being wrong); importance of data generated; cost and schedule impacts; complexity of a packaging or transportation process; importance of reproducibility or replacement; history of a packaging or transportation process problem; importance of standardization; application of regulations, codes, and standards (Note: The 10 CFR 830 Rule does not allow for the use of the graded approach with regard to implementing unreviewed safety questions (USQ) or in implementing technical safety requirements.); need for process control/special controls; importance of functional compliance by inspection or test; importance of special handling, shipping or storage; adequacy of existing safety documentation; and complexity of products or services involved.

The basis and methodology for selecting an action pursuant to the graded approach, to the extent that is consistent with its importance to safety, should be documented in the QAPP.

## **2.4 Applicable Standards/Requirements**

All pertinent standards and requirements are as cited in DOE Order 461.1A, 10 CFR 71, 49 CFR 100-185, and 10 CFR 830.120.

## **SECTION 3.0**

### **PROGRAMS AND PROCESSES**

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#### **3.1 Introduction**

This section provides requirements and guidance for establishing and maintaining a program and processes for gaining and maintaining approval for packaging and/or shipping DOE/NNSA nuclear weapon components, Category I and II SNM, nuclear weapon program special assemblies, and other materials of national security interest. It also contains information on when a user's authorization to use a certified Type B package may be revoked and who can authorize vehicles used to perform the associated off-site transportation operations.

#### **3.2 Cargo Packing, Loading and Transportation Requirements**

In accordance with 49 CFR 173, nuclear components with greater than  $A_1/A_2$  quantities should be packaged in Type B containers. Hazardous materials combinations for special assemblies are packaged in accordance with the following criteria:

- A.** Explosives with depleted uranium and/or Be/BeO should be packaged in accordance with 49 CFR.
- B.** High explosives (HE) with the detonators attached and depleted uranium should be packaged in accordance with 49 CFR and the explosive contents should be classified.
- C.** Radioactive materials greater than  $A_1/A_2$  quantity and live detonators with mock HE should be packaged in accordance with 10 CFR 71 or equivalent criteria, and an OTC/OTA should be issued on a case-by-case basis by DOE/NNSA Certifying Official.
- D.** Radioactive materials less than  $A_1/A_2$  quantity with HE should be shipped in accordance with 49 CFR performance based packaging criteria under an OTA.
- E.** Hazardous components other than the DOT Class 1, Division 1.1 explosives (49 CFR 173.50) with depleted uranium should be transported in accordance with 49 CFR.

#### **3.3 Pre-Packaging/Shipment Determinations and Document Requirements**

Upon determination of the need for packaging/shipment of NNSA nuclear weapon components, Category I and II SNM, nuclear weapon program special assemblies, and other materials of national security interest containing RAM, the DOE/NNSA contractor (customer) determines whether the quantity of RAM should be categorized as a Type A or Type B quantity.

After the quantity of RAM is determined, the customer uses that information to determine which of the following processes described in the Sections 3.4 and [3.5](#) is applicable.

### **3.4 Type A Quantity RAM**

#### **3.4.1 DOT Compliant Shipments**

For shipments that contain a Type A quantity of RAM and are otherwise 49 CFR compliant, the Site/Contractor may make shipments of Type A packaging in compliance with the Department of Transportation regulations.

#### **3.4.2 Type AF Package Certified by United Kingdom Ministry of Defence (UK MOD) Transported in TSS**

The Weapon System Program Manager shall submit a request to PCD and OST for authorization to transport Type AF package UK MOD in the TSS. The PCD Manager shall assign a CE or TSRP to evaluate the proposed UK MOD Type AF package's compliance with 10 CFR 71 and 49 CFR 173 requirements, and to assess the adequacy of the UK MOD's safety documentation and the package by conducting or managing an independent confirmatory technical assessment . This review shall consist of validation of the proper use of the packaging for the application intended. The PCD shall assure that the proposed configuration is within maintenance and serviceability dates, and can be delivered within prescribed deadlines. Review of DOE/NNSA users operating procedures are completed in accordance to work process defined for US origin Type A packaging designs. The CE shall also work with OST to ensure that the package is compatible with TSS equipment and the tiedown procedures are contained in TP 45-51D, DOE Tiedown Manuals or approved in a separate correspondence from OST to PCD before an OTC/OTA is issued.

#### **3.4.4 Shipment of Nuclear Weapon Special Assemblies that contain less than Type B quantity of RAM or no RAM**

The shipper and receiver must be in the possession of the current version of the OTA whose authorized content matches the content of the special assembly proposed for off site shipment; or, must submit a request for an OTA supported by a HAR, and wait until the OTA is issued before making the shipment. See [Appendix B](#) for guidance developing the HAR.

### **3.5 Type B Quantity RAM**

Shipments that contain a Type B quantity of RAM must be packaged and shipped in:

- A.** Type B packaging certified under a DOE/NNSA OTC (see [Section 3.5.1](#));
- B.** Packaging or weapon handling gear specified in an OTA, (see [Section 3.5.4](#), as applicable);

- C. Type B packaging certified under a DOE certificate of compliance (CofC), (see [Section 3.5.5](#));
- D. Type B packaging certified under an NRC or International Atomic Energy Agency (IAEA)/DOT certificate of competent authority (CofCA), (see [Section 3.5.6](#)); or,
- E. Type B packaging certified under a UK MOD certificate (see [Section 3.5.7](#)).

### 3.5.1 Type B Packaging Certified Under an DOE/NNSA OTC

- A. The Site working with the Packaging Line Manager identify Type B quantity RAM and agree that the material must be shipped offsite. Initial Certification: The SARP owner/applicant should comply with the responsibilities listed in [Sections 2.2.8](#) and [2.2.12](#) for taking a proposed Type B package through the initial certification process.
- B. Applying for Recertification and/or Approval of Modifications for NNSA Previously Certified Type B Packages: The SARP owner should use the protocol provided in [Section 3.5.3](#) when applying for a recertification and/or an approval of a modification of a NNSA previously certified Type B package.
- C. Refer to [Appendix A Section 3.1](#) for details on the SARP review and approval process and timelines.
- D. Use the following joint checklist to ensure that all the principles (i.e., applicant, PCD and line Management) are exchanging information needed to support a packaging and/or offsite transportation authorization project:

<b>Joint PCD Certification Engineer, Site POC and Packaging Line Manager Packaging Project Checklist</b>			
<b>WARNING: All of the information on this data sheet must be unclassified.</b>			
Action	Due Date	Information Provided	Action Owner
<b>OTC or OTA Number Assigned</b> (When PCD starts work on the project.)			PCD
<b>PCD CE</b> assigned (Name, Phone Number and e-mail address)			PCD
<b>Site POC</b> (Name, Phone number and e-mail address)			Site in coordination with the NNSA Packaging Line Manager
<b>NNSA Line Management POC</b> (Name, Phone Number and e-mail address)			NNSA Packaging Line Manager
<b>Site</b> (LANL, LLNL, SNL/NM, SNL/CA, etc) & <b>Project Identifier</b> if Assigned			Site in coordination with the NNSA Packaging Line Manager
<b>On-site Location of Material</b>			Site in coordination with the NNSA Packaging Line Manager
<b>Provide Security Classification Level of Material and identify the Security Guide that specifies the material's security classification level.</b>			Site in coordination with the NNSA Packaging Line Manager

<b>Joint PCD Certification Engineer, Site POC and Packaging Line Manager Packaging Project Checklist</b>			
<b>WARNING: All of the information on this data sheet must be unclassified.</b>			
Action	Due Date	Information Provided	Action Owner
<b>A. OTC/Shipping need date</b>			Site in coordination with the NNSA Packaging Line Manager
<b>B. Proposed Destination</b>			Site in coordination with the NNSA Packaging Line Manager
<b>Work with SARP/TSRA Owner &amp; PCD to Determine Documentation Required</b> (Using proposed specific content(s)' chemical and physical properties, isotopic characterization and activity, A <sub>2</sub> s, thermal properties/decay heat/wattage, criticality potential, and three-dimensional volume and weight in the proposed shipping configuration(s) and the candidate Packages' SARPs.			Site in coordination with the NNSA Packaging Line Manager
<b>Identify Candidate Packaging</b>			SARP/TSRA Owner & NNSA Packaging manager in coordination with PCD
<b>If OTC, Determine whether SARP or SARP Addendum is appropriate</b>			SARP Owner in coordination with PCD
<b>Establish a formal agreement, with the SARP/TSRA owner that documents the project's actions and milestones.</b>			Site in coordination with the NNSA Packaging Line Manager
<b>Draft SARP/SARP Addendum/TSRA Submitted</b>			SARP/TSRA Owner (Y-12, LANL, LLNL, etc.)
<b>SARP/TSRA Review</b>			PCD
<b>Review SARP/SARP Addendum/TSRA &amp; prepare &amp; submit comments to the TSRP chairman</b>			TSRP
<b>Perform Confirmatory Analysis</b>			Confirmatory organization under the direction of PCD
<b>Consolidate comments and distribute to TSRP members and the SARP/TSRA Owner</b>			TSRP Chairman
<b>TSRP &amp; Applicant meet to discuss draft Q<sub>0</sub>s (comments)</b>			TSRP & SARP/TSRA Owner
<b>Finalize and issue Q<sub>0</sub></b>			TSRP Chairman
<b>Complete confirmatory Analysis &amp; submit comments to SARP/TSRA owner</b>			Confirmatory organization under the direction of PCD
<b>Develop and issue confirmatory report</b>			Confirmatory organization under the direction of PCD
<b>Prepare &amp; submit Q<sub>0</sub> Responses to TSRP</b>			SARP/TSRA Owner (Y-12, LANL, LLNL, etc.)
<b>Review Q<sub>0</sub> responses, &amp; prepare &amp; submit Q<sub>1</sub> comments which include confirmatory comments</b>			TSRP
<b>Review Q<sub>1</sub> comments &amp; prepare &amp; submit responses</b>			SARP/TSRA Owner
<b>Close out comments &amp; approve SARP/SARP Addendum/TSRA</b>			Service Center
<b>Complete and distributes approved SARP/SARP Addendum/TSRA</b>			SARP/TSRA owner
<b>Complete &amp; distribute OTC/OTA, SER and transmittal letter</b>			Service Center

<b>Joint PCD Certification Engineer, Site POC and Packaging Line Manager Packaging Project Checklist</b>			
<b>WARNING: All of the information on this data sheet must be unclassified.</b>			
Action	Due Date	Information Provided	Action Owner
For OTC, Prepare Draft Packaging Procedures & Submit to PCD for approval			Prospective Package Users
For OTC, Submit QAP that meets 10 CFR 71 Subpart H requirements to PCD for Approval			Prospective Package Users
For OTC, Publish & disseminate copies of the approved packaging procedures & QAP.			Prospective Package Users
For OTC, Approve Site Packaging Procedures & QAP & add the organization as an authorized user of the package on the PCD Web Site			PCD
Close out data sheet & remove hyperlink		NA	PCD

### 3.5.1.1 Actions Required of Prospective Package Users

Prospective users of Type B packagings must verify the following prior to any use of a packaging to package any Type B quantity of RAM for off-site shipment:

- A.** The specific package (packaging and content) is certified under a current OTC; and,
- B.** The prospective user (Site/Contractor) is an authorized user of the package; and has:
  1. Current copies of the SARP, OTC and SER;
  2. DOE/NNSA approved packaging procedures for the specific package;
  3. DOE/NNSA approved QAPP; and,
  4. Personnel that are trained and qualified to perform the applicable packaging and associated shipping functions.

Once the prospective user has verified all of the items listed above, the user is authorized to prepare the package for shipment and to ship the package via the transportation conveyance(s) authorized in the OTC.

### 3.5.1.2 How to Become an Authorized User of a Currently Certified Package

The applicant is not an Authorized User for the Package, and/or does not have one or any of the items listed in [3.5.1.1B\(1\) through \(4\)](#). In this situation, the applicant must apply to PCD for and be approved as an authorized user of the package and have the items listed in [3.5.1.1B\(1\) through \(4\)](#) in place before that applicant can be authorized to use the package.

### 3.5.1.3 Process for Qualifying Tritium Reservoirs for Packaging and Shipping in the H1616-1 and the H1616-2 Without Getter

- A.** Applicant must evaluate the tritium reservoir proposed for shipment as outlined in the current issue of Sandia Specification *Reservoir Qualification AL-SX (H1616)(U)*, SS393217.

- B. Applicant must submit reservoir qualification report that documents the evaluation of the reservoir proposed for shipment. The report must be prepared in the format specified in SS393217.
- C. The PCD reviews the reservoir qualification report and provides Qs to applicant based on the results of the review.
- D. Applicant provides responses to Qs that include proposed verbatim changes to the reservoir qualification report.
- E. Applicant and PCD achieve consensus on Qs and responses and PCD approves qualification report. If applicant and PCD are unable to achieve consensus, DOE/NNSA Service Center notifies the applicant, applicable Weapon System Program Manager, and DOE/NNSA management that the review was terminated.
- F. Applicant publishes and distributes the PCD-approved reservoir qualification report.
- G. The PCD directs the Sandia National Laboratories to add the newly qualified reservoir to the H1616-1 and H1616-2 Without Getter section of the Shipping Configuration Index, H1616 Container (U), SC395685.
- H. Sandia National Laboratories updates and distributes the revised SC395685.
- I. Authorized users of the H1616 use the updated SC395685 as their authorization to package and ship the qualified reservoir in the H1616-1 or the H1616-2 without getter.

**3.5.1.4 Process for Getting Authorization to Package and Ship Unqualified or Suspect Tritium Reservoirs in the H1616-2 With Getter**

- A. A unqualified reservoir is a reservoir that has not been approved as qualified by the PCD in accordance with the SS393217 defined process, and therefore is not listed in the H1616-1 and H1616-2 Without Getter section of the Shipping Configuration Index, H1616 Container (U), SC395685. A suspect reservoir is a reservoir that has been approved as qualified by the PCD in accordance with the SS393217 defined process, but which the current custodian of the reservoir has determined that the reservoir may not meet the SS393217 requirements and/or could present a safety hazard to the workers, the public and/or the environment.
- B. Notify Sandia National Laboratories California (H1616 SARP Owner) and PCD about situation concerning the reservoir.
- C. Prepare and submit a request for authorization to package and ship the reservoir in the H1616-2 with getter and submit it to the PCD with a copy to Sandia National Laboratories California. In addition to the reservoir information described in SS393217 Section 4.3, the request should, at a minimum, provide the following additional information:
  - 1. For Unqualified Reservoirs the applicant must follow the process prescribed in [Section 3.5.1.3](#) above with the following modification:
    - a. Identify the SS393217 requirements that the reservoir proposed for shipment is unable to comply with and why;
    - b. Provide proof that the safety issues that could result from this reservoir being packaged and shipped offsite have been mitigated;
    - c. Provide any other supporting information, data and/or analysis requested by the Sandia National Laboratories and/or the PCD.
  - 2. For Suspect Reservoirs, the applicant must provide the following:
    - a. Detailed information on the condition of the reservoir and why it is suspect;

- b. How the consequences associated with the failure of the suspect safety features of the reservoir will be mitigated during packaging and/or offsite shipment;
- c. Provide any other supporting information, data and/or analysis requested by the Sandia National Laboratories and/or the PCD.
- D. Sandia National Laboratories shall review the information/data provided by the applicant, perform any required analysis and provide their recommendations to the PCD.
- E. The PCD in consultation with the Sandia National Laboratories shall develop a recommendation on this issue for presentation to the DOE/NNSA Certifying Official and upper DOE/NNSA management.
- F. If the packaging and offsite transportation of an unqualified or suspect tritium reservoir is approved by the DOE/NNSA Certifying Official and/or upper DOE/NNSA management, the PCD shall prepare and distribute the correspondence to notify all concerned about the decision and to provide the applicable implementing instructions.

### **3.5.2 Process Options for Packages Not Currently Certified**

- A. The package is not a certified Type B package, but the applicant believes that the package can be certified. In this situation, the applicant must develop a draft SARP using the format provided in [Appendix B](#), a completed SG 200 SARP Completeness Review Checklist and other supporting documents and submit copies to the individuals listed on a list provided by PCD and one copy to the Package Line Manager not later than nine months prior to the OTC need date.
- B. The package is not certified and cannot be shown to meet the letter of the requirements of 10 CFR 71 or 49 CFR 173. In this situation, the applicant must apply to PCD for an OTA by submitting an application that is supported by a SARP and supporting documents, and a TSRA for review and consideration not later than nine months prior to the OTC need date. The applicant must provide copies of the SARP, TSRA and supporting documents to the individuals listed on a list provided by PCD and one copy to the Package Line Manager. See Appendix B for guidance for developing TSRAs for these packages.
- C. The package is not certified and cannot be shown to meet the requirements of 10 CFR 71 or 49 CFR 173, but must still be shipped in the interest of national security. In this situation, the applicant can apply to NA-10 via its management chain, and PCD.

### **3.5.3 -Applying for and Processing Recertification and/or Modification Applications for NNSA Previously Certified Type B Packages**

NNSA previously certified packages proposed for recertification and/or modification must satisfy the current 10 CFR 71 and 49 CFR 100-185 requirements, or if they cannot satisfy the current 10 CFR 71 and 49 CFR 100-185 requirements they must satisfy the previous 10 CFR 71 and 49 CFR 100-185

requirements in accordance with the provisions contained in the 10 CFR 71 section titled *Previously approved packages*.

- A.** If the package's certification has expired and the packaging is determined to be a viable candidate for return to service, the SARP owner should proceed to [Section 3.5.3.1](#). If the package's certification has not expired the SARP owner should continue the process in this section.
- B.** If the package is not being modified but must be recertified because its certification period is due to expire and the package is still needed to support the Department's mission, the SARP owner should proceed to [Section 3.5.3.2](#). If the package is being modified, the SARP owner should continue the process in this section.
- C.** If the modification involves a proposed change in the approved content and not a design change, the SARP owner should proceed to SG 500 [Section 3.5.3.3](#). If the modification involves a design change, the SARP owner should continue the process in this section.
- D.** The SARP owner should determine whether the design change is significant with respect to the design, operating characteristics, or safe performance of the containment system, when the package is subject to the tests specified in 10CFR71.71 and 10CFR71.73. If the SARP owner determines that the design change is significant, the SARP owner should proceed to [Section 3.5.3.4](#). If the SARP owner determines that the design change is not significant, the SARP owner should continue the process in this section.
- E.** The SARP owner should develop an application that contains the following:
  - 1. a detailed explanation of the proposed design change;
  - 2. the analysis used to verify that the determination that the design change with respect to the design, operating characteristics, or safe performance of the containment system, when the package is subject to the tests specified in 10CFR71.71 and 10CFR71.73 is not significant; and,
  - 3. a detailed plan for implementing the design change that includes the quality assurance process that will be used to ensure that the package continues to comply with 10CFR Subpart H and other quality assurance requirements.

The SARP owner should submit the application to PCD for review and approval.

- F.** The PCD will review the application, and based on the results of the review will notify the SARP owner via a memorandum that PCD:
  - 1. approves the design change and implementation plan; or,
  - 2. approves the design change, but does not approve the implementation plan. In this case, the PCD should provide comments on the implementation plan. The SARP owner should rework the implementation plan based on the guidance provided in the PCD comments, and resubmit the revised plan to

- PCD for approval. PCD approves the design change and implementation plan once PCD and the SARP owner reach consensus; or,
3. determined that the design change is significant and directs the SARP owner to use the process specified in [Section 3.5.3.4](#).

### **3.5.3.1 Process for Applying and Processing Applications for Returning Previously Certified Type B Packages to Service**

The SARP owner supported by the Sites(s) that need to make the shipment(s), performs an assessment to confirm that the previously certified NNSA packaging is a viable candidate for recertification and documents the results. The SARP owner submits the resultant documents to PCD for review and concurrence. If PCD determines that the candidate packaging is viable, and:

1. if the previously certified package does not need to be modified and the proposed contents are identical to or bounded by the previously certified package's authorized content it advises the SARP owner to proceed to [Section 3.5.3.2](#); or,
2. if the package must be modified it advises the SARP owner to proceed to [Section 3.5.3.C](#).

### **3.5.3.2 Process for Applying for and Processing Applications for Recertifying Currently Certified Type B Packages with no Modifications**

Prepare a revised SARP, Supplemental Report, completed SG 200 SARP Completeness Review Checklist and other supporting documents, and submit them not later than 26 workweeks prior to OTC renewal need date to the individuals on a list provided by PCD. Refer to [Appendix B](#) for guidance on preparing the SARP and Supplemental Report. Refer to [Appendix A Section 3.2](#) for the recertification review and approval process sequence and timelines.

### **3.5.3.3 Process for Applying and Processing Applications for Adding New Content to a Currently Certified Type B Package**

This section is designed to guide the key participants through the process of screening DOE/NNSA currently certified Type B packages for candidate packaging(s) that might be suitable for packaging and shipping Type B quantities of RAM (hereafter called specific content(s)), preparing and submitting documents for approval of the new proposed package, and the processing of these requests. [Section 3.5.3.3.1](#) describes the process, in the prescribed chronological sequence, that should be used by the key participants, and [Section 3.5.3.3.2](#) contains checklists that are designed to assist the key participants ([applicant](#), DOE/NNSA [line management](#), [SARP owners](#), [other prospective package users](#), DOE/NNSA [Deputy Administrator for Defense Programs](#), [PCD](#), DOE/NNSA [Certifying Official](#), and [Federal Site Managers](#)) through this process.

### 3.5.3.3.1 Process Description Listed in Process Sequence-

The DOE/NNSA line management, and the site (hereafter called applicant) at which an item that contains a Type B quantity of RAM (hereafter called specific content(s)) is located determine that the specific content must to shipped off site.

The applicant determines and documents all of the pertinent information such as the proposed specific content(s)' chemical and physical properties, isotopic characterization and activity,  $A_{2s}$ , thermal properties/decay heat/wattage, criticality potential, and three-dimensional volume and weight in the proposed shipping configuration(s).

The applicant identifies the security classification level of the proposed specific content(s), the security guide that specifies the proposed specific content(s)' security classification level, and the projected shipping need date.

The applicant, assisted by DOE/NNSA line management, screens DOE/NNSA currently certified Type B packages to identify possible candidate packaging(s) for this application based on the dimensions of the proposed specific content(s) and the dimensions of the packaging(s) of currently certified package(s). If no candidate packaging is identified during this screening, the screening process will be terminated and the applicant and DOE/NNSA line management can pursue the design, development, certification and procurement of a new package. If candidate packaging(s) are identified, the screening should continue, and the applicant should determine if the site has a copy of the SARP(s) for the candidate packaging(s).

For those candidate packaging(s) that the applicant has a copy of the approved SARP, the applicant should compare the proposed specific content(s)' chemical and physical properties, isotopic characterization and activity,  $A_{2s}$ , thermal properties/decay heat/wattage and criticality potential, and three-dimensional volume and weight in the proposed shipping configuration(s) to the capabilities of the candidate packaging(s) to further refine the list of possible candidate packaging(s). Once the applicant refines the list of candidate packaging(s), the applicant should contact the owner(s) of the SARP(s) of the candidate packaging(s) on the refined list with a request that the SARP owner(s) assess the feasibility of packaging the proposed specific content(s) in packaging(s) covered by their SARP(s). The request should be supported by a data package that includes the proposed specific content(s)' chemical and physical properties, isotopic characterization and activity,  $A_{2s}$ , thermal properties/wattage and criticality potential and three-dimensional volume and weight in the proposed shipping configuration(s).

For those candidate packaging(s) that the applicant does not has a copy of the approved SARP(s), the applicant should contact the owner of the SARP(s) to request that the SARP owner(s) assess the feasibility of packaging the proposed

specific contents in packaging covered by their SARP(s). The request shall be supported by a data package that includes the proposed specific content(s)' chemical and physical properties, isotopic characterization and activity,  $A_{2s}$ , thermal properties/decay heat/wattage, criticality potential, and three-dimensional volume, and weight in the proposed shipping configuration(s).

The SARP owner(s) contacted shall review the applicant's request(s) using the data package provided by the applicant and the applicable approved SARP. Once the review and associated analysis are completed, the results will be provided to the applicant and PCD.

The applicant, using the information provided in the SARP owner(s) response(s) and the requirements of 10 CFR 71 Section titled *Previously approved package*, and in consultation with the SARP owner(s), selects the best possible packaging candidate for the proposed application, or determines that there is no packaging candidate that can meet the needs of the proposed application. The screening should be terminated if no candidate packaging, that can meet the needs of this application, is identified.

If a candidate package is identified, the applicant, DOE/NNSA line management, and the SARP owner of the candidate packaging should work together to provide/identify the funding and to develop the schedule needed to continue the screening process, and the DOE/NNSA line management authorizes the SARP owner to begin the follow-on screening process.

The SARP owner's initial task should include analytical work that can be used to assess the candidate package's (candidate packaging with proposed content(s)) viability for the proposed application. This analytical work should include analysis on the candidate package's criticality per 10 CFR 71, and shielding (or actual proposed content(s) dose rate measurements which can be used to determine that shielding is not an issue), and structural viability. The structural analysis should be a complete analysis, or at a minimum, should be sufficiently comprehensive to prove that the proposed configuration(s) is bounded by the candidate packaging's currently approved configuration(s). The SARP owner should document this analytical work and submit a copy of the documentation to the applicant and PCD.

The applicant, concurrent with the SARP owner's submission of the results of their criticality, shielding and structural analytical work, should submit the proposed specific content(s)' chemical and physical properties, isotopic characterization and activity,  $A_{2s}$ , thermal properties/decay heat/wattage, criticality potential, and three-dimensional volume, and weight in the proposed shipping configuration(s), and proposed shipping campaign information to the PCD.

The PCD, using the information provided by the SARP owner and the applicant, will assess the viability of the candidate package. If the PCD determines that the candidate package is not a viable candidate for certification, the applicant and SARP owner should terminate the screening process, but the applicant still has the option of pursuing the development, certification and procurement of a new package, or of developing and submitting a request for a DOE/NNSA Deputy Administrator for Defense Programs exemption (addressed later in this process). If the PCD determines that the candidate package is a viable candidate for certification, the PCD should determine whether the application for certification of the candidate package should be supported by a SARP or a SARP addendum, and should inform the SARP owner and applicant of the determination.

The applicant, SARP owner and DOE/NNSA line management should establish a formal agreement that documents the agreed to actions and milestones for each participant, and the data and other resources that the applicant and/or DOE/NNSA line management will provide to the SARP effort.

The applicant and/or DOE/NNSA line management should provide the additional resources to the SARP owner before the SARP owner will commence the work stipulated in the formal agreement.

The SARP owner performs the tasks required to support the development of a draft SARP/SARP addendum and associated documents, develops the draft SARP/SARP addendum and associated documents that complies with the applicable requirements of 10 CFR 71 and 49 CFR 100-185, as specified in DOE Order 461.1A (See the protocol that is provided in [Appendix B.](#)), and submits the SARP/SARP addendum and associated documents to the PCD for review. The SARP owner shall keep the PCD informed of the project status, project delays and/or any project difficulties.

The PCD performs a review and confirmatory analysis (hereafter called review) of the SARP/SARP addendum and associated documents and provides comments to the SARP owner, as specified in [Sections 2.2.3](#), [2.2.3.1](#), and [Appendix A](#). The PCD will keep the DOE/NNSA Certifying Official informed of project status, project delays and/or any project difficulties. The SARP owner performs the SARP/SARP addendum review process activities specified in [Section 2.2.8](#).

The applicant and other prospective package users begin the development of their packaging quality assurance plans that comply with the requirements of 10 CFR 71 Subpart H, and begin their review and, if required, revision of their Site's quality assurance plan.

The PCD, through its SARP/SARP addendum review, and responses from the SARP owner determines that the proposed package meets or doesn't meet the applicable 10 CFR 71/49 CFR 100-185 requirements and can or cannot be

certified. If PCD determines that the proposed package can be certified, proceed to Section A. If PCD determines that the proposed package cannot be certified, proceed to [Section B](#).

#### **A. Proposed Package Can Be Certified**

If the PCD determines that the proposed new package meets the applicable 10 CFR 71 and 49 CFR 100-185 requirements and can be certified:

1. The PCD and the SARP owner resolve all of the draft SARP/SARP addendum review comments, and the PCD approves the draft SARP/SARP addendum.
2. The applicant and prospective users submit their draft packaging quality assurance plans that comply with the requirements of 10 CFR 71 Subpart H to the PCD for review and approval.
3. The PCD reviews the draft packaging quality assurance plans to verify their compliance with 10 CFR 71 Subpart H, and approves the plans that comply with 10 CFR 71 Subpart H.
4. The SARP owner publishes and distributes the final (approved) SARP/SARP addendum to the PCD, applicant and other prospective package users. If the PCD and the SARP owner are unable to resolve the SARP/SARP addendum review comments, the issues will be presented to DOE/NNSA upper management for resolution.
5. The applicant and prospective users publish and distribute the packaging quality assurance plans that comply with 10 CFR 71 Subpart H.
6. The PCD develops additional, if applicable, packaging and shipping restrictions for inclusion in the OTC and communicates them to the applicant and other prospective package users.
7. The applicant and other prospective users start the development of the draft packaging procedures. The packaging procedures are based on the SARP/SARP addendum and OTC restrictions.
8. The PCD follows the applicable portions of [Sections 2.2.3](#) and [2.2.3.1](#), and Appendix C to develop a draft OTC, SER and distribution memorandum and submits them to the DOE/NNSA Certifying Official for approval.
9. The DOE/NNSA Certifying Official certifies or doesn't certify the candidate package as specified in [Section 2.2.2](#).
  - a. If the DOE/NNSA Certifying Official disapproves the certification of the new package the PCD Certification Engineer shall proceed as specified in [Section 2.2.3.1.B.4\(c\)\(4\)](#).
  - b. If the DOE/NNSA Certifying Official certifies the new package the process continues.
10. The PCD distributes copies of the new OTC, SER and associated distribution memorandum to DOE/NNSA headquarters, Office of Secure Transportation, applicant, and other authorized package users.
11. The applicant and other prospective users submit their draft packaging procedures and their Site quality assurance plans to the PCD for review and

approval, and support the review/approval process as specified in [Section 2.2.14.L.3](#).

12. The PCD processes the draft packaging procedures and Sites' quality assurance plans as specified in [Section 2.2.3.1](#).
13. The PCD identifies the approved package users by updating the DOE/NNSA OTA/OTC Web Page.
14. The applicant and other prospective users check the DOE/NNSA OTA/OTC Web Page to verify that their Site is designated an approved user of the package. If the Web Site does not list their Site as an approved user of the package, they should contact the PCD for resolution.
15. The Federal Site Managers shall provide oversight of the packaging and off-site transportation associated activities at their site.
16. The authorized users of the newly certified package:
  - a. May commence packaging operations with the newly certified package as prescribed in SARP/SARP addendum, OTC, and SER.
  - b. May submit a transportation services request to the Office of Secure Transportation, in accordance to their prescribed format, to request and schedule off-site transportation services.
  - c. May commence shipping operations as prescribed in SARP/SARP addendum, OTC, and SER.
17. The SARP owner must ensure that when the SARP is revised for package recertification, the new SARP includes this new content(s), if there is still a need to ship these new content(s).

## **B. Proposed Package Cannot Be Certified**

The DOE/NNSA Service Center determines that the proposed new package does not meet the applicable 10 CFR 71/49 CFR 100-185 requirements as specified in DOE Order 461.1A and cannot be certified.

1. The PCD notifies the applicant, SARP owner and applicable DOE/NNSA line managers of the determination.
2. If the specified content(s) still needs to be shipped off site, the applicant, under the direction of applicable DOE/NNSA line management, must determine whether to initiate a request for the design of a new Type B package that will meet this need, or whether the applicant should request an exemption from the requirements of DOE Order 461.1A from the DOE/NNSA Deputy Administrator for Defense Programs.
3. If the decision is made to request an exemption from the DOE/NNSA Deputy Administrator for Defense Programs, the applicant must prepare the exemption request. The exemption request must include evidence that indicates that the proposed shipment is not prohibited by law, and a technical analysis that supports a conclusion that the packaging and transportation operations of the proposed package do not present an undue risk to the public health and safety, the environment, or workers. The exemption request should be submitted via the applicant's contractor and Federal Site management, and the DOE/NNSA Service Center for their technical review

and recommendations for approval/disapproval. The Federal Site Managers and DOE/NNSA Service Center must review the exemption request and provide their recommendations for approval/disapproval to the DOE/NNSA Deputy Administrator for Defense Programs.

4. The DOE/NNSA Deputy Administrator for Defense Programs reviews the exemption request, and based on the results of its review of the analysis and documentation provided in the request, its own independent analysis, the exemption criteria of DOE Order 461.1A, and the recommendations provided by the other exemption request reviewers, grants or denies the exemption request.
  - a. If the DOE/NNSA Deputy Administrator for Defense Programs denies the exemption request, the correspondence which communicates the DOE/NNSA Deputy Administrator for Defense Programs' denial of the exemption should indicate whether the exemption request would be reconsidered if additional information/data were provided or whether the applicant should seek another solution for packaging the proposed content(s) (i.e., initiate a new packaging design).
  - b. If the DOE/NNSA Deputy Administrator for Defense Programs grants the exemption request, the correspondence that announces the granting of the exemption may include exemption implementing instructions, if applicable. The DOE/NNSA Deputy Administrator for Defense Programs shall address the correspondence to the Federal Site Manager of the applicant's Site and provide copies to the applicant, the DOE/NNSA Service Center Manager, and all other organizations to which the exemption applies.
    - (1) The applicant, the applicant's Federal Site Managers and any other organization to which a DOE/NNSA Deputy Administrator for Defense Programs exemption is granted shall comply with the exemption and its implementing instructions.
    - (2) The Federal Site Managers must ensure that the applicable contractors under their cognizance comply with the requirements of the DOE/NNSA Deputy Administrator for Defense Programs exemption and its implementing instructions.
    - (3) The PCD and the SARP owner reach consensus on all SARP/SARP addendum comments.
    - (4) The applicant and prospective users work with PCD to get their approval for the packaging quality assurance plans' format and content, and submit the packaging quality assurance plans to PCD for approval.
    - (5) The PCD reviews the draft packaging quality assurance plans and approves, as applicable.
    - (6) Applicant and prospective users publish and distribute their approved packaging quality assurance plans.
    - (7) The PCD approves the draft SARP/SARP addendum, and the SARP owner publishes and distributes the final SARP/SARP addendum.

- (8) The PCD provides a list of the restrictions that will be imposed, via the OTA, on this package's packaging and shipping operations to the applicant and other prospective user(s).
- (9) The applicant/other prospective package users develop draft packaging procedures and Site quality assurance plans based on the final SARP/SARP addendum, DOE/NNSA Deputy Administrator for Defense Programs exemption and packaging and shipping restrictions contained in the OTA, and submits them to the PCD for review and approval.
- (10) The PCD processes the draft packaging procedures and quality assurance plans as specified in [Section 2.2.3.1](#).
- (11) The PCD uses the final DOE/NNSA Deputy Administrator for Defense Programs exemption and approved SARP/SARP addendum to develop a draft OTA, SER and distribution memorandum and submits them to the DOE/NNSA Certifying Official for approval.
- (12) The DOE/NNSA Certifying Official processes the draft SER, OTA and distribution memorandum as specified in [Section 2.2.2.B.4](#).
- (13) The PCD distributes the new OTA, SER and distribution memorandum, and updates the DOE/NNSA OTA/OTC Web Page.
- (14) The applicant's Federal Site Manager is the final authority for authorizing the shipment. Therefore, no packaging or transportation, with this packaging, may commence until the applicant's Federal Site Manager authorizes the packaging/shipment.
  - (a) Disapproves the proposed packaging and shipment and advises the applicant on how to proceed, and the DOE/NNSA Deputy Administrator for Defense Programs, PCD, and other prospective users of the decision; or,
  - (b) Authorizes the packaging and transportation to commence.
- (15) The authorized users of this packaging may commence packaging operations with this packaging as prescribed in SARP/SARP addendum, OTA, and SER, DOE/NNSA Deputy Administrator for Defense Programs exemption, and restrictions and/or guidance provided by the applicant's Federal Site Manager.
- (16) Authorized users of this packaging may submit a transportation services request to the Office of Secure Transportation, in accordance to their prescribed format, to request and schedule off-site transportation services.
- (17) Authorized users of this packaging may commence shipping operations as prescribed in SARP/SARP addendum, OTA, SER, DOE/NNSA Deputy Administrator for Defense Programs exemption, and restrictions and/or guidance provided by the applicant's Federal Site Manager.

### 3.5.3.3.2 Process Checklists

<b>Applicant's Checklist</b>		
Process for Getting Approval for Adding New Content to a DOE/NNSA Currently Certified Type B Package		
<b>Step</b>	<b>Activity</b>	<b>Completion Date</b>
1	Identifies item containing a Type B quantity of RAM and works with DOE/NNSA line management to determine whether the item must be shipped off site. If the determination indicates that the item must be shipped off site, this process should continue. Otherwise the process should end.	
2	Determines and documents all of the pertinent information such as the proposed specific content(s)' chemical and physical properties, isotopic characterization and activity, $A_2s$ , thermal properties/decay heat/wattage, criticality potential, and three-dimensional volume and weight in the proposed shipping configuration(s).	
3	Identifies the security classification level of the proposed specific content(s), the security guide that specifies the proposed specific content(s)' security classification level, and the projected shipping need date.	
4	Screens DOE/NNSA currently certified Type B packages to identify possible candidate packaging(s) for this application based on the dimensions of the proposed specific content(s) and the dimensions of the candidate packaging(s) with the assistance of DOE/NNSA line management. If no candidate packaging is identified during this screening, the screening process will be terminated and the applicant and DOE/NNSA line management can pursue the design, development, certification and procurement of a new package. If candidate packaging(s) are identified, the screening should continue.	
5	Determines whether or not the site has a copy of the SARP(s) for the candidate packaging(s).	
5.a	If approved SARP(s) for those candidate packaging(s) are available, compare the proposed specific content(s)' chemical and physical properties, isotopic characterization and activity, $A_2s$ , thermal properties/decay heat/wattage, criticality potential, and three-dimensional volume and weight in the proposed configurations to the capabilities of the candidate packaging(s) to further refine the list of possible candidate packaging(s).	
5.b	If approved SARP(s) for candidate packaging(s) are not available, but the site still believes that the packaging(s) could be a viable candidate packaging(s), adds the packaging(s) to the refined list of possible candidate packaging(s).	
6	Develops request(s) that are supported by a data package that includes the proposed specific content(s)' chemical and physical properties, isotopic characterization and activity, $A_2s$ , thermal properties/wattage and criticality potential, and three-dimensional volume and weight in the proposed shipping configuration(s).	
7	Submits the request(s) to the SARP(s) owner(s) of the candidate packaging(s) requesting that the SARP owner(s) assess the feasibility of packaging the proposed specific content(s) in packaging(s) covered by their SARP(s).	

<b>Applicant's Checklist</b>		
Process for Getting Approval for Adding New Content to a DOE/NNSA Currently Certified Type B Package		
8	Reviews the results of the SARP owner(s)' assessment(s).	
9	Uses the information provided in the SARP owner(s) responses and the requirements in 10 CFR 71 Section titled <i>Previously approved package</i> , and consults with the SARP owner(s) to select the best possible packaging candidate or to determine that there is no viable packaging candidate for the proposed application. If no packaging candidate is identified, the screening process should end.	
10	Works with DOE/NNSA line management and the SARP owner of the candidate packaging to provide/identify the funding and schedule needed to continue the screening process.	
11	Submits the specific content(s)' chemical and physical properties, isotopic characterization and activity, $A_{2s}$ , thermal properties/decay heat/wattage, criticality potential, and three-dimensional volume and weight in the proposed shipping configuration(s), plus information on the proposed shipping campaign to PCD concurrently with the SARP owner's submission of the results of their criticality, shielding and structural analysis.	
12	Reviews the SARP owner(s)' submissions.	
13	When the PCD, after their review of the SARP owner's criticality, shielding and structural analysis, and the information provided by the SARP owner, determines that the candidate packaging is/isn't a viable candidate for certification:	
13.a	Terminates the screening process and pursues the development, certification and procurement of a new package, or develops and submits a request for a DOE/NNSA Deputy Administrator for Defense Programs exemption if PCD determines that the candidate packaging is not a viable certification candidate.	
13.b	Continues the screening process if PCD determines that the candidate packaging is a viable candidate for certification.	
14	Works with the SARP owner and DOE/NNSA line management to determine the need date for the certification of the new package, and determine the funding, data, and/or other resources needed by the SARP owner to revise the SARP or to develop a SARP addendum in support of this effort.	
15	Establishes a formal agreement, with the SARP owner and DOE/NNSA line management that documents the agreed to actions and milestones for each participant, and the resources that will be provided to the SARP owner.	
16	Works with DOE/NNSA line management to provide the additional resources to the SARP owner before the SARP owner commences the work stipulated in the formal agreement discussed immediately above.	
17	Supports the SARP owner during the SARP/SARP addendum development and approval process.	
18	Participates in draft SARP/SARP addendum comment resolution, as required by the formal agreement addressed in Step 15 above.	
19	Begins the development of their packaging quality assurance plans that comply with the requirements of 10 CFR 71 Subpart H, and begins their review and, if required, revision of their Site's quality assurance plan.	
20	If the PCD determines that the proposed package can be certified, the process may proceed to <a href="#">Step 23</a> . If the PCD determines that the proposed package cannot be certified, the process must proceed to <a href="#">Step 21</a> .	

<b>Applicant's Checklist</b>		
Process for Getting Approval for Adding New Content to a DOE/NNSA Currently Certified Type B Package		
21	Works with DOE/NNSA line to determine whether to initiate the design of a new Type B package that will meet this need, or whether to request an exemption from the requirements of DOE Order 461.1A from the DOE/NNSA Deputy Administrator for Defense Programs.	
22	Performs the following functions/activities if the decision is to pursue a DOE/NNSA Deputy Administrator for Defense Programs exemption:	
22.a	Prepares the exemption request. The exemption request must include evidence that indicates that the proposed shipment is not prohibited by law, and a technical analysis that supports a conclusion that the packaging and shipment of the proposed package do not present an undue risk to public health and safety, the environment, or workers.	
22.b	Submitted the request via the Site's contractor and federal management, and the DOE/NNSA Service Center Manager via PCD for their technical review and recommendations for approval/disapproval.	
22.c	<u>Do not proceed with any subsequent process steps unless</u> the DOE/NNSA Deputy Administrator for Defense Programs grants the exemption.	
23	Submits draft packaging quality assurance plan to the PCD for approval:	
23.a	For certified packages, the plan must comply with the requirements contained in 10 CFR 71 Subpart H in its entirety.	
23.b	For packaging authorized under a DOE/NNSA Deputy Administrator for Defense Programs grants the exemption, the plan format and content must be approved by the PCD.	
24	Ensures that the Site receives a copy of the new SARP/SARP addendum.	
25	Publishes and distributes the approved packaging quality assurance plan.	
26	Ensures that the Site receives a copy of restrictions that will be contained in the OTC/OTA from the PCD.	
27	Develops draft packaging procedures that are based on the SARP/SARP addendum and OTC/OTA restrictions, and if applicable the DOE/NNSA Deputy Administrator for Defense Programs exemption and restrictions and/or guidance provided by the applicant's Federal Site Manager.	
28	Submits the draft packaging procedures and the associated Site quality assurance plan to the PCD for review and approval, and supports the review process as specified in SG 500 <a href="#">Section 2.2.14.L.3</a> .	
29	Publishes and disseminates copies of the approved packaging procedures and Site quality assurance plan (if revisions are made).	
30	Ensures that the Site receives a copy of the new OTC/OTA and SER.	
31	Checks the DOE/NNSA OTA/OTC Web Page to verify that the Site is an authorized user for this package. Contacts the PCD if the Site is not listed as an authorized user of this package, but should be listed.	

<b>Applicant's Checklist</b>		
Process for Getting Approval for Adding New Content to a DOE/NNSA Currently Certified Type B Package		
32	Does not commence packaging operations that must be performed under a DOE/NNSA Deputy Administrator for Defense Programs exemption until the Site has implemented all of the requirements specified in the DOE/NNSA Deputy Administrator for Defense Programs exemption and the Federal Site Manger has authorized the Site to proceed with these operations.	
33	Commences packaging operations with the newly certified package or the packaging authorized under a DOE/NNSA Deputy Administrator for Defense Programs exemption, as applicable, using the approved packaging procedures, SARP/SARP addendum, OTC/OTA, SER, and if applicable the DOE/NNSA Deputy Administrator for Defense Programs exemption instructions and restrictions and/or guidance provided by the applicant's Federal Site Manager.	
34	Submits a transportation services request to the Office of Secure Transportation, in accordance to their prescribed format, to request and schedule off-site transportation services.	
35	Commences shipping operations as prescribed in SARP/SARP addendum, OTC/OTA, SER, and if applicable the DOE/NNSA Deputy Administrator for Defense Programs exemption instructions and restrictions and/or guidance provided by the applicant's Federal Site Manager.	

<b>DOE/NNSA Line Management's</b>		
<b>Step</b>	<b>Activity</b>	<b>Completion Date</b>
1	Works with site (applicant) to determine whether the item must be shipped off site. If the determination indicates that the item must be shipped off site, this process should continue. Otherwise the process should end.	
2	Assists the applicant in the screening of currently certified packages to identify possible candidate packaging(s) for this application based on the dimensions of the proposed specific content(s) and the dimensions of the packaging(s) of DOE/NNSA currently certified Type B package(s). If no candidate packaging is identified, the screening process should be terminated and a determination on whether the applicant should pursue the design, development, certification and procurement of a new package will be made. If candidate packaging(s) are identified, the screening can continue.	
3	Works with the applicant and the SARP owner of the candidate packaging to provide/identify the funding and to develop schedule needed by the SARP owner to perform the criticality, shielding and structural analysis.	
4	Authorizes the SARP owner to perform the criticality, shielding and structural analyses using the funding provided/identified in the step immediately above.	
5	Works with the SARP owner and applicant to establish a formal agreement that documents the agreed to actions and milestones for each participant, and the data and other resources that the applicant and/or DOE/NNSA line management will provide for the SARP effort.	
6	Provides the additional resources to the SARP owner before the SARP owner commences the formal work agreed to in the step immediately above.	
7	Assists the applicant pursue the design, development, certification and procurement of a new package after it has been determined that the content(s) still need to be shipped off site, and the packaging of a DOE/NNSA currently certified package can not be certified for this use, a request for a DOE/NNSA Deputy Administrator for Defense Programs exemption that would allow the use of an package that can not be certified has been denied, or the Federal Site Manager will not approve the proposed packaging and shipping operations after the DOE/NNSA Deputy Administrator for Defense Programs has granted an exemption	

<b>SARP Owner's Checklist</b>		
Process for Getting Approval for Adding New Content to a DOE/NNSA Currently Certified Type B Package		
<b>Step</b>	<b>Activity</b>	<b>Completion Date</b>
1	Complies with the applicant's initial screening request(s) by using the data package provided by the applicant and the applicable approved SARP, performing the applicable analysis, and providing the results to the applicant and PCD.	
2	Consults with the applicant as needed.	
3	Works with the applicant and DOE/NNSA line management to secure funding and to develop a schedule for any follow-on screening.	
4	Performs and documents analytical work that can be used to assess the candidate package's viability for the proposed application. This analytical work should include analysis on the candidate package's criticality per 10 CFR 71, and shielding (or actual proposed content(s) dose rate measurements which can be used to determine that shielding is not an issue), and structural viability. The structural analysis should be a complete analysis, or at a minimum, should be sufficiently comprehensive to prove that the proposed configuration(s) is bounded by the candidate packaging's currently approved configuration(s).	
5	Submits the results of the analytical work to the applicant and PCD, and continues or terminates the process based on guidance provided by the applicant and PCD.	
6	Establishes a formal agreement with the applicant that includes the actions and milestones that will be used to support the need date for the certification of the new package, and the funding, data, and/or other resources that will be provided to the SARP owner to revise the SARP or develop a SARP addendum in support of this effort.	
7	Receives the additional resources from the applicant and/or DOE/NNSA line management before commencing the work stipulated in the formal agreement.	
8	Performs the activities required to support the development of the new SARP or SARP addendum and associated documents.	
9	Develops a draft SARP/SARP addendum and associated documents.	
10	Submits the SARP/SARP addendum and associated documents to the PCD for review, and performs the SARP/SARP addendum review activities specified in SG 500 <a href="#">Section 2.2.8</a> .	
11	Proceeds to <a href="#">Step 13</a> once all of the comments are resolved, the PCD determines that the package meets the applicable 10 CFR 71 and 49 CFR 100-185 requirements, and approves the SARP/SARP addendum and associated documents, or continues to <a href="#">Step 12</a> if the PCD determines that the proposed package cannot be certified.	
12	Meets with the applicant to determine the path forward based on the formal agreement and resources available.	
13	Participates in the resolution of the SARP/SARP addendum and associated documents comments.	
14	Comes to consensus with the PCD on the SARP/SARP addendum and associated documents comments.	
15	Publishes and distributes the final (approved) SARP/SARP addendum to the PCD, applicant and other prospective package users.	

**SARP Owner's  
Checklist**

Process for Getting Approval for Adding New Content to a  
DOE/NNSA Currently Certified Type B Package

<b>Step</b>	<b>Activity</b>	<b>Completion Date</b>
16	Prior to the package's recertification, the SARP owner must ensure that the revised SARP includes this new content(s) if there is still a need to ship these new content(s) off site.	

<b>Other Prospective Package Users'</b>		
<b>Step</b>	<b>Activity</b>	<b>Completion Date</b>
1	Begin the development of their packaging quality assurance plan that complies with the requirements of 10 CFR 71 Subpart H, and their review, and, if required, revision of the Site's quality assurance plan.	
1.a	For certified packages, the packaging quality assurance plan must comply with all of the requirements of 10 CFR 71 Subpart H.	
1.b	For packaging authorized under a DOE/NNSA Deputy Administrator for Defense Programs exemption: work with PCD to get their approval for the packaging quality assurance plans' format and content. <u>Do not proceed with any subsequent process steps unless</u> the DOE/NNSA Deputy Administrator for Defense Programs grants the exemption.	
2	Submit their packaging quality assurance plan to PCD for approval.	
3	Ensure that the Site receives a copy of the SARP/SARP addendum, and the DOE/NNSA Deputy Administrator for Defense Programs exemption, if applicable.	
4	Publish and distribute the approved packaging quality assurance plan.	
5	Start the development of draft packaging procedures that are based on the SARP/SARP addendum, OTC/OTA restrictions, and the DOE/NNSA Deputy Administrator for Defense Programs exemption, if applicable.	
6	Submit the draft packaging procedures and the associated Site quality assurance plan to the PCD for review and approval, and supports the review process as specified in SG 500 <a href="#">Section 2.2.14.L.3</a> .	
7	Publish and disseminate copies of the approved packaging procedures and Site quality assurance plan (if revisions are made).	
8	Ensure that their Site receives a copy of the new OTC/OTA and SER.	
9	Check the DOE/NNSA OTA/OTC Web Page to verify that their Site is an authorized user for this package. Contact the PCD if their Site is not listed as an authorized user of this package, but should be listed.	
10	Do not commence packaging operations that must be performed under a DOE/NNSA Deputy Administrator for Defense Programs exemption until their Site has implemented all of the requirements specified in the DOE/NNSA Deputy Administrator for Defense Programs exemption and the Federal Site Manager has authorized their Site to proceed with these operations.	
11	Commence packaging operations with the newly certified package or the packaging authorized under a DOE/NNSA Deputy Administrator for Defense Programs exemption, as applicable, using the approved packaging procedures, SARP/SARP addendum, OTC/OTA, SER, and if applicable the DOE/NNSA Deputy Administrator for Defense Programs exemption instructions and restrictions and/or guidance provided by the applicant's Federal Site Manager.	
12	Submit a transportation services request to the Office of Secure Transportation, in accordance with the Office of Secure Transportation prescribed format, to request and schedule off-site transportation services.	
13	Commence shipping operations as prescribed in SARP/SARP addendum, OTC/OTA, SER, and if applicable the DOE/NNSA Deputy Administrator for Defense Programs exemption instructions and restrictions and/or guidance provided by the applicant's Federal Site Manager.	

**Office of the DOE/NNSA Deputy Administrator for Defense Programs'**  
**Checklist**

Process for Getting Approval for Adding New Content to a  
 DOE/NNSA Currently Certified Type B Package

<b>Step</b>	<b>Activity</b>	<b>Completion Date</b>
1	Reviews the exemption request, and based on the results of its review of the analysis and documentation provided in the request, its own independent analysis, the exemption criteria of DOE Order 461.1A, and the recommendations provided by the other exemption request reviewers, grants or denies the exemption request.	
1.a	If the exemption request is denied, the correspondence which communicates the denial should indicate whether the exemption request would be reconsidered if additional information/data were provided or whether the applicant should seek another solution for packaging the proposed content(s) (i.e., initiate a new packaging design).	
1.b	If the exemption is granted, the correspondence that issues the exemption should be addressed to the Federal Site Manager of the applicant's Site, copy to the applicant, the NNSA Service Center Manager, and all other organizations to which the exemption applies, and should provide exemption-implementing instructions, if applicable.	

<p style="text-align: center;"><b>DOE/NNSA Service Center's Packaging Certification Division's Checklist</b></p> <p style="text-align: center;">Process for Getting Approval for Adding New Content to a DOE/NNSA Currently Certified Type B Package</p>		
<b>Step</b>	<b>Activity</b>	<b>Completion Date</b>
1	Supports SARP owners and applicants as needed.	
2	Uses the information on the proposed content(s) provided by the applicant and the SARP owner's documentation of the results of the analytical work on criticality, shielding and structural to assess the candidate packaging's viability for certification and notifies the SARP owner, applicant, DOE/NNSA Certifying Official, and DOE/NNSA Service Center management of the determination. If the PCD determines that the candidate packaging is a viable candidate for certification the process should continue, otherwise the process should stop.	
3	Determines whether the application for certification should be supported by a SARP or a SARP addendum and notifies the SARP owner and the applicant.	
4	Performs review/confirmatory analysis of SARP/SARP addendum and develops comments based in the review/confirmatory analysis as specified in SG 500 <a href="#">Sections 2.2.3</a> and <a href="#">2.2.3.1</a> and Appendix A, and keeps the DOE/NNSA Certifying Official and DOE/NNSA Service Center management informed of project status, project delays and/or any project difficulties.	
5	Through its SARP/SARP addendum review and responses from the SARP owner, determines that the proposed package meets or doesn't meet the applicable 10 CFR 71 and 49 CFR 100-185 requirements and can or cannot be certified.	
6	Notifies the SARP owner, applicant, DOE/NNSA Certifying Official that the proposed package can or cannot be certified.	
7	If the proposed package can be certified proceed to <a href="#">Step 9</a> , otherwise continue to Step 8.	
8	If the proposed package cannot be certified, but the applicant applies for a DOE/NNSA Deputy Administrator for Defense Programs exemption:	
8.a	Reviews the applicant's exemption request and provides recommendation for approval/disapproval to the DOE/NNSA Deputy Administrator for Defense Programs via the DOE/NNSA Certifying Official and the DOE/NNSA Service Center Manager.	
8.b	Terminates all activities on this project if the DOE/NNSA Deputy Administrator for Defense Programs denies the exemption request. Continues the process if the DOE/NNSA Deputy Administrator for Defense Programs grants the exemption request.	
8.c	Works with applicant and other perspective users of packaging authorized under a DOE/NNSA Deputy Administrator for Defense Programs exemption and approves the format and content of their packaging quality assurance plans.	
9	Resolves all of the draft SARP/SARP addendum review comments, and approves the draft SARP/SARP addendum. If the PCD and the SARP owner are unable to resolve the SARP/SARP addendum review comments, the issues may be presented to DOE/NNSA upper management for resolution.	

<b>DOE/NNSA Service Center's Packaging Certification Division's Checklist</b> Process for Getting Approval for Adding New Content to a DOE/NNSA Currently Certified Type B Package		
<b>Step</b>	<b>Activity</b>	<b>Completion Date</b>
10	Review the applicant's and other perspective users' draft packaging quality assurance plans:	
10.a	For certified packages: approve if the plans are in compliance with the 10 CFR 71 Subpart H requirements.	
10.b	For packaging authorized under a DOE/NNSA Deputy Administrator for Defense Programs exemption: approve if the format and content are in compliance with the format and content approved earlier.	
11	Develops additional, if applicable, packaging and shipping restrictions for inclusion in the OTC/OTA and communicates them to the applicant and other prospective package users.	
12	Uses the final SARP/SARP addendum to develop a draft OTC for certifying the new package, or the final SARP/SARP addendum and the DOE/NNSA Deputy Administrator for Defense Programs exemption to develop a draft OTC or OTA for authorizing the use of packaging approved under a DOE/NNSA Deputy Administrator for Defense Programs exemption, and the associated SER and distribution memorandum.	
13	Submits the OTC/OTA, SER and distribution memorandum to the DOE/NNSA Certifying Official for approval. Proceeds as specified in SG 500 <a href="#">Section 2.2.3.1.B.4.c.(4)</a> if the DOE/NNSA Certifying Official disapproves the SER, OTC/OTA or distribution memorandum.	
14	Distributes the approved OTC/OTA, SER and distribution memorandum to DOE/NNSA Headquarters, applicant, SARP owner, Office of Secure Transportation, and other prospective package users.	
15	Processes the Sites'/other prospective user'(s) draft packaging procedures and associated Site quality assurance plans as specified in SG 500 <a href="#">Section 2.2.3.1.B.4.c.(1)</a> . If the draft packaging procedures and quality assurance plan are approved the process continues. Otherwise the review and approval process stops until the issues are resolved.	
16	Updates the DOE/NNSA OTA/OTC Web Page.	

<p style="text-align: center;"><b>DOE/NNSA Certifying Official's Checklist</b>            Process for Getting Approval for Adding New Content to a            DOE/NNSA Currently Certified Type B Package</p>		
<b>Step</b>	<b>Activity</b>	<b>Completion Date</b>
1	If the proposed package is certifiable:	
1.a	Reviews the draft OTC, SER and distribution memorandum.	
1.b	Certifies the new package by approving the draft OTC, SER and distribution memorandum and signing the OTC and distribution memorandum, or disapproves the new package's certification. Identifies the reason for the disapproval and provides the PCD instructions on how to proceed if the OTC, SER or distribution memorandum is disapproved.	
2	If the proposed package is not certifiable and the applicant requests an exemption from the DOE/NNSA Deputy Administrator for Defense Programs:	
2.a	Reviews the applicant's exemption request and provides recommendation for approval/disapproval to the DOE/NNSA Deputy Administrator for Defense Programs.	
3	If the DOE/NNSA Deputy Administrator for Defense Programs grants the exemption:	
3.a	Reviews the draft OTC/OTA, SER and distribution memorandum.	
3.b	Approves/disapproves the OTC/OTA, SER or distribution memorandum. Identifies the reason for the disapproval and provides the PCD instructions on how to proceed if the OTC/OTA, SER or distribution memorandum is disapproved,.	

<b>Federal Site Manager's Checklist</b> Process for Getting Approval for Adding New Content to a DOE/NNSA Currently Certified Type B Package		
<b>Step</b>	<b>Activity</b>	<b>Completion Date</b>
1	Works with site (applicant) to determine whether the item must be shipped off site. If the determination indicates that the item must be shipped off site, this process should continue. Otherwise the process should end.	
2	If the proposed package is certified, provides oversight of packaging and off-site transportation associated activities at the Site.	
3	If the package is not certified, and the decision is made to submit an exemption request to the DOE/NNSA Deputy Administrator for Defense Programs, review the applicant's exemption request and provide recommendation for approval/disapproval to the DOE/NNSA Deputy Administrator for Defense Programs.	
4	If the DOE/NNSA Deputy Administrator for Defense Programs grants the exemption:	
4.a	Implements the exemption and its implementation instructions, and ensures that the applicable contractor(s) under his/her cognizance comply with the exemption and its implementation instructions.	
4.b	Exercises final authority for authorizing/not authorizing the shipment(s) after all other documents and processes have been approved.	
4.b (1)	Disapproves the proposed packaging and shipment and advises the applicant on how to proceed, and the DOE/NNSA Deputy Administrator for Defense Programs, PCD, and other prospective users of the decision; or,	
4.b (2)	<u>Authorizes</u> the packaging and shipment of the content(s) and provides oversight of the activities.	

### **3.5.3.4 Process for Applying for and Processing Recertification Applications for Currently Certified Type B Packages with Significant Design Changes**

The SARP owner must prepare this package certification application the same as he/she would prepare an application for any other package that hasn't been certified. Refer to [Sections 2.2.8](#) and/or [2.2.12](#), as applicable, for guidance on SARP development, and [Appendix A Section 3.2](#) for information on SARP review process steps and timelines.

### **3.5.4 Nuclear Weapon Program Special Assemblies Containing Type B Quantity RAM**

For shipments of nuclear weapon special assemblies that contain Type B quantities of RAM, the applicant shall apply for an OTA by submitting an application that is supported by a TSRA. The application must also submit a copy of the written authorization, granted by the senior DOE/NNSA Headquarters nuclear weapons program line manager who has responsibility for granting this approval to build and test the special assembly that is addressed in the application. This authorization must be granted before PCD will accept a request

to review the TSRA. See Appendix B for guidance for developing TSRAs for special assemblies.

### **3.5.5 Type B Packages Certified Under DOE CofCs**

If the proposed contents and configurations match the authorized contents and configurations of packages certified by the DOE Certification Office (EM-5), there is packaging reciprocity between the DOE Certification Office and the NNSA Approval Authority for packaging certification and shipment authorizations. The user of these packages must have DOE approved packaging procedures and a DOE/NNSA approved quality assurance plan.

### **3.5.6 Type B Package Certified Under NRC or IAEA/DOT CofCA Transported in TSS**

The prospective applicant must be an authorized NRC licensee. The proposed NNSA user/applicant of Type B Package certified under an NRC or IAEA/DOT CofCA must submit a request to PCD and OST via the Package Line Manager/Weapon System Program Manager requesting authorization to transport the NRC or IAEA/DOT CoCA package in the TSS. The applicant and the Package Line Manager/Weapon System Program Manager must understand that DOE/NNSA cannot issue revisions to NRC or IAEA/DOT CofCAs or their certified packagings. The only viable alternative would be for the applicant to submit a SARP that would be reviewed by a TSRP. The applicant's request to ship a NRC or IAEA/DOT package under a valid CofCA in the TSS must comply with the CofCA requirements and applicable federal regulations, and must provide the documentation needed to validate the packages compatibility with the TSS loading, unloading, tiedown and any other specified requirements. The PCD Manager shall assign a CE or TSRP to evaluate the package's compliance with 10 CFR 71 and 49 CFR 173 requirements, and to assess the adequacy of the NRC or IAEA/DOT package's safety documentation and the package by conducting or managing an independent confirmatory technical assessment . This review shall consist of the validation of the proper use of the packaging for the application intended. The PCD shall assure that the proposed configuration is within maintenance and serviceability dates, and that it can be delivered within the prescribed deadlines. PCD shall issue a memorandum to OST that documents the results of the review. The CE shall also work with OST to ensure that the package is compatible with TSS equipment and the tiedown procedures are contained in either TP 45-51D, DOE Tiedown Manuals or approved in a separate correspondence from OST to PCD before an OTC/OTA is issued.

### **3.5.7 Type B Package Certified by UK MOD Transported in TSS**

The Weapon System Program Manager shall submit a request for authorization to transport Type B Package certified by UK MOD in the TSS to PCD and OST. The PCD Manager shall assign a CE or TSRP to evaluate the proposed UK MOD Type B package's compliance with 10 CFR 71 and 49 CFR 173

requirements, and to assess the adequacy of the UK MOD's safety documentation and the package by conducting or managing an independent confirmatory technical assessment. This review shall consist of validation of the proper use of the packaging for the application intended. The PCD shall assure that the proposed configuration is within maintenance and serviceability dates, and can be delivered within prescribed deadlines. Reviews of DOE/NNSA users operating procedures are completed in accordance with work process defined for US origin Type B packaging designs. The CE shall also work with OST to ensure that the package is compatible with TSS equipment and that the tiedown procedures are contained in TP 45-51D, Technical Manual, Tiedown Procedures for Type-B Containers Shipped in Safe-Secure Trailer/Safeguards Transporter (SST/SGT), DOE/OST Tiedown Manuals or approved in a separate correspondence from OST to PCD before an OTC/OTA is issued.

### **3.6 Revocation of Authorization to Use Type B Package**

Revocation of a certificate for a specific shipper or class of shippers may occur if any of the following situations arises:

- A.** Failure of the packaging.
- B.** Disclosure that the currently certified package fails to meet the applicable regulatory requirements (requirements in effect when the package was first designed and certified).
- C.** User violates the OTC.
- D.** User violates the associated SARP.
- E.** Use of packaging to package something other than the authorized content.
- F.** Violation of shipment loading limits.
- G.** Changes in the regulations or the law that would invalidate the certification.
- H.** Noncompliance with the DOE-approved QAPP that conforms to 10 CFR 71 Subpart H.

### **3.7 Authorization of Shipping Conveyances**

Only OST owned and operated vehicles or other vehicles authorized by the OST, as provided in DOE Order 461.1A, are authorized for off site transport of nuclear weapon components, Category I and II special nuclear materials, nuclear weapon program special assemblies, and other materials of national security interest.

### **3.8 Identification and Control of Items**

The users of the DOE/NNSA Service Center Package Certification and Offsite Transportation Authorization products and services should maintain quality assurance programs that provide for a management system that establishes and implements methods to identify, maintain, and control items and activities and to prohibit the use of incorrect or unidentified items.

When required, physical identification of items should be used to the maximum extent possible. Identifying markings should be permanent and legible and should not adversely affect the function, service, or archival life of the item. When identification directly on the item is impractical, physical segregation, record traceability, or other tracking methods should be described in procedures. When applicable and safe, each part or piece of an item, when removed from the sample lot, should have a unique identifier affixed.

### **3.9 Handling, Storing, and Shipping**

The users of the DOE/NNSA Service Center Package Certification and Offsite Transportation Authorization products and services should maintain quality assurance programs that define the basic requirements for a system of controls to ensure that packagings are handled, stored, shipped, cleaned, and preserved to prevent deterioration or damage. These controls are established according to instructions, specifications, drawings, and technical manuals for items that are sensitive, have a high cost, or have been identified as having a significant impact on the environment, public, employees, cost or schedule.

Handling, storage, and shipping of items, (e.g., nuclear components and special assemblies) should be conducted in accordance with established procedures specified for use in conducting the activity.

All items to be shipped should be processed by appropriately qualified personnel. The cognizant individual should assure that documentation (e.g., carrier shipping forms, chain-of-custody forms, labels, property release forms) is prepared and if required, signed by the appropriate person(s).

Shipping documentation should accurately reflect tag and serial numbers for tagged items. Traceability should be maintained at all times for the items to be shipped, from the point of origination to the final receipt of the item or material. Offsite transportation should be conducted in accordance with local, state, and federal regulations.

Measures should be established and documented to control handling, storage, and shipping, including cleaning, packaging, and preservation of material and equipment in accordance with established instructions, procedures, or drawings to prevent damage, deterioration, and loss. When necessary for particular items, special coverings, special equipment, and special protective environments such as inert gas atmosphere, specific moisture content levels, and temperature levels should be specified, provided, and their existence verified.

For critical, sensitive, perishable, or high-value articles, specific written procedures for handling, storage, packaging, shipping, and preservation should be used. Special handling tools and equipment should be provided and controlled to ensure safe and adequate handling.

Special handling tools and equipment should be inspected and tested in accordance with written procedures and at specified times to verify that the tools and equipment are adequately maintained.

Special attention should be given to providing adequate instruction for marking and labeling for packaging, shipment, and storage of items. Marking should be adequate to identify, maintain, and preserve the shipment, including indication of the presence of special environments or the need for special control. DOT regulations provide the necessary instructions for marking and labeling.

#### **A. Special Handling Equipment**

When required for nuclear components and special assemblies, special equipment (such as containers, fork lifts, shock absorbers, and accelerometers), special protective environments (such as inert gas atmosphere), and specific moisture content levels and temperature levels should be specified and provided, and the condition of each item should be verified and documented.

#### **B. Packaging/Shipment**

Requirements should be specified for protection of a packaging/shipment against corrosion, contamination, physical damage, or any effect that would negatively impact the packaging/shipment or cause deterioration during the time it is handled, stored, or shipped in accordance with 49 CFR 73.

#### **C. Storage of Items**

Limited-access areas should be designated, when required, for storage of packaging quality-related items.

Storage areas should be protected, should provide for access control, and should maintain environmental storage conditions, as necessary (e.g., temperature, humidity, light).

### **3.10 Control of Engineered Items**

Control of engineered items that have been specifically designed to DOE/NNSA Defense Programs requirements and those that require traceability should be assigned a unique identifier through the use of identification numbers, color coding, or similar means. 10 CFR 71 Subpart H requires that the quality category of each packaging component be identified using a graded approach. These category designations are identified in the SARP and approved by DOE/NNSA Service Center when DOE/NNSA issues the OTC. Subsequent design changes to selected category items must be submitted to DOE/NNSA PCD for review and approval before the design changes are issued for use.

### **3.11 Control of Commercially Procured Items**

Commercially available items should have identification requirements established by the DOE/NNSA Service Center. These requirements should be included in procurement documents when traceability is to be maintained by the user. Traceability is maintained through batch numbers, heat numbers, lot numbers, purchase order numbers, or similar means that are affixed to the item and that appear in supporting documentation. Identification should be maintained on installed items and in documents traceable to these items.

### **3.12 As Low As Reasonably Achievable (ALARA)**

DOE/NNSA and contractor management should ensure that procedures and practices are developed and used to ensure that personnel exposure to radiation is maintained *as low as reasonably achievable* as required in 10 CFR 835.

### **3.13 Packaging Design Control**

#### **A. Introduction**

Packaging design related activities should have measures established and documented to assure that the applicable specified design requirements, such as design bases, regulatory requirements, codes, and standards are correctly translated into the specifications, drawings, procedures, or instructions. These measures must include provisions to assure that appropriate quality standards are specified and included in the design documents.

Items and processes should be designed using sound engineering/scientific principles. Design inputs refer to the criteria, parameters, or other design requirements upon which the final detailed design is based. Design measures should include provisions to assure that appropriate quality standards are specified and included in design documents. Changes or deviations from specified design requirements or quality standards should be identified, documented, and controlled. Records of implementation of these measures for design control should be available for review.

#### **B. Package/Packaging Design Input**

##### **1. Input Criteria and Records:**

- a. Design inputs such as design bases, performance and regulatory requirements, codes and standards, and safety criteria should be identified and recorded.
- b. Changes from approved design inputs, including reasons for the changes, should be identified and approved by the organization that approved the

original design input. These changes should also be documented, controlled, and retrievable.

## 2. Analyses:

Design input should provide for package design analyses such as criticality physics, radiation shielding, stress, thermal, hydraulic, accident, compatibility of materials, accessibility for in-service inspection, maintenance and repair, hazard assessment, features to facilitate decontamination and delineation of acceptance criteria for inspections, and tests.

## 3. Suitability Selection and Review

- a. Measures should be established for the selection and review for suitability of materials, parts, equipment, and processes that are essential to the safety-related functions of the packaging/shipment.
- b. Design input selection should be reviewed and approved by the organization that requested the design and should be reviewed and approved by the design organization during design verification.
- c. Structures, systems or components (SSC) important to the safe and reliable operation of the packaging/shipment should be identified. For those SSC, procedures should be established to ensure that required maintenance/modifications are performed and documented.

## C. Package/Packaging Design Process

### 1. Design Interfaces

Measures should be applied, as necessary, to identify and control design interfaces and to coordinate participating DOE/NNSA packaging design organizations. These measures should include the establishment of written procedures and/or instructions for the review. Approval, release, distribution, and revision of documents involving design interfaces should also be controlled.

## D. Package/Packaging Design Output

### 1. Design Output Requirements

- a. The results of packaging design processes should be verified or checked for adequacy of design according to pre-established design control measures.
- b. Design output documents should relate to the design input in sufficient detail to permit design verification.

- c. Design outputs such as drawings, specifications, results of scientific investigations, computer programs, etc. should be established in formal written documents that have a unique identification and revision status, and are approved prior to issue.
- d. Design output documents should indicate that the required reviews and approvals have been accomplished prior to release for use in other design activities.

## E. Package/Packaging Design Verification

### 1. Adequacy of Design

- a. Design verification of the packaging design should be performed by technically competent, independent reviewer(s) other than the individual(s) performing the original design or developing design inputs. The reviewer(s) may be from the same organization and may have provided technical assistance for a portion of the design.
- b. The reviewer(s) performing the verification should be competent, through education and/or work experience, to perform the design being verified.
- c. Verification may be performed by the originator's supervisor. However, cursory supervisory reviews are not design verification.
- d. Where state-of-the-art technology is involved, a peer review should be used.
- e. The concerns which design and technical reviews should address, include but are not limited to, the following:
  - (1) Were the design inputs correctly selected?
  - (2) Are the assumptions necessary to perform the design adequately identified and described, and are they reasonable?
  - (3) Was an appropriate design method used?
  - (4) Were the design inputs correctly used in the design?
  - (5) Are the necessary design input and verification requirements specified in the design document or in supporting procedures and instructions?
  - (6) Were the alternate calculations and analyses that were used to verify the correctness of the original calculations or analyses (performed by an independent individual or organization) of sufficient rigor to determine the adequacy of assumptions, input data, and the computer program calculation method, or other calculation methods?

### 2. Design Control Measures

- a. Design reviews, alternate or simplified calculation methods, or a suitable testing program are examples of measures that should be used to verify or check the adequacy of the packaging design.

- b. A packaging design should be verified and validated before approval for implementation of the design, and before use as a design input for other design activities. When such timing cannot be met, the portions of the design activities that have not been verified should be identified and controlled.

### 3. Performance Standards

- a. The verifying or checking process should be performed by individuals or groups other than those who performed the original design; they may be from the same organization, however.
- b. A graded approach to design reviews should be developed and applied as appropriate to consider the importance and complexity of the design being reviewed, the degree of standardization, the state of the art, hazards identified, and the similarity with previously proven designs.
- c. When a standardized or previously proven packaging design could be used, every application should be verified for conformance with pertinent design requirements such as 10 CFR 71.
- d. When the adequacy of packaging design will be verified by testing, the test requirements must be identified. These tests should demonstrate adequacy of performance under the most adverse conditions (10 CFR 71.73). Operating modes and environmental conditions in which the packaging/shipment must perform satisfactorily should be considered in determining the most adverse conditions. (See SG600)
- e. If testing indicates that changes to the packaging/shipment are necessary to obtain acceptable performance, then the item should be modified and retested or analyzed to assure satisfactory performance.

### 4. Minimum Requirements

Verifying or checking should consist of, at a minimum, reviewing the packaging design, spot checking the calculations or analyses, and assessing the results against the original design bases and functional requirements. The particular design verification methods used should be identified and documented.

#### **F. Package/Packaging Design Changes**

Packaging design changes, including field (operational) changes, should be governed by measures for control of design commensurate with those applied to the original design, including review and approval by the organization that performed the original design, or another designated organization which is

competent in the design area of interest, and has access to pertinent background information.

Note: If any Quality Category A design feature, requirement, or specification on certified packaging, or any additional feature specified by the certifying agency is changed, it must be approved by the agency granting the Certificate of Compliance or OTC/OTA.

### **3.14 Procurement**

Measures should be established and documented to assure that purchased components, equipment, and services, whether purchased directly or through contractors, conform to the DOE/NNSA approved drawings and specifications detailed in the procurement documents, and that specific quality requirements are identified for the items being procured and are specified in the procurement documents. These measures should include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor, inspection and audit at the source, and examination of items upon delivery. (See DOE/AL QC-1, Section III, 4.2, Supplier Assessment.)

DOE/NNSA organizations have responsibility for following the procurement process to ensure that procured items and services comply with documented requirements and perform acceptably. Suppliers are evaluated and selected to meet these criteria under management controls compliant with the DOE regulations. Quality assurance personnel perform vendor surveillances as directed by the project management plans, the design authority, and specifications, or other engineering requirements. The DOE quality personnel should maintain records of any DOE/NNSA lead evaluations and performance for reference in future procurements. The identification and resolution of Suspect/Counterfeit items continues to be a part of procurement quality, and purchasing activities and function.

### **3.15 Inspection and Acceptance Testing**

Inspection and acceptance testing of specified items (i.e., packagings, transport vehicles, aircraft, and prime movers) and processes should be conducted using established written acceptance and performance criteria.

### **3.16 Computer Software Control**

DOE/NNSA package certification applicants and support contractors must establish, maintain and use computer software controls that are based on the American Society of Quality Control (ASQC) standards.

# **APPENDIX A**

## **Guide for Reviewing SARPs and TSRAs and Performing Confirmatory Analysis**

## **1.0 Introduction**

The information on SARP/TSRA/HAR reviews and SARP/TSRA confirmatory reviews provided in this Appendix is intended as guidance for the PCD CEs and PCD customers.

## **2.0 Guidance for Reviewing SARPs and TSRAs**

The PCD uses NRC NUREG-1609, *Standard Review Plan for Transportation Packages for Radioactive Materials* as a guide for performing these reviews.

## **3.0 SARP and TSRA Review Process and Timelines**

### **3.1 Review Process and Timelines for Initial Certification of a Type B Package and for Certifying a NNSA Currently Certified Type B Package with New Content(s), and for the Initial Issuance of an OTA Based on a TSRA**

The process and timelines for a typical SARPs review for an initial certification of a Type B Package and for certifying a NNSA Currently Certified Type B package with new content, and issuance of the associated OTC, and for reviewing a TSRA and issuing an initial OTA are summarized below. Unless funding or other resources dictate otherwise, the review timeline begins when the TSRP receives the SARP/TSRA from the SARP/TSRA Owner on the prearranged schedule. The processes described in Sections A, C, D, E, F, G and H below must be performed in sequence. The processes described in Section B must begin not later than two weeks after the SARP/TSRA review begins (Section A processes begin).

#### **A. Perform SARP/TSRA Review: 12 weeks**

1. TSRP reviews SARP/TSRA and prepares and submits comments to the TSRP chairman: 10 weeks
2. TSRP Chairman consolidates comments and distributes to TSRP members and the SARP/TSRA Owner prior to TSRP meeting, when possible: 4 days
3. TSRP meeting: 2 days
4. Finalize and issue Q<sub>0</sub> comments: 4 days

#### **B. Perform Confirmatory Analysis: 18 weeks**

1. Develop and issue confirmatory comments: 16 weeks
2. Develop and issue confirmatory report: 2 weeks

#### **C. SARP/TSRA Owner prepares and submits Q<sub>0</sub> responses: 7 weeks**

#### **D. TSRP reviews Q<sub>0</sub> responses, and prepares and submits Q<sub>1</sub> comments which include confirmatory comments: 4 weeks**

- E. SARP/TSRA Owner reviews Q<sub>1</sub> comments and prepares and submits responses: 6 weeks
- F. TSRP closes out comments and approves SARP/TSRA: 5 weeks
- G. SARP/TSRA Owner completes and distributes approved SARP/TSRA: 2 weeks
- H. Service Center completes, approves and distributes OTC/OTA, SER and transmittal letter: 4 weeks

Additional time may be required when more than two rounds (Q<sub>0</sub> and Q<sub>1</sub>) of TSRP comments and SARP/TSRA Owner response cycles are needed to resolve all comments, and/or if significant comments are generated from the TSRP's confirmatory analyses, and/or delays inherent in transmitting classified documents among the process participants are experienced.

### **3.2 Review Process and Timelines for Recertification of a NNSA Currently Certified Type B Package or Revision of an OTA Based on a Revised TSRA**

The process and timelines for a typical SARP and associated documents review for the recertification of a NNSA Currently Certified Type B package and revision of OTAs based on a revised TSRA are summarized below. Unless funding or other resources dictate otherwise, the review timeline begins when the TSRP receives the TSAR or SARP and associated documents from the SARP/TSRA Owner on the prearranged schedule. The processes described in Sections A, C, D, E, F, G and H below must be performed in sequence. The processes described in Section B must begin not later than one week after the SARP/TSRA review begins (Section A processes begin).

- A. Perform SARP Review: 8 weeks**
  - 1. TSRP reviews TSRA or SARP and associated documents, and prepares and submits comments to the TSRP chairman: 6 weeks
  - 2. TSRP Chairman consolidates comments and distributes to TSRP members and the SARP/TSRA Owner prior to TSRP meeting, when possible: 4 days
  - 3. TSRP meeting: 2 days
  - 4. Finalize and issue Q<sub>0</sub> comments: 4 days
- B. Perform Confirmatory Analysis: 12 weeks**
  - 1. Develop and issue confirmatory comments: 10 weeks
  - 2. Develop and issue confirmatory report: 2 weeks
- C. SARP/TSRA Owner prepares and submits Q<sub>0</sub> responses: 5 weeks**

- D. TSRP reviews Q<sub>0</sub> responses, and prepares and submits Q<sub>1</sub> comments which include confirmatory comments: 3 weeks
- E. SARP/TSRA Owner reviews Q<sub>1</sub> comments and prepares and submits responses: 4 weeks
- F. TSRP closes out comments and approves TSRA or SARP and associated documents: 2 weeks
- G. SARP/TSRA Owner completes and distributes approved TSRA or SARP and associated documents: 2 weeks
- H. Service Center completes, approves and distributes OTC/OTA, SER and transmittal letter: 2 weeks

Additional time may be required when more than two rounds (Q<sub>0</sub> and Q<sub>1</sub>) of TSRP comments and SARP/TSRA Owner response cycles are needed to resolve all comments, and/or if significant comments are generated from the TSRP's confirmatory analyses, and/or delays inherent in transmitting classified documents among the process participants are experienced.

#### **4.0 HAR Submission Schedule and Review Timelines**

The 60-day window starts the day the HAR is received by PCD. The process/timelines for reviewing HARs and developing a new or revised OTA and SER are summarized as follows:

- A. CE receives HAR, performs HAR review provides initial Qs to applicant - 3 weeks
- B. Applicant develops responses to Qs and submits to CE and through an iterative process the CE approves the applicant's responses - 3 weeks
- C. CE develops SER and OTA, OTA is approved and distributed – 2 weeks

#### **5.0 Guidance for Performing SARP Confirmatory Analysis**

The confirmatory analysis begins as soon as the SARP is received by the organization tasked to perform the analysis, and typically takes approximately 16 weeks. The following sections describe the objectives of the confirmatory analysis and a brief description of what the reviewer does to perform the analysis.

## A. Structural Confirmatory Analysis

The primary objective of the structural confirmatory analysis is to provide a detailed confirmation of the validity of the applicant's calculational methods and resulting conclusions used for demonstrating acceptable regulatory compliance. Also, due to the importance of ASME Boiler and Pressure Vessel Code (BPVC) requirements in demonstrating acceptable structural performance, the applicant's ASME BPVC calculations and interpretations are verified by independent calculations. The verification of the applicant's calculational methods is accomplished by various alternate methods selected by the reviewer based on the complexity of the applicant's analysis.

In most free drop, crush, and puncture evaluations, the applicants will use complex finite element analysis (FEA) computer simulations and/or testing to demonstrate acceptable structural performance of the package. In other cases, the applicant will use simplified quasi-static evaluations and empirical methods. The reviewer selects an appropriate alternate method to verify that the applicant's evaluations and results are technically valid, the computer program is appropriate for the application, the assumptions are valid, appropriate material properties are used, applicable code requirements are met, and the evaluation is consistent with physical laws.

When an applicant uses complex FEA elastic-plastic computer simulations to predict acceptable performance and structural behavior, detailed verification of the accuracy of programming codes and numerical modeling assumptions are not economically feasible due to the complexity of the codes and enormous amount of data generated by the computer simulation. Subsequently, the reviewer uses conservative, independently developed FEA computer simulations to assess the technical validity of the results stated by the applicant. When possible, the computer simulations used by the reviewer are developed using different and appropriately comparable computer codes. The reviewer uses these computer simulations to verify that the applicant's results, predictions, and conclusions about the structural behavior of the package are valid.

When the applicant uses testing to verify packaging compliance, the tests should be performed using the initial conditions specified in Regulatory Guide 7.8. The reviewer then uses confirmatory computer simulations to verify the validity of the applicant's predictions of acceptable package performance for environmental conditions specified in the regulations. In all cases, the objective of the confirmatory analysis is to verify that package performance is accurately demonstrated and meets regulatory requirements for maintaining containment, subcriticality, and shielding.

## **B. Thermal Confirmatory Analysis**

The primary objective of the thermal confirmatory analysis is to provide a detailed confirmation of the validity of applicant's calculational methods and resulting conclusions used for demonstrating acceptable regulatory compliance. The verification of the applicant's calculational methods is accomplished by various alternate methods selected by the reviewer based on the complexity of the applicant's analysis.

In most cases for normal and fire accident conditions, the applicants will use complex computer simulations and/or testing to demonstrate acceptable performance of the package. In other cases, the applicant will use empirical methods. The reviewer selects an appropriate alternate method to verify that the applicant's evaluations and results are technically valid, the computer program is appropriate for the application, the assumptions are valid, appropriate material properties are used, applicable code requirements are met, and the evaluation is consistent with physical laws.

When an applicant uses computer simulations to predict acceptable performance and thermal behavior, detailed verifications of the accuracy of programming codes and numerical modeling assumptions are not economically feasible due to the complexity of the codes and enormous amount of data generated by the computer simulation. Subsequently, the reviewer uses conservative and independently developed computer simulations to assess the technical validity of the results stated by the applicant.

When possible, the computer simulations used by the reviewer are developed using different and appropriately comparable computer codes. The reviewer uses these computer simulations to verify that the applicant's results, predictions, and conclusions about the thermal performance of the package are valid.

When the applicant uses testing to verify packaging compliance, the tests are normally performed under nominal ambient conditions. The reviewer then uses confirmatory computer simulations to verify the validity of applicant's predictions of acceptable package performance for environmental conditions specified in the regulations. In all cases, the objective of the confirmatory analysis is to verify that package performance is accurately demonstrated and meets regulatory requirements for maintaining containment, subcriticality, and shielding.

## **C. Containment Confirmatory Analysis**

The containment chapter is reviewed to determine the bounding source term and what was analyzed to demonstrate compliance with 10 CFR 71 normal conditions of transport (NCT) and hypothetical accident conditions (HAC) leakage rate limits.

Confirm that the source term selected as bounding for the containment evaluation is consistent with the allowable payloads in Chapter 1, and confirm overall consistency of source term with that used in the shielding and criticality evaluations, while recognizing that these evaluations have different considerations.

Independently calculate the bounding source term for the containment evaluation (i.e.,  $A_2$  for mixture, activity-to- $A_2$  value ratios, etc.) using ORIGEN-S to build in decay products for various decay times. Verify that the correct decay time was selected as bounding for the source terms used in the containment evaluation in the SARP.

Calculate the reference leakage rates per ANSI 14.5 using the bounding source term(s) and compare against the SARP results to verify correctness. Verify that the NCT and HAC pressures and temperatures used in the leak rate calculations are consistent with the results from the thermal evaluation in Chapter 3.

#### **D. Shielding Confirmatory Analysis**

The shielding chapter is reviewed to determine the bounding source term and what package configurations were analyzed to demonstrate compliance with 10 CFR 71 NCT and HAC dose rate limits. Confirm that the source term selected as bounding for the shielding evaluation is consistent with the allowable payloads in Chapter 1, and confirm overall consistency of source term with that used in the containment and criticality evaluations, while recognizing that these evaluations have different considerations.

Independently calculate the gamma and neutron radiation emission rates for the bounding source term using ORIGEN-S for various decay times. Verify that the correct decay time was selected as bounding for the gamma and neutron source terms used in the SARP.

Develop three-dimensional Monte Carlo Neutral Particle (MCNP) models for NCT and HAC consistent with the models contained in the SARP. Calculate NCT and HAC dose rates and compare against the SARP results and confirm that they are within the allowable limits. Ensure that no anomalies exist between the MCNP and SARP results. If anomalies exist, investigate and document conclusions in the confirmatory report and/or provide additional questions.

#### **E. Criticality Confirmatory Analysis**

The criticality chapter is reviewed to determine the bounding source term.

Confirm that the source term selected as bounding for the criticality evaluation is consistent with the allowable payloads in Chapter 1, and confirm overall consistency of source term with that used in the shielding and containment

evaluations, while recognizing that these evaluations have different considerations.

Develop three-dimensional MCNP models for NCT and HAC consistent with the models contained in the SARP. Duplicate the criticality calculations performed in the SARP to ensure all-important conditions were properly considered. Include additional confirmatory cases if the SARP did not adequately address certain parameter sensitivities. Ensure that no anomalies exist between the MCNP and SARP results. If anomalies exist, investigate and document conclusions in the confirmatory report and/or provide additional questions.

## **6.0 Guidance for Performing TSRA Confirmatory Analysis**

The TSRA document is reviewed to determine the postulated normal and credible accident conditions and their relation to the NCT and HAC in 10 CFR 71. The number of confirmatory analyses to be performed will be based on the 10 CFR 71 NCT and HAC events that are addressed in the TSRA. The appropriate structural and thermal confirmatory analyses will be performed for all NCT and HAC structural and thermal events that are evaluated in the TSRA.

The objective of both the structural and thermal confirmatory analyses is to provide a detailed confirmation of the validity of the applicant's calculational methods and resulting conclusions used for demonstrating compliance with 10 CFR 71. The verification of the calculational methods is accomplished by various alternate methods that are selected by the reviewer based on the complexity of the applicant's analysis. The reviewer selects an appropriate method to verify that the applicant's evaluations and results are valid, the computer program is appropriate for the application, the assumptions are valid, appropriate material properties are used, applicable design code requirements are met, and the evaluation is consistent with physical laws.

In addition to the structural and thermal confirmatory analyses, shielding, criticality, and containment confirmatory analyses are also performed. The shielding section is reviewed to determine the bounding source term and then the source term is independently confirmed using the ORIGEN-S code. A three-dimensional model of the package is developed using the MCNP code and the dose rates are calculated and compared to the results listed in the TSRA. For fissile material, the criticality source term is confirmed and a three-dimensional model of the package is prepared using MCNP. The MCNP model is used to confirm the criticality calculations in the TSRA and is also used to perform additional sensitivity analyses to determine if the worst-case scenarios were addressed. For the containment section, the bounding source term is confirmed and compared to the source term used in the shielding and criticality sections. The reference leakage rates are calculated per ANSI N14.5 using the bounding source term and the results are used to verify the results in the TSRA.

The TSRA will contain a probabilistic risk assessment (PRA) for those requirements in 10 CFR 71 that cannot be met by the package. The PRA confirmatory analysis includes an independent assessment of the variables and basic data used to calculate accident frequencies and consequences, critical review of the accident progression models (i.e., combinations of events that lead to a release of radioactive materials), hand calculations which attempt to duplicate the results of the accident frequency calculations, validation of release fractions used in the analysis, application of alternative atmospheric dispersion models to calculate concentrations of released radioactive and hazardous materials at various receptor locations, and verification that risk-related conclusions are valid. If necessary, an independent PRA will be prepared to verify the results in the TSRA.

# **Appendix B**

## **Guide for Developing SARPs, SRs, TSRAs and HARs**

## 1.0 Introduction

The guidance provided in this Appendix, if followed and all of the required elements are met, will facilitate the processing of OTC/OTA application and/or SARP/TSRA/HAR approval by PCD and will improve the probability of an applicant receiving authorization in time to support their program.

## 2.0 Guide for Developing SARPs/SARP Addendums

DOE Order 461.1A specifies that DOE/NNSA SARPs must conform to NRC Regulatory Guide 7.9, *Standard Format and Content of Part 71 Applications for Approval of Packaging for Radioactive Material*. However, Regulatory Guide 7.9 is extremely out of date. NRC NUREG-1609, *Standard Review Plan for Transportation Packages for Radioactive Material* provides guidance for performing and documenting SARP reviews, and it is more comprehensive than Regulatory Guide 7.9. Therefore, NUREG-1609 is the preferred guide for developing DOE/NNSA SARPs, and applicants are encouraged to use the template provided in NUREG-1609 for their SARPs.

The SARP should document the structural, thermal, containment, shielding, and criticality safety features; the acquisition and maintenance control programs; operating procedures; and associated quality assurance measures for the packaging (10 CFR 71, and NUREG-1609/Regulatory Guide 7.9). A SARP should be developed in conformance with: this guide; Safety Guide 100; Safety Guide 200; Safety Guide 600; NRC NUREG/CR-3019, *Recommended Welding Criteria for Use in the Fabrication of Shipping Containers for Radioactive Materials*; NUREG/CR-3854, *Fabrication Criteria for Shipping Containers*, NUREG/CR-4775, *Guide for Preparing Operating Procedures for Shipping Packages*; NUREG 7.8, Regulatory Guide 7.6, Regulatory Guide 7.11, and NUREG-1609/Regulatory Guide 7.9, as amended, for Type A or B quantities. The SARP would include:

- A. A description of the proposed packaging in sufficient detail to identify the packaging accurately and provide the basis for evaluating the packaging.
- B. Identification of established codes and standards proposed for use in package design, fabrication, assembly, testing, maintenance, and use. In the absence of any established codes and standards, the DOE/NNSA/contractor should describe the basis and rationale used to establish the packaging quality assurance program.
- C. Demonstration of compliance with each applicable section of 10 CFR 71 and any other requirements specified by DOE/NNSA. For example, DOE/NNSA PCD thermal testing guidance contained in Safety Guide 141.1, *Combination Test/Analysis Method Used to Demonstrate Compliance to DOE Type B Packaging Thermal Test Requirements*. The SARP's format and content

shall conform to the guidance provided in NUREG-1609/Regulatory Guide 7.9. The SARP shall provide evidence that the test performed in compliance with the requirements of 10 CFR 71 conform to the initial conditions provided in Regulatory Guide 7.8 tests, and that the fabrication of the containers conform to the guidance provided in NUREG/CR-3019 and NUREG/CR-3854.

- D. A completed SG-200 Checklist that provides evidence for determining the completeness of the SARP in addressing the regulatory requirements.
- E. This submittal should be made 9 months before the first use date for new packagings and/or 9 months before the packaging certification expiration date. Submittal in this context means that the SARP must be in the hands of PCD and the recipients identified in the list provided by PCD.

### **3.0 Guide for Developing Supplemental Reports**

The SR must be prepared in support of package recertification requests and must be submitted by the applicant to PCD prior to or with the revised SARP. The purpose of the SR is to document the information concerning the package use and performance during the most recent certification period (generally the last 5 years), the current inventory of packagings, and a summary of the changes made to the SARP.

The SR should be organized in a manner consistent with the format provided below and should address the issues discussed in the format:

#### Current Packaging Inventory

This section should include the following information:

- A. Available Packaging – The number of packagings available for shipping throughout the complex, including those temporarily at Department of Defense (DoD) or en route between DOE and DoD;
- B. Onsite Storage – Number of packagings used for onsite storage at sites throughout the complex, including DoD, if applicable;
- C. Procurement – Specify plans, if any to procure additional packagings. In this context, container refers to drums and/or inner containers (for drum-type containers); and,
- D. Vendors of Packaging Components – The manufacturer of packaging components (e.g., drum, inner container, O-rings, insulation) should be specified, as well as any contemplated changes in suppliers. The PCD may perform surveys of the suppliers, or review the applicant's survey documents/reports and all other related quality assurance records.

#### Package History

The package history section must cover the package's activities during the most recent certification period. That is, the last five years or the time between the last

certification and the recertification process period if it happens to be less than five years. The package history section must contain the following information:

- A. Package Use** – Items which must be discussed include: the number of shipments made; the reportable occurrences, their root causes, and how they were resolved/corrected; packages removed from service due to damage or radioactive contamination; and any other incidents during their use that are relevant to the package performance. Reportable occurrences for the same container with different contents must also be provided.
- B. Acceptance and Maintenance Data** – The following information should be included:
  1. Summary of data obtained from acceptance tests on procured materials/components;
  2. Summary of data obtained during refurbishment and/or maintenance activities; and,
  3. Summary of reports obtained from vendor surveys and quality assurance appraisals.

#### Continued Use of Package

Discuss the need for continued use of the package, including the expected time period, and any anticipated changes in use.

#### Container Modifications

Identify and discuss all modifications made to the design of the certified container since the current certification was issued. All modifications require the approval of DOE/NNSA PCD (10 CFR 71.107(c)). The rationale for the design change should be identified and the effect that the change has on the container's ability to comply with applicable regulations should be discussed. Tests and associated analysis performed to demonstrate the modified container's compliance with the federal regulations should be presented in the Testing section of the SR.

#### Testing

Discuss the additional testing and associated analysis performed (if any) to support recertification, and summarize the results. For packages with a modified design, provide justification if the entire 10 CFR 71 Normal Conditions of Transport and Hypothetical Accident Conditions test series were not performed. Provide confirmation that the initial conditions specified in Regulatory Guide 7.8 were used.

#### Compliance with Orders and Regulations

Discuss changes made to applicable requirements since the package was certified, and provide test data or analysis that documents the package's compliance with the current requirements.

#### **A. Federal Regulations**

Discuss any changes made to 10 CFR 71 or 49 CFR 170-173, and the effect that these changes had on the package's certification basis.

**B. DOE/NNSA Requirements**

Discuss changes made to DOE Orders and DOE/NNSA guidance documents such as the DOE/NNSA PCD issued safety guides. Include a discussion of the effects that these changes had on the package's certification basis.

**C. NRC Guides**

Discuss the packages' conformance to the requirements specified in Regulatory Guide 7.8, NUREG/CR-3019, and NUREG/CR-3854.

**D. Miscellaneous Requirements**

Identify changes to other requirements that affect the packaging program.

SARP Changes

Summarize all approved changes to the SARP. Changes that are discussed in other sections of the SR may be referenced rather than repeated.

**4.0 Guide for Implementing SARP Document Control Measures**

The purpose of these control measures is to promote consistency among SARPs and to provide adequate controls to ensure that sites will maintain up-to-date SARPs. The focus of the policy is on administrative policies related to document production and distribution, and not on classification or classified document control requirements. Users are responsible for following security and classification policies effective at their site. This policy is mandatory for all SARPs under the jurisdiction of DOE/NNSA. This policy may also be used for other types of documents. The Manager, Packaging Certification Division, is responsible for revisions and changes to this policy. Changes should be reviewed and approved by the same organizations that performed the original review and approval, unless other organizations are specifically designated by an individual with the authority to do so. The reviewing organization should have access to pertinent background information upon which to base its approval, and should have adequate understanding of the requirements and intent of the original record. The changes should include the date and the identification of the person authorized to issue such changes.

- A.** Document pages may be numbered sequentially (1, 2, 3) or by SARP Chapter (1-1, 1-2). If a change will not fit in the existing pages, additional pages may be added, e.g., 123A or 4-3A. These extra pages should be renumbered at the next revision.
- B.** Each page in the body of the SARP shall include a footer that, as a minimum, identifies the SARP or document number, revision, change number (if

applicable), and the issue date of the change. Organizations are free to add other information and choose the format of the footer.

- C. A return receipt is issued for all revisions and changes. The addressee's name will be given on the return receipt for all revisions and changes. The addressee should send the return receipt back to the place of issuance.
- D. The organization issuing a change or revision shall verify that receipts are returned. If receipts are not returned, the issuing organization should make reasonable attempts to contact the site. DOE/NNSA PCD should be notified if the problem cannot be resolved.
- E. The initial issue of a SARP will be referred to as "Revision 0" (R0). The SARP cover page is required to contain a title, an issue date, a document and revision number, and the name and location of the issuing organization. The initial SARP revision will not contain change pages. Revisions will be issued with return receipts for all distribution copies. If a large number of pages have been changed either by one specific change or cumulatively by several changes, the SARP TSRP chairman may decide that a new revision should be issued. New revisions will incorporate all prior changes with new and proper pagination and include a new cover page with the new date and revision number.
- F. All information that is revised by a change will be marked in the margin as shown in the following example:

The mass of the content is less than the mass of the package. |  
Also, the mass of the... |

**Note:** Changes should be numbered sequentially starting with "C1."

- G. Issuance of a Change should include return receipts, instruction sheets, and a list of affected pages. Requirements are noted below:

The Instruction Sheet will contain the information listed below:

1. Instructions for posting changes such as, "Please remove pages and replace with new change pages as described below. Destroy all superseded pages according to appropriate procedures."
2. A two-column list that shows pages which are to be removed on the left and corresponding pages to be inserted on the right. See example below:

Old Pages	New Pages
iii-x	iii-x
1-1 thru 1-6	1-1 thru 1-6

1-9 thru 1-18	1-9 thru 1-18D
1-27 thru 1-30	Deleted
1-157 thru 1-188	1-157 thru 1-188
1-203 thru 1-204	1-203 thru 1-204

H. The List of Affected Pages is a summary of all changes that have been posted to the revision. The column on the left indicates the page number(s) of the changed page(s) and the column on the right indicates the number of the change that changed that specific page. The example shown indicates that two changes have been issued to the revision. Pages that are not noted in the table have not been changed. This table can be included on the back of the instruction sheet.

Page	Change
iii-x	2
1-1 thru 1-6	2
1-7 thru 1-8	1
1-9 thru 1-18D	2
1-27 thru 1-30	2
1-45 thru 1-48	1
1-157 thru 1-188	2
1-203 thru 1-204	2

- I. When a set of change pages is received, the changes will be posted to the document as instructed. A note to that effect, with the date posted and name of person posting the change, should be included.
- J. The Instruction Sheet and List of Affected pages will be in front of the title page. All portions of the change will be retained. All superseded pages will be destroyed in accordance with applicable procedures.
- K. The return receipt will be signed by the addressee and returned to the place of issuance. A copy of the return receipt may be retained with the document.

**5.0 Guide for Developing TSRA's for Containers Used to Package Type B Quantity RAM**

The following outline identifies the minimum information that should be included in each section of a TSRA. In general, a TSRA will address the issues of package shielding, containment, and subcriticality for both NCT and HAC. A TSRA should conform to the extent practicable with the general outline of NUREG-1609/Regulatory Guide 7.9, *Standard Format and Content of Part 71 Applications for Approval of Packaging for Radioactive Material* (NRC 1986). It should address the Type B package requirements of 10 CFR 71, "Packaging and Transportation of Radioactive Material," and to the extent possible, (1) identify the specific conditions the packaging system is unlikely to withstand without releasing material in excess of established limits and (2) indicate instances in

which approval to ship will be based on a PRA. A summary of composite risk to the public (consequences and frequency) from all hazard mechanisms should be provided.

## 1. General Information

### a. Introduction

This section should include a brief overview of the packaging system and description of the cargo and shipping campaign. The introduction should incorporate a general discussion of 10 CFR 71 NCT and HAC requirements as applied to the package safety basis for shielding, containment, and subcriticality. Requirements that are addressed through the conduct of a probabilistic risk assessment should be identified. The section is to include a summary of composite risk to the public (consequences and frequency) from all hazard mechanisms associated with the proposed shipping campaign. Operational controls necessary to mitigate risk to the public should be identified if required. The criticality transport index and shielding transport index should be included.

### b. Packaging System and Shipping Campaign Description

This section should include descriptions of the packaging system (including the transport vehicle and separate internal packagings, where applicable) and shipping campaign. Package information should include gross weight, materials, dimensions, internal and external structures including over-packs, lifting and tiedown devices, shielding, valves, ports, and other special package features. The confinement and containment (if applicable) boundaries should be clearly identified. Descriptions of the transport and tie-down configurations should also be provided. Sketches should be included to clarify the packaging system description. Special operational features required for the mitigation of risk should be discussed.

A general payload description should be included with sketches. Materials in the payload should be clearly identified with information on mass, physical and chemical form, and density. All hazardous material including RAM should be described completely and accurately. The description for the RAM must include the material's mass, radionuclide activity, isotopic composition, physical and chemical form, decay heat, and density. Maximum decay heat, maximum pressure buildup in the inner container, and loading restrictions should be identified. Specify conditions for maximum pressure buildup in both the expected NCT and HAC.

A general description of the shipping campaign should be included. Information should be given on the number of units per vehicle, total units to be shipped, campaign time period, and routing.

c. Regulatory Compliance

This section is to include a discussion of compliance with each section of 10 CFR 71 Subpart D, E, F, G and H applicable to a Type B quantity of material in each AS or package. Package response to the 10 CFR 71 NCT and HAC should be described. This section should provide confirmation that the tests complied with the initial conditions specified in Regulatory Guide 7.8, and provide confirmation that the packages are/will be fabricated in conformance with NUREG/CR-3019 and NUREG/CR-3854. Package failure thresholds or equivalent should be provided. Package responses being addressed via a probabilistic risk assessment should be identified where the unit is non-compliant with 10 CFR 71 equivalence. Identification of established DOE, NRC, or NNSA contractor codes and standards proposed for application to package testing, maintenance, quality assurance, and use will be included.

d. Summary of TSRA Sections

Synopses of each of the TSRA sections will be prepared that summarize the results of the analysis and/or testing of the packaging system. This will include a statement of the risk (consequences and frequency of potential accidents) from all hazards to the public resulting from the proposed shipment campaign.

e. Appendix

The Appendix of Section 1 should include detailed dimensional drawings of the packaging, packaging contents, overpack, tiedown, and loading configurations.

2. Structural Evaluation

Follow guidance given in NRC (1986) for structural design, weights and centers of gravity, mechanical properties of materials, general standards for all packages (include all subsections of 10 CFR 71.43), and lifting and tiedown standards (10 CFR 71.45).

For NCT assess packaging system performance through test or analysis to conditions specified in 10 CFR 71.71, "Normal conditions of transport." The packaging system, including payload, payload container, overpack (if applicable), tie-down system, and external packaging, if applicable (e.g., TSS), should be assessed against each condition separately and a

determination made that the applicable performance requirements specified in the regulations have or have not been satisfied. If they have not been satisfied, provide a safety basis and justification for package use. For NCT, the assessment should consider package only (contents plus container/overpack), it should not take credit for tie-down system or SST/SGT. Same comment applies for thermal evaluation.

For hypothetical accident conditions, assess packaging system performance through test or analysis to conditions specified in 10 CFR 71.73, "Hypothetical accident conditions." The packaging system should be assessed against each condition in the sequence specified by the regulations. A determination should be made that the applicable performance requirements specified in the regulations have or have not been satisfied. If they have not been satisfied, provide packaging system failure thresholds or equivalent for use in the PRA. Please note that there is a need to clearly define the packaging system. This will simplify the analysis, as it is preferable to evaluate the package alone if possible.

The tests should conform to the initial conditions specified in Regulatory Guide 7.8.

### 3. Thermal Evaluation

Follow the guidance given in NRC (1986) for thermal evaluation. For NCT and HAC assess packaging system performance through test or analysis to conditions specified in 10 CFR 71.71 and 71.73, respectively. Evaluate the packaging system performance with respect to the results of the thermal analysis or tests. Compare the results with allowable limits of temperature, pressure, etc., of the package components and determine if the applicable performance requirements specified in the regulations have or have not been satisfied. If NCT allowable limits have not been satisfied, provide a safety basis and justification for package use. If HAC requirements have not been met, provide packaging system failure thresholds or equivalent for use in the PRA. Knowledge of the packaging system failure threshold may be compared to a fully compliant package, which helps to establish a safety basis. This helps the reviewer to identify the margin of safety and further establishes a justification for use of the package.

### 4. Containment

Identify the containment boundary (if applicable), penetrations, seals, welds, and closure devices. Determine compliance with 10 CFR 71.51, "Additional requirements for Type B packages," for NCT and HAC using ANSI standard 14.5-1997 and the performance of the packaging system following application of normal and accident conditions as determined in the structural, thermal, and PRA sections. If the package is not compliant with 10 CFR

71.51, provide a safety basis and justification for package use. In the case of NCT, the safety basis may be provided from historical data and/or test data (e.g., stockpile sampling). For HAC, noncompliance with containment requirements may be addressed in the PRA. If there is not a leak-testable containment boundary then additional emphasis should be placed on the content and any potential dispersal.

## 5. Shielding Evaluation

Following the outline provided in NRC (1986), give an analysis to demonstrate compliance with 49 CFR 173, "Shippers—General Requirements for Shipments and Packagings;" 173.441, "Radiation level limitations;" and 10 CFR 71.47, "External radiation standards for all packages." Include determination of a transport index.

## 6. Criticality Evaluation

This section is to follow the general outline of NRC (1986) updated by incorporating 10 CFR 71.55, "General requirements for fissile material packages," and 71.59, "Standards for arrays of fissile material packages." Credible HAC for use in modeling should be adopted from the results of the structural, thermal, and PRA sections. All fissile material package requirements should be discussed. If the packaging system does not meet the requirements for NCT or HAC, a safety basis and justification for use must be provided. If HAC requirements cannot be met, the PRA section must predict the likelihood that the component might be subjected to the conditions required to achieve a potential criticality event during the entire duration of the transportation campaign and justification for packaging system use. If possible, a criticality transport index must be calculated.

## 7. Operating Procedures

Provide a list of operating procedures per NRC (1986). Any special procedures that result from the PRA should be included. Note that any special requirements should be highlighted.

## 8. Acceptance Tests and Maintenance Program

This section should include descriptions of acceptance tests (if applicable) and maintenance program elements to be used on the package in conformance with NRC (1986).

## 9. Quality Assurance

This section should document the shipper's quality assurance program and its implementation for all manufacturing phases of the package. It should also address the implementation of the quality assurance program in the

preparation of the payload for packaging, determination of the radioactive material contents, loading, unloading, tiedown, maintenance, and transportation.

## 10. Probabilistic Risk Assessment

This chapter provides an assessment of public risk attributable to the proposed shipping campaign. An assessment of the frequencies of accidents and the consequences of those accidents to members of the public is required. The Probabilistic Risk Assessment chapter should include details on the shipping campaign, the number of units in a shipment, number of potential shipments, routes (or generic routes if specific information is not available), and any other campaign information that would have potential impact on public safety or the environment.

The PRA should determine consequences and frequencies of accidents using input from structural, thermal, containment, and criticality analyses of the packaging system as appropriate. The significant potential hazards (flammable gas, explosives, toxic, hazardous when wet, and etc.) in the package payload should be considered in the PRA with the dominant contributors to accident frequency and consequences identified. Other potential accidents that the 10 CFR 71 addresses may be considered given any unique transportation environments.

A composite summary of the risk to the public presented by the shipping campaign should be provided. The PRA should estimate the frequency and consequences of potential accidents. The PRA should include sensitivity/uncertainty information to support decision-making and development of administrative controls and operating procedures, where appropriate. Risk may be subdivided by accident type (for instance, criticality versus particulate dispersion) or hazard type (radiological versus toxicological). Transportation authorization will be based on the estimation of composite public risk and will be decided on a case-by-case basis. The overall risk consequence should be expressed in person-rem (LCF) for a population or for the maximum exposed individual or radiation dose (mrem/h) at some distance from the source (See BWXT-12 document, Y/LF-504, Rev.1, *Effect of a Postulated Uranium Transportation Accident*, September 1999). The likely shipping configurations will have a direct impact on the assessment and the TSS may be included in the assessment for the HAC.

### **6.0 Guide for Developing TSRAs for Special Assemblies Containing Type B Quantity of SNM**

The following paragraphs identify the minimum information that should be contained in each section of the subject TSRA:

#### **1. Executive Summary.**

## 2. Revision Log.

3. Lists of figures and tables, definition of terms, and list and definition of the acronyms used in the report.
4. **Introduction** section must, at a minimum, include the following:
  - a. **Introduction** subsection that provides a short description of the purpose of the TSRA.
  - b. **Content Description** section that provides a short description and associated figures/graphic depiction of the Nuclear Explosive-Like Assembly (NELA) and its subcomponents.
  - c. **Transportation Configuration Description** section that describes each of the NELA configurations proposed for shipment and provides detailed hazardous material information (identity of material, quantity and location) for each of the proposed configurations, identification of transportation conveyance, origin and destination of each off-site transportation operation (include the specific routes that will be used during each transportation segment), start and end dates of campaign, number of shipments per year, tests and reconfigurations that will be performed at the units intermediate destinations, and packaging and/or handling equipment (H-gear) that will be used for each of the transportation segments.
  - d. **Summary of Subsequent Sections** that includes summaries of the Transportation Environment, Criticality, Shielding, Containment, Probability Risk Assessment, and Quality Assurance sections.
5. **Transportation Environment** section must, at a minimum, describe the transportation environments that are considered during each of the NELAs off-site transportation segments, include a section on how the NELA meets the 10 CFR 71.71 Normal Conditions of Transport, a section on Credible Hypothetical Accident Conditions, a section on the Analysis of the Transportation Conveyance, and a section on any other relevant information.
6. **Criticality** section must, at a minimum, provide a Discussions and Results of the criticality evaluation section; Package Fuel Loading section; Model Specifications section that includes subsections on description of calculation models, calculation model used to analyze the transportation safety critical NELA subassembly(s), single-unit packaging calculational model, array packaging calculational model, package regional densities, material compositions used in the transportation safety critical subassembly(s) calculational model, material composition used in the single-unit packaging calculational model, and material composition used in the array packaging calculational model; Criticality Calculation section that includes subsections on Calculational or Experimental Method, Fuel Loading or Other Contents Loading Optimization, Criticality Results, single –unit packaging calculational results, infinite array packaging calculational results, and conclusions; Criticality Benchmark Experiments section that includes subsections on Benchmark

Experiments and Applicability, Details of Benchmark Calculations, and Results of Benchmark Calculations.

7. **Shielding** section must, at a minimum, describe the shielding evaluation performed on the NELA. The objective of the evaluation is to demonstrate the NELA's compliance with the NCT and HAC performance requirements specified in 10 CFR 71 and 49 CFR 173.
8. **Containment** section must, at a minimum, describe the containment evaluation performed on the NELA. The objective of the evaluation is to demonstrate the NELA's compliance with the requirements of 10 CFR 71 and ANSI N14.5-1997.
9. **Probabilistic Risk Assessment** section must, at a minimum, include a bounding analysis that demonstrates that the consequences resulting from a bounding credible noncriticality transportation accident scenario are acceptably low. At a minimum, the following five conservative bounding accidents must be evaluated and documented: (1) direct radiation exposure; (2) exposure of hazardous materials released by a fire; (3) effects associated with the release of potential energy by a fire; (4) release of hazardous materials into a waterway and uptake into drinking water supply; and (5) hazards associated with explosives, if applicable.
10. **Quality Assurance** section must, at a minimum, provide a description of the NELA's Preparation and Test Procedures. The Preparation and Test Procedures shall include information on the NELA assembly process, each of the tests performed with the NELA, the post-test recovery procedures of each test and the associated reconfiguration process between the tests, and the planned disposition of the NELA after the completion of the final test.

## 7.0 Guide for Developing HARs

HARs and their associated transmittal memoranda are used to request authorizations for off site shipments of special assemblies that contain either a Type A quantity of RAM or no RAM ( e.g., Type A quantity RAM and other hazardous materials or no other hazardous material, or no RAM but other hazardous materials, or no hazardous materials but must be shipped via the TSS). The HAR must contain the following:

1. Identity of current OTA that applicant believes the "new" unit should be covered by, if applicable.
2. The high-level part number and high-level graphic number for the proposed configuration.
3. Copy of drawing(s) that define the proposed configuration.
4. The identity of the container or handling gear in which the unit will be shipped. If the tie-down procedures for the proposed configuration are not contained in TP45-51D or the DOE tie-down manuals, the applicant must submit the proposed tie-down procedures, the analysis performed to verify the adequacy of the proposed tie-down procedures and the associated

documentation for the proposed procedures to the OST and a copy included in the data package submitted to DOE/NNSA PCD.

5. Indicate whether the shipments will be only pre-test or both pre-test and post-test.
6. The identity of the unit's point of origin, destination and intermediate locations, if applicable.
7. A list of all components that contain hazardous material, and the identity of the hazardous materials and the associated quantity of each hazardous material contained in each of the components.
8. The component's MC number and Part Number (P/N). If no MC number is associated with the component, the applicant must provide the component's name and the P/N.
9. The applicable DOT and TP 20-11 designators for components that contain explosives.
10. For post-test units, indicate the planned status of each component that contains hazardous material. Indicate whether a component that contains hazardous material will be fired, unfired, or unchanged as a result of the planned test. Provide a copy of the approved pretest and post-test procedures that will be used to ensure that the special assembly is safe to package and ship for review.
11. An analysis of the potential hazards and associated consequences posed by the hazardous material in the proposed shipping configuration(s).

The HAR shall be submitted to arrive at DOE/NNSA PCD no later than 60 days prior to the OTA need date.

# **APPENDIX C**

## **Guide for Developing SERs, OTAs and OTCs and Description of TSRP Process**

## 1.0 Introduction

The guidance provided in this Appendix is intended to assist the PCD CEs and to communicate to the customers documentation that must be developed and maintained in support of Type B package certifications and offsite transportation authorizations. The SER serves the following functions:

- A. Provides a description of the package design, if applicable.
- B. Documents the results of the SARP and/or TSRA review and confirmatory analysis, or the results of the analysis of the HAR.
- C. Confirms that the methodology, assumptions, and technical data used are in compliance with safety standards and regulations.
- D. Identifies packaging design deficiencies or SARP/TSRA and how they were resolved.
- E. Documents restrictions on the use of the packaging/shipment that will be repeated in the OTA/OTC.
- F. Provides the basis for recommending approval or disapproval of the OTA/OTC.

A SER is not required for a NRC/DOT approved package, and may not be required for a “package” that contains no hazardous material, or the hazardous material contained in the “package” presents very little risk and the hazardous materials are fully documented in the OTA.

## 2.0 Guide for Developing SERs for Type B Packages

NUREG-1609, *Standard Review Plan for Transportation Packages for Radioactive Material* contains guidance for reviewing SARPs and a format and content for documenting those reviews. Copies of NUREG-1609 can be obtained from the Nuclear Regulatory Commission Web Site located at [www.nrc.gov](http://www.nrc.gov) or by going directly to [www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1609/](http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1609/).

The SER should describe how the package and SARP conform to the specifications provided in Regulatory Guide 7.8, NUREG/CR-3019 and NUREG/CR-3854.

## 3.0 Guide for Developing SERs for Type A Packages and Special Assemblies that contain No SNM or Less than Type B Quantity of SNM

### 1. General Information

This section should state the following:

“The applicant’s request, Reference number, for a new OTA or OTA revision for the off-site shipment of SA BXX-X YYY (the weapon designator and the Joint Test Assembly (JTA), Joint Test Subassembly (JTS), Flight Test Unit (FTU), Laboratory Test Unit (LTU), etc. SA designators) and its supporting HAR,

Reference number, were reviewed in accordance to DOE Order 461.1A and SG 500.” “Because the amount of radioactive material in this unit is not a Type B quantity, a Transportation System Risk Assessment is not required.”

“The hazardous material information provided in the HAR has been reviewed and has been determined to be acceptable for issuing the OTA. This SER supports OTA **DOE/NNSA/XXXXXX/JTA**. If the SER is a revision of a previous SER, this paragraph should identify the reason for changing the SER and OTA (e.g., change of authorized SA, changes of components or their hazardous material constituents, changes in shipping configurations or mode of transport, etc.).”

## 2. Description of Units

This section should provide the following:

“The special assemblies addressed in this SER are NELAs.”

This section should indicate whether the SA(s)/SA variant(s) addressed in this SER will be pre- and post-test configurations or just pre-test or just post-test, and shall also identify the handling gear or packaging for each of the configurations authorized.

This section should also provide a short description of the SA variant(s) addressed in the SER, and each of the delivery modes that the SA(s) may be tested under and what the physical differences among the units are for the different delivery modes.

This section should also list the shipments origination and destination points and the modes of transportation that are authorized and any modes of transportation that are prohibited

## 3. Drawing Definition

The following table lists the SA variant and its associated top level drawing and part numbers:

SA Variant	Top Level Part/Drawing Number
BXX JTA 10	678945/AY92854*

\* Used for example purposes only

Notes to convey other information may be used to supplement this table.

## 4. Hazardous Materials Analysis

This section should provide the following:

“The pre-test and planned post-test (if needed) TP 20-11, Reference Y, hazardous materials categories/designators for the SA variant(s) addressed in this SER are provided in the following Table.”

Pre-test and Post-test (if shipment of post-test configuration is planned) BXX-X JTA 10 (the weapon designator and the JTA, JTS, FTU, etc. SA designators) TP20-11 Hazardous Materials Categories/Designators		
SA Variant	Pre-test Categories/Designators	Planned Post-test Categories/Designators (if needed)
BXX-X JTA 10	Category/designator from TP 20-11	Category/designator from TP 20-11

Notes to convey additional information may be used to supplement this table.

“The hazardous materials contained in the SA(s) addressed in this SER are contained within DOE/NNSA components and are packaged in strong, tight envelopes that will not release any of the hazardous materials during conditions normal to transport. For post-test units, the test engineer is required by the OTA to inspect the unit to ensure that it is in a condition that is safe to transport prior to offering the unit for shipment.”

“The following table lists SA variant(s), the identity of every component that contains hazardous materials and its association with the SA variant(s), the planned post-test (if applicable) status of each of the components, and the identity and quantity of each of the hazardous materials constituents of each component. Part numbers are required for all units built at or shipped to the Pantex Plant.”

SA Hazardous Materials*					
Component	Hazardous Material Description and Quantity	Planned Post-test Status	Variant (To which the listed component applies)		
			JTA 1	EFI-A	JTA2
Identity of Major Subassembly (e.g., JTA2 Telemetry Assembly)					
MC XXXX Actuator (Part Number)	X.X mg Explosive A	Expended			X
MC XXXX (Part Number) <b>or</b> MC YYYY (Part Number)	X.X g Lithium  X.X g Lithium/Mercury Compound	No Change  No Change	X		X
Identity of Major Subassembly (e.g., Witness Plate Assembly)					
MC XXXX (Part Number)	XXX mg Explosive Z	Expended		X	

\*The information contained in the table is for examples only.

Notes to convey additional information may be used to supplement this table.

## 5. Packaging and Transportation

“The pre-test BXX-X (and other SA(s) addressed in the SER) are transported in the HXXXX Bomb Cradle and are secured in the transport conveyance using XXXXXX (e.g., TP 45-51, Technical Manual *Tiedown Procedures for Type-B Containers Shipped in Safe-Secure Trailer/Safeguards Transporter (SST/SGT)*, and/or Technical Manual *DOE/TSD Aircraft Cargo Tiedown Manual*, as applicable).”

After the BXX-X (and other SA(s) addressed in the SER) undergoes the planned test, the Sandia test director shall determine whether the test was normal and utilize the Sandia procedure SPXXXX (e.g., SP472837, *B83 Joint Test Assembly and Type –3E Post-test Inspection at the Tonopah Test Range*) to recover the unit. The procedure outlines the hazards posed by the unit and methods used to recover the unit(s). It is also used to inform personnel of the external hazards that exist or may exist after a normal and abnormal test. DOE/NNSA PCD must be notified prior to offering the post-test unit for shipment anytime observations during the test or the post-test inspection indicate that the unit experienced an abnormal test. DOE/NNSA PCD shall perform a safety assessment of the unit and authorize its shipment before it can be offered for shipment. The DOE/NNSA PCD assessment may include the development and imposition of additional administrative measures that are designed to mitigate the hazards associated with the post-test unit.

This section will also identify applicable transportation restrictions (e.g., “The pre-test and post-test shipments will be made via the TSS”. “These units shall be transported via ground transport only.”).

## 6. Conclusions

This section should provide a recommendation to approve or disapprove the OTA request (e.g., “The risk posed by the shipment of these units is within the safety and security bases of the TSS and should be authorized.”).

## 7. References

This section should list the memorandum submitted to request the OTA or OTA revision, the HAR, applicable tiedown manuals, TP 20-11 and all other publications used to develop the SER.

### **4.0 Guide for Developing SERs for Special Assemblies that Contain Type B Quantity RAM**

The SER for SAs that contain Type B quantity of RAM is a hybrid of a SER for a TSRA as described in Section 2 of this Appendix and for a HAR as described in Section 3 of this Appendix and must address all of the areas addressed by those two types of SERs.

### **5.0 TSRP Process**

The PCD Manager, in coordination with the PCD staff and in advance of the start of a TSRP review:

- A.** Establishes procedures to witness/inspect any field performance tests on which the determination of packaging adequacy is based.
- B.** Witnesses/inspects any field performance tests on which the determination of packaging adequacy is based.
- C.** Ensures that all procedures required by DOE/NNSA contractor QAPP are identified to the TSRP.
- D.** Verifies that the contractor-performed inspections that will be used during package processing are documented in the procurement paperwork (10 CFR 71.109). This documentation is required from DOE Category A or B vendors and should include the vendor's quality assurance plan and other quality assurance records (10 CFR 71.101-105). These documents should be available for review by DOE/NNSA upon request (10 CFR 71.101-105), and should show in-depth, clear compliance with regulatory and/or standards and criteria requirements (10 CFR 71.101-105).

E. Assigns organization that will perform the confirmatory review.

The applicant submits one copy of the draft SARP/TSRA to the Package Line Manager/Weapons System Program Manager, as applicable, and four copies to the recipients identified on a list provided by DOE/NNSA PCD. TSRP chairperson convenes the TSRP.

TSRP conducts review and reports the results.

## **6.0 Guidance for Developing OTAs and OTCs**

An OTA may be issued for a one-time shipment or for a transportation campaign covering a period of time not to exceed five years. An OTC may be issued for a period of time not to exceed five years. Each OTA/OTC is assigned a unique number and that number will not change throughout the life of that particular OTA/OTC. The original version of each OTA/OTC is assigned revision number zero and each subsequent change to the OTA/OTC will result in a change to the revision number. Section 3 of the OTC must list the SARP and supporting documents (for OTCs), or the TSRA (if applicable) and/or HAR (for OTA), and applicant's correspondences and/or other documents that contain data/information relative to the operations authorized by the OTA/OTC. Section 7.a shall provide a short description of the packaging/handling gear. Section 7.b shall identify the contents that are authorized to be shipped under the OTA/OTC. Information in this section and/or in the documents that this section may refer the user to, shall be definitive and unambiguous. Section 7.c shall contain a list of transportation and handling restrictions that are applicable to the operations authorized under the OTA/OTC. For example, it will list the type(s) of off-site transportation conveyance that is authorized to perform the off-site transportation operations authorized, direct the user to secure the items in the transport vehicle using the tiedown documents specified, provide marking and labeling requirements, require the person in charge of providing security during the transportation to have a copy of the OTA/OTC, specify conditions of operation including transporter and shipment configuration, positive measures, administrative controls, and declared maximum number of specified shipments per calendar year and various other restrictions that are specific to the operations authorized under the OTA/OTC. Section 7.d may include a listing of documents such as tiedown manuals, TP 20-11 (Firefighting Guide), etc. that may be referenced in the OTA/OTC. The following OTA and OTC are provided as examples:

U. S. Department of Energy  
DOE/NNSA Service Center  
**OFFSITE TRANSPORTATION CERTIFICATE**

1a. Certificate Number  <b>DOE/NNSA/2003XX for new OTC or DOE/AL/2002XX for a revision of an OTC</b>	1b. Revision Number  - # -	1c. Total No. Pages  - # -
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2. This Certificate is issued pursuant to 49 CFR 173.7 (d), DOE Order 461.1A, Reference 7.d.1. Willful violation of the provisions of this Certificate is subject to action under Title 49 U.S.C. 1809(b).
- 
3. This Certificate is issued on the basis of the following Safety Analysis Report for Packaging (SARP), SARP supporting documents listed below, and the Safety Evaluation Report for the H1616 Package:
- a. Title and issue date of SARP.
  - b. Title and issue dates of associated documents. For example, the additional documents listed could be the SR, SARP Attachment(s), SARP Addendum(s) and the SER
- 
4. The packaging and contents described in the SARP and further described in Item 7 must meet the standards prescribed in Item 2 above.
- 
5. Containers and/or shipping papers will be identified by the Certificate Number shown in Item 1a. on this form.
- 
6. This Certificate does not relieve the consignor from compliance with applicable requirements of the regulations of the U. S. Department of Transportation or other applicable regulatory agencies except as noted in Item 7c on this form.

7. Description of Packaging and Authorized Contents, Restrictions and References:

a. **Description of Packaging:**  
Provide short description of the packaging to include the packaging's identity, composition and dimensions.. For example: AL-SX/2 (H1616-1), etc. Both consist of a stainless steel outer drum lined with a 0.5-inch thick high-performance alumina silica ceramic fiber thermal barrier and rigid polyurethane foam. An approximately 0.030 inch thick stainless steel liner that encapsulates the thermal barrier and polyurethane foam is welded to the drum. The stainless steel liner is shaped to accept a stainless steel containment vessel. The drum and outer lid are manufactured from 18-gauge 304 stainless steel. The drum's size is 16 gallons and its dimensions are 21.3 inches high and 16.4 inches in diameter. The drum lid is secured to the drum body by a stainless steel locking ring with a 0.375 diameter bolt and nut. The containment vessel is made from 304 austenitic steel. The H1616-1 containment vessel's inner diameter is 12.16 inches and its height is 14.3 inches. The H1616-2 containment vessel's inner ...

8a. Address of DOE Certifying Authority:  <p style="text-align: center;"><b>U. S. Department of Energy National Nuclear Security Administration DOE/NNSA Service Center P.O. Box 5400 Albuquerque, New Mexico 87185-5400</b></p>	8b. Signature	
	8c. Name and Title  <b>Name and title of Certifying Official</b>	
	9. Expiration Date	10. Date

#### 7.b. **Authorized Contents**

This section must provide a short description of the authorized content. The description must be sufficiently definitive to preclude anyone from misinterpreting what is authorized to be shipped under this OTC.

#### 7.c. **Transportation and Handling Restrictions**

- (1) Under the authority of DOE Order 461.1A, this shipment is made for the purpose of national security. These shipments must be escorted by personnel specifically designated by the DOE, and the OTC must be in the possession of the person in charge of providing security during transportation. These packages must be transported off site via the TSS.
- (2) These packages may be transported in – *the identity of the authorized conveyance* - (For example air and ground, ground only, etc.). For transportation via ground, the escorts shall be in a separate vehicle from that carrying the packages authorized under this OTC.
- (3) These packages shall not be transported in the same conveyance with nuclear weapons, nuclear explosives, or other DOE, NRC, or DOT-regulated quantities of hazardous material except for nuclear weapon components or radioactive material contained in certified Type B packages.
- (4) The - *identity of the package authorized under this OTC* - users must be specifically approved by the DOE/NNSA PCD prior to any use of these packages. Site specific operating procedures approved by DOE/NNSA PCD and DOE/NNSA approved QAPPs must be used for all operations with these packages. The operating procedures shall be in accordance with the SARP and – list other pertinent documents – (For example SS393218 for the H1616.).
- (5) Each package must be inspected prior to loading the authorized contents and off-site shipment.
- (6) List of package specific restrictions/requirements.
- (7) A radiological survey must be conducted on each package; validation that the survey was performed must be communicated to the package destination and retained by the shipper as part of the shipment records. Surface contamination on any part of the package must not exceed the limits specified in 49 CFR 173.443, Table 11. Emanations must not exceed the limits specified in 49 CFR 173.441. Measuring equipment used for surveys must be calibrated and of sufficient accuracy.
- (8) Exterior package marking and labeling must be legible and visible and in conformance with 49 CFR 172, Sections D and E (49 CFR 172.310 and 172.403 (c)) except that classified information shall not be revealed.
- (9) The package shall be secured in the transport conveyance in accordance with the procedures contained in the – *list of documents that contain the applicable approved tiedown procedures for the package and conveyance(s) authorized under the OTA* - (For example: *DOE/TSD Aircraft Cargo Tiedown Manual*, Reference 7.d.3, *Tiedown Procedures for Type-B Containers*, Reference 7.d.4 or TP 45-51D, Reference 7.d.5, as applicable).

#### 7.d. **References**

List DOE Order 461.1A, tiedown manuals referenced and other documents, as applicable.

U. S. Department of Energy  
DOE/NNSA Service Center  
**OFFSITE TRANSPORTATION AUTHORIZATION**

1a. Authorization Number  <b>DOE/NNSA/2003XX for new OTA or DOE/AL/2002XX for a revision of an OTA</b>	1b. Revision Number  - # -	1c. Total No. Pages  - # -
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2. This Authorization is issued pursuant to 49 CFR 173.7 (b), DOE Order 461.1A, Reference 7.d.1. Willful violation of the provisions of this Authorization is subject to action under Title 49 U.S.C. 1809(b).

3. This Authorization is issued on the basis of the following Safety Analysis Report for Packaging (SARP); SARP supporting documents 3.b, 3.c, and 3.d; the Transportation System Risk Assessment listed in 3.e; and the Safety Evaluation Report for the H1616 Package in 3.f:

**For a package:**

- a. Titles and issue dates of the SARP and TSRA.
- b. Title and issue dates of associated documents. For example, the additional documents listed could be the SR, SARP Attachment(s), SARP Addendum(s) and the SER.

**For HiFi (Contains Type B quantity of RAM) NELAs:**

- a. Title and issue date of the TSRA and the SER.

**For other (Contains Type A quantity or no RAM) NELAs:**

The title(s) and issue date(s) of the applicable HAR(s), and the SER.

4. The packaging and contents described in the Hazards Analysis Report and further described in Item 7 must meet the format and content specified in SG 500 for special assemblies or nuclear component shipments.

5. As appropriate, containers and/or shipping papers will be identified by the Authorization Number shown in Item 1a. on this form.

6. This Authorization does not relieve the consignor from compliance with applicable requirements of the regulations of the U. S. Department of Transportation or other applicable regulatory agencies.

7. Description of Shipment and Authorized Contents, Restrictions, and References:

a. **Description of Packaging:**

This section must provide a short description of the packaging or handling gear and configurations authorized under this OTA.

8a. Address of DOE Certifying Authority:  <p style="text-align: center;"><b>U. S. Department of Energy National Nuclear Security Administration NNSA Service Center P. O. Box 5400 Albuquerque, New Mexico 87185-5400</b></p>	8b. Signature	
	8c. Name and Title <b>Name and title of Certifying Official</b>	
	9. Expiration Date	10. Date

7.b. **Authorized Contents**

This section must provide a short description of the authorized content. The description must be sufficiently definitive to preclude anyone from misinterpreting what is authorized to be shipped under this OTA. For NELAs this paragraph should include the unit’s high-level part and drawing number.

7.c. **Transportation and Handling Restrictions**

- (1) Under the authority of DOE Order 461.1A, this shipment is made for the purpose of national security. These shipments must be escorted by personnel specifically designated by the DOE, and the OTA must be in the possession of the person in charge of providing security during transportation. These – *identity of the packages or NELA, as applicable* - must be transported off site via the TSS.
- (2) These – *identity of the packages or NELAs - may be transported in – the identity of the authorized conveyance* - (For example air and ground, ground only, etc.). For transportation via ground, the escorts shall be in a separate vehicle from that carrying the packages authorized under this OTA.
- (3) These – *identity of the packages or NELAs, as applicable* - shall not be transported in the same conveyance with nuclear weapons, nuclear explosives, or other DOE, NRC, or DOT-regulated quantities of hazardous material.
- (4) For Packages:

The - *identity of the package(s) authorized under this OTA* - users must be specifically approved by the DOE/NNSA PCD prior to any use of these packages. Site-specific operating procedures approved by DOE/NNSA PCD and DOE/NNSA approved QAPPs, must be used for all operations with these packages. The operating procedures shall be in accordance with the SARP and – *list other pertinent documents* – (For example SS393218 for the H1616.).

Each package must be inspected prior to loading the authorized contents and off-site shipment.

List of package specific restrictions/requirements.

- (5) For NELAs:

The shipper and receiver are both responsible for ensuring that the receiving site is authorized to receive the type of NELA proposed for shipment prior to offering the NELA for shipment.

This section of the OTA must list the TP 20-11 hazardous material designators/categories that are applicable to each of the NELAs variants and configurations authorized under this OTA. For example:

NELA Variant	TP 20 –11 Hazardous Material Designators/Categories	
	Pre-test	Post-test
BXX-4 JTA2	E-3, E-4, R-3	R-3

- (6) A radiological survey must be conducted on each package/NELA; validation that the survey was performed must be communicated to the package destination and retained by the shipper as part of the shipment records. Surface contamination on any part of the package must not exceed the limits specified in 49 CFR 173.443, Table 11. Emanations must not exceed the limits specified in 49 CFR 173.441. Measuring equipment used for surveys must be calibrated and of sufficient accuracy.
- (7) Exterior package marking and labeling must be legible and visible and in conformance with 49 CFR 172, Sections D and E (49 CFR 172.310 and 172.403 (c)) except that classified information shall not be revealed.
- (8) The package or NELA, as applicable, shall be secured in the transport conveyance in accordance with the procedures contained in the – *list of documents that contain the applicable approved tiedown procedures for the package and conveyance(S) authorized under the OTA* - (For example: *DOE/TSD Aircraft Cargo Tiedown Manual*, Reference 7.d.3, *Tiedown Procedures for Type-B Containers*, Reference 7.d.4 or TP 45-51D, Reference 7.d.5, as applicable).

7.d. **References**

List DOE Order 461.1A, tiedown manuals referenced and other documents as applicable.

**Appendix D**

**PCD**

**Surveillance Process**

## **1.0 Introduction**

Surveillance is the act of monitoring or observing to verify whether an item or activity conforms to specified requirements.

This surveillance process provides the mechanism for PCD to ensure that the users of its products (certified packages, OTA, OTC, etc.) have programs and processes for ensuring that the requirements specified for the use of the PCD products are correctly implemented. This surveillance process is also designed to meet PCD oversight responsibilities specified in DOE Order 461.1A.

## **2.0 Surveillance Process**

As the DOE/NNSA organization responsible for DOE/NNSA package certifications and offsite transportation authorizations, PCD has the responsibility to ensure that the users of these certified packages and authorizations comply with the requirements contained in DOE/NNSA Orders, federal requirements, SARPs, SERs, OTCs and/or OTAs, and other supporting documents. The PCD will perform surveillances of OTC and OTA users on an as needed basis. The following information is provided to guide PCD in the performance of their surveillance responsibilities:

### **A. Activities of PCD Manager:**

1. Maintain cognizance of OTA and OTC users performance and their compliance with the requirements specified for their use and conduct surveillances of user sites as needed.
2. Appoint Surveillance Team Leader and members when required.
3. Meet with Surveillance Team Leader to assign and provide guidance on tasking.
4. Review and approve Surveillance Team's surveillance plan for high profile/complex surveillance assignments, as needed.
5. Approve surveillance report for distribution, and determine distribution recipients.
6. Oversee post-surveillance activities until all issues have been resolved.

**B. Activities of Surveillance Team Leader:**

1. Pre-surveillance Activities:

- a. Review the requirements for the area(s)/activities which will be the focus of the surveillance.
- b. Develop surveillance plan that contains a checklist and proposed initial inquiries for the areas which will undergo the surveillance.
- c. Identify principal point of contact and subject matter points of contact at the site undergoing the surveillance.
- d. Develop draft agenda.
- e. Work with the site's principal point of contact to finalize agenda and to pair the surveillance team members with the site's subject matter points of contact at specified times.
- f. Present proposed plan to PCD Manager for approval.
- g. Provide copies of agenda, surveillance plan and subject matter/team member pairings to the site's principal point of contact and the surveillance team members.

2. On-site Surveillance Activities:

- a. Conduct in-brief for the surveillance team, and the site's points of contact and management to convey the purpose of the surveillance, the areas to be reviewed and the responsibilities of the participants.
- b. Perform surveillance as scheduled.
- c. Keep PCD Manager advised of surveillance activities.
- d. Conduct out-brief for surveillance team, and site's points of contact and management to convey the outcome of the surveillance.

3. Post Surveillance Activities:

- b. Prepare surveillance report and distribute to the PCD Manager and the management of the site that underwent the surveillance.
- c. Lead post-surveillance activities until all issues have been resolved.

# **Appendix E**

## **PCD Web Page**

## **1.0 Introduction**

The Web Page provides tables that lists the current OTCs , OTAs and their respective issue and expiration dates, applicable SARPs and/or TSRAs, graphics of applicable certified containers, approved package users, and the DOE/NNSA Service Center points of contact for the Web Page.

The guidance provided in this Appendix is to assist the PCD maintain a Web Page that contains information that is useful to our customers, and is current and accurate. The PCD is committed to maintaining a Web Page that provides a wide array of useful information to our customers.

## **2.0 Web Page Master Responsibilities**

- A.** Revise Web Page as needed by using Microsoft FrontPage software to update Web Page files.
- B.** Notify the Albuquerque (AL) Publish group via e-mail when any Web Page file is updated and ask them post the change to the Web Page.
- C.** Notify Web Page customers via e-mail of any significant changes to the Web Page.

## **3.0 Modifying Data on Web Page**

- A.** Activate FrontPage Software
- B.** Open NNSA-OTA Web Page
- C.** Double Click on folder that contains the data that must be changed
- D.** Change the data as needed
- E.** Save file with changes
- F.** Close and exit FrontPage
- G.** Send e-mail message to Publish group to inform them that you have made changes to the NNSA-OTA Web Page files and ask them to post the changes.

### **3.1 Linking Certified Container Designator in OTC File (table) to File that Contains Container Information**

- A.** Activate FrontPage Software

- B. Open NNSA-OTA Web Page
- C. Double Click on OTC\_update.htm
- D. Double Click on container designator that needs to be linked to its data sheet
- E. Select *Create or Edit Hyperlink*
- F. Go to Container ID Folder
- G. Highlight file that contains the container data
- H. Click OK
- I. Save
- J. Notify the Albuquerque (AL) Publish group via e-mail when any Web Page file is updated and ask them post the change to the Web Page.

#### **4.0 CEs Responsibilities**

- A. Notify Web Master of OTA/OTC undergoing review/revision.
- B. Provide the following information to the Web Page Master when new or revised OTCs/OTAs are issued:
  - 1. OTA/OTC number, OTC/OTA revision number, issue date, expiration date, plus the following:
    - a. For current OTC: changes in SARP owner, changes in SARP revision (SARP identifying information), Sites approved to perform packaging maintenance, Sites approved to provide packaging supplies, and number of packagings in service.
    - b. For new OTC: SARP owner, SARP identifying information, Sites approved to perform packaging maintenance, Sites approved to provide packaging supplies, number of packagings manufactured, number of packagings in service, package's highest approved gross weight, empty weight, external height and diameter and cavity height and diameter, and electronic graphic of the packagings.
- C. Provide updates to the Web Master any time they lead activities that result in changes to the information contained in the PCD Web Page.

## **5.0 Web Page Users Services and Responsibilities**

### **A. Refer to Web Page to determine:**

1. Current OTAs and OTCs, their revision numbers, issue dates and expiration dates.
2. Organizations that are Authorized Users of a specific OTC and associated certified package.
3. Brief descriptions of DOE/NNSA certified packagings.
4. Basic dimensions, and maximum approved gross and empty weights of DOE/NNSA certified packagings.
5. Sites approved to perform maintenance on DOE/NNSA certified packagings.
6. Sites approved to provide supplies for DOE/NNSA certified packaging.
7. SARP owner and identification of current SARP.
8. Number of certified packagings manufactured.
9. Approximate certified packagings in service.
10. Information to indicate that a current OTA/OTC is undergoing review/revision.

### **B. Provide PCD suggested changes and/or additions to the information contained in the Web Page.**

### **C. Contact the PCD Web Page Master with any questions via the e-mail or telephone listed on the Web Page.**

# **Appendix F**

**Guide  
for  
Developing a Scope of Work (SOW)  
and for  
Developing the Support Contractor's Monthly Report**

## **1.0 Introduction**

The guidance provided in this Appendix is to assist the PCD in developing scopes of work for technical support contractors, and to provide guidance to the technical support contractor on the required content of the Monthly Activity Report.

## **2.0 Scope of Work Outline**

The following outline should be used by the PCD to develop a SOW for tasking contractors.

Objective: Reference to DOE Order 461.1A, guidance and standards, support for organization, workspace, security classification level of tasks, computer skills, document storage requirements.

Scope and Technical Requirements: a break out of specific elements included in the task.

Background: providing subject matter experts for specific support.

Tasks: Describe each functional task

Travel: Indicate locations where travel is expected to perform the tasks.

Security Clearance: Requirements for clearance level needed (i.e., "Q" or "L") and Need to Know and locations where work is performed.

Schedule and Deliveries: Period of performance with an identification of fiscal years for tasks.

Key Personnel: Identify essential technical personnel that are required to perform the tasks that will be required by the SOW.

Level of Effort: The number of hours assigned to the task involved.

Cost Estimate: by fiscal Year.

## **3.0 Support Contractor's Monthly Report Outline**

The following outline should be used by PCD support contractor to develop their required monthly activity report.

Reference assigned tasks.

Scope, Schedule, and Status of Deliverables:(Usually in a table format).

Cost Summary: (By fiscal year (FY) funds provided for the approved Work Scope, any prior FY carry-over funds, funds approved for the assigned task, and funds expended during the monthly reporting period, as well as cumulative totals to date, - usually a table).

Open Items and Status of Work: (By task providing only a highlight sentence).

Distribution: Program Manager and each Project Engineer that the task supports.

# **Appendix G**

## **DOE/NNSA PCD Quality Assurance Program Plan**

## **SECTION 1.0 INTRODUCTION**

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### **1.1 Purpose**

The DOE/NNSA PCD is responsible for the Type B packaging certification program, and for reviewing and recommending approvals or disapprovals of requests for offsite transportation authorizations.

NRC regulations in 10 CFR 71, Subpart H, Quality Assurance, require that users of Type B packaging have an approved quality assurance program that meets Subpart H requirements. 10 CFR 830.120 and DOE Order 414.1A require that DOE organizations/elements develop their QAPPs by applying the quality assurance criteria using a graded approach. DOE Order 414.1A also endorses the use of a single integrated quality assurance program to satisfy the requirements for the regulated work, and any additional quality requirements imposed by DOE elements, and the requirements of DOE Order 414.1A.

### **1.2 Scope**

This QAPP applies to the DOE/NNSA PCD's organization and programs. The overall management systems for the administration and operation of this organization are provided by DOE/NNSA and Service Center policies and procedures developed to meet the requirements of this QAPP, applicable DOE Orders, regulatory and industry documents, and good management practices.

This program description contains the quality requirements necessary to meet the requirements of 10 CFR 830.120, DOE Order 414.1A, and 10 CFR 71 Subpart H, Quality Assurance.

### **1.3 Graded Approach**

This QAPP was developed on the premise that the degree of application of the program is based on a graded approach to quality commensurate with the identified risk associated with the failure of items, processes, or services as related to the safety of employees or the public; protection of the environment; and achievement of DOE/NNSA programmatic missions. Management controls are applied consistent with consideration of risk and cost associated with the activity.

### **1.4 Integrated Safety Management (ISM) Relationship**

The elements of this QAPP are intended to be fully consistent with and supportive of DOE/NNSA Integrated Safety Management Program functions and principles. This QAPP details the methodologies employed to do work processes safely, securely, and in accordance with established procedures.

## **SECTION 2.0**

### **QUALITY ASSURANCE PROGRAM**

---

#### **2.1 Quality Policy**

It is the policy of PCD to provide reliable quality-based products and services in a cost-effective manner. The PCD is committed to meeting and exceeding both internal and external customer's requirements and expectations by focusing on problem prevention and providing quality improvement in all of its products and services. This QAPP applies to those services, projects, and activities that may have an impact upon the accomplishment of the DOE/NNSA mission objectives, the safety of personnel, and the protection of the public and the environment.

#### **2.2 Program**

This document is responsive to, and meets the requirements of ,10 CFR 830.120 and DOE Order 414.1A. It focuses on quality improvement by using management systems for planning, performing, controlling, and evaluating work. This QAPP has been developed and implemented to address the commitments contained in the requirements documents and will be maintained as required.

This document is the basis of the PCD quality assurance program. This program is based on a business strategy, philosophy, and commitment that emphasizes the continuous improvement of DOE/NNSA PCD products, services, and processes and actions that are intended to increase the satisfaction of both its internal and external customers. The PCD does this by empowering its staff through the use of teamwork among its members and customers, and by establishing and ensuring the attainment of well-defined, measurable goals that support the success and quality of its products and services. The PCD management has the authority, responsibility, and accountability for establishing/maintaining management systems that are consistent with the requirements of this document and that will ensure its continued successful implementation.

The PCD management is responsible for ensuring that the requirements of the quality program are appropriately adopted in programs and procedures and are communicated and understood by appropriate personnel.

## **2.3 Responsibilities**

- A.** Senior management is accountable and responsible for the development, scope and successful implementation of the quality assurance program through:
1. Providing for the development of a PCD integrated quality program that includes procedures for implementing the work.
  2. Disseminating philosophies and guidance that promote the establishment and maintenance of a workplace in which quality performance is paramount, goals are established, achievement is monitored and measured, and personnel are empowered and rewarded for mission success.
  3. Providing an integrated line and quality function that will effectively implement the quality program and ensure that work is performed in a safe and secure manner.

The DOE/NNSA Service Center management retains the primary responsibility for the scope and implementation of the DOE/NNSA Package Certification and Offsite Transportation Authorization Program including quality assurance related activities. However, individuals associated with the program are responsible for achieving quality in the activities for which they are responsible.

Senior management is to ensure that adequate resources are provided to accomplish these quality objectives.

- B.** Line management personnel are responsible for the implementation of the quality program. They are accountable for the attainment of quality and for conducting management assessments to ensure the effectiveness of the quality program. Line management is also responsible for identifying, monitoring, evaluating, and reporting measured results of selected performance indicators and achieving mission success.
- C.** The quality system establishes that employees are empowered to achieve continuous quality improvement as they perform their daily and routine tasks. Empowered employees identify and report problems in quality so that problems may be evaluated and corrective actions be initiated when necessary. Every employee has the right, obligation, and authority to “stop work” IMMEDIATELY when any operation or activity jeopardizes safety, security, health, the environment, has imminent life-threatening implications, or creates a significant condition adverse to quality. The employee notifies responsible management of the discrepant conditions so that remedial action can be taken.
- D.** For certain activities, QA specialists may be matrixed to provide support for an activity, including site observations and surveillance, quality studies, and further support dictated by the project or activity.

## **SECTION 3.0**

### **PERSONNEL TRAINING AND QUALIFICATIONS**

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#### **3.1 Introduction**

Both 10 CFR 71, Subpart H and 10 CFR 830.120 require that training programs and procedures for safety packaging and transportation of nuclear materials associated with DOE/NNSA Defense Programs be developed and implemented. This training program should ensure that all DOE/NNSA Service Center employees who support packaging certification and offsite transportation authorization requests are trained and qualified to perform their assigned work, and provide continuing training which ensures that the employee's job proficiency is maintained. These requirements may be satisfied through formal training, in-house training, seminars, on-the-job training, or educational opportunities available through outside organizations. The principal components of the DOE/NNSA PCD training program are the CE TQS and Manager TQS, and the associated Technical Qualification Cards.

#### **3.2 Responsibilities**

- A.** Management (the individuals identified in Section 2, "Responsibilities" of this guide) should ensure that DOE/NNSA PCD personnel receive on-the-job training or classroom training sufficient to enable them to perform their assigned tasks and meet the PCD CE and Manager TQS and Technical Qualification Card requirements. This should be accomplished through coordination with, and guidance from, the DOE/NNSA Service Center's Training and Development Department.
- B.** Management should commit resources to facilitate the training qualification processes, to establish qualification and training requirements for personnel in their organizations, and to ensure that personnel hired or transferred into positions meet the appropriate TQS requirements.
- C.** Management should ensure that specifications are established for each level of their organization which describe training and qualification processes, including requirements, interfaces, training methods, and the assignment of training responsibilities and duties. These specifications should comply with the guidance provided by DOE/NNSA Service Center's Training and Development Department.
- D.** Training records and written test scores should be maintained for qualified packaging and transportation personnel.

#### **3.3 Qualification of Personnel**

DOE/NNSA Service Center management is responsible for ensuring that a packaging certification personnel qualification system continues to be

implemented and maintained. The purpose for evaluating experienced packaging personnel currently supporting the packaging program and for the subsequent qualification process is to ensure that the performance levels of the individuals working in these programs are maintained at high levels. Packaging certification personnel will be re-certified at three-year intervals unless otherwise specified. Packaging certification personnel who are assigned as TSRP Chairman are selected and qualified on the basis of education, experience, and proficiency. 10 CFR 830.120, paragraph 2.3 "Qualification of Personnel" states that "policies and procedures that describe personnel selection requirements should be established for each position." DOE Order 5480.20A, *Personnel Selection, Qualification, and Training Requirements for Nuclear Facilities*, addresses "selection, qualification, and training requirements for...personnel involved in the operation, maintenance, and technical support of DOE-owned...nuclear facilities." It also states the following - "qualification is defined in terms of education, experience, training, examination, and any special requirements necessary for performance of assigned responsibilities."

### **3.4 Training**

DOE/NNSA Service Center management is responsible for ensuring that the packaging certification personnel associated with approving radioactive material packages and authorizations for offsite shipments made in the interest of national security and associated activities achieve and maintain the qualifications they need to perform their assigned work. To ensure that all identified training needs are fully met, training is obtained from a variety of sources. Training for each individual is obtained in accordance with an individual development plan or equivalent document. The contents of each individual's development plan are the result of consideration of a number of factors. These factors include the individual's unique background, the formal training and certification requirements established for a particular job and the individual's developmental needs.

This information should be reviewed annually by the packaging management and be updated as needed to provide more current, in-depth, and complete training. Special attention should be paid to maintaining the availability of training that will encourage workers to maintain and enhance proficiency. Required re-training or refresher training will also be identified and provided, as appropriate.

DOE/NNSA Service Center personnel who perform and/or control packaging and offsite transportation tasks require special training. They are to be qualified and certified as determined by the DOE/NNSA CE and Manager TQS and Technical Qualification Card and Service Center management. These special training needs should be documented in the individual's development plan or equivalent documentation. The following suggested training and the required training (shaded areas) are listed:

1. Effective Public Presentations,	
2. Effective Letter Writing,	
3. Fundamentals for DOE Operations Course,	NNSA Service Center
4. Radiation Worker Safety	SNL/NM
5. Hazardous Materials Transport 49 CFR (12 Modules),	DOE
6. Basic RAM Packaging	DOE
7. Advanced RAM Packaging	DOE
8. Social Styles, Wilson Learning,	
9. Authorized Derivative Classifier,	NNSA Service Center
10. Methods of Probabilistic Risk Assessment,	DOE/INEL
11. Nuclear Weapons Systems Safety,	LANL/LLNL/SNL
12. Nuclear Weapons Electrical Testers,	SNL/NM
13. Nuclear Weapons Design Workshop for DOE	SNL/NM
14. Containment Criteria for shipping containers	LLNL
15. Welding Criteria for Shipping Containers.	LLNL
16. SARP Reviewers Workshop	LLNL
17. Quality Assurance for RAM Packages,	LLNL
18. Design of Type B Packages Workshop,	NNSA Service Center
19. DOE Hoisting and Rigging,	DOE/Hanford
20. Communications Skills,	NNSA Service Center
21. Criticality Safety,	LANL/ORNL
22. Explosive Firing Site and Laboratory Safety Course,	NM/TECH

### **3.5 Reading File**

Because training is an ongoing process, a reading file should be established and maintained. Newly issued regulations, lessons learned and other relevant materials concerning individual work assignments should be distributed and/or readily available (electronic files/Web Pages), and their mandatory reading should be discussed in open forums and documented. This is required for DOE employees certified to the Personnel Security Program (PSP) and should be applied as appropriate to non-PSP staff.

### **3.6 Records**

10 CFR 830.120 and 10 CFR 71, Subpart H require that records that reflect the results of training and qualification activities are maintained. These records should be compiled into a records management system that ensures the records are auditable.

DOE/NNSA Service Center training should be documented in accordance with Section 4.0 of this Appendix and according to the DOE/NNSA Training Coordinator protocols.

Objective documentation of personnel job proficiency, both satisfactory and unsatisfactory, should be maintained for the duration of the project or activity affected, or longer if required by statute.

## **SECTION 4.0**

### **PROGRAM IMPROVEMENT**

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#### **4.1 Introduction**

As stated in DOE G 414.1-2, *Quality Assurance Management System Guide*, an effective planned and implemented quality assurance management system is one that:

- A.** Uses feedback information to improve items, services, and the processes that produce them.
- B.** Prevents or minimizes quality problems.
- C.** When necessary, corrects problems that occur.

DOE/NNSA PCD programs and procedures provide systems for continually pursuing quality improvement by reducing the variability of activity results and through promotion of problem prevention, identification, and correction. The PCD has established and implemented systems to detect and prevent quality problems. It emphasizes problem prevention, problem correction, and continuous improvement. This strategy consists of these elements: worker involvement, goal setting, measurement, feedback, and teamwork.

A no-fault environment is promoted in which all personnel have the freedom (and are expected) to identify potential problems and nonconformances and recommend improvements without fear of reprisal.

#### **4.2 Activities**

Work product should be checked to ensure conformance with the approved management system controlling that work activity. Services and products that do not meet established requirements are identified, controlled, and corrected according to the importance of the problem and the work affected. Personnel that are responsible for analyzing and dispositioning non-compliances are required to have an adequate technical understanding of the noncompliance and have access to pertinent information associated with the noncompliance. Included within the management control system is the corrective action planning, tracking, validating, verifying, and closing of issues. Root cause analyses are performed in accordance with procedures, to identify basic causal factors to prevent recurrence of the problem.

## SECTION 5.0 DOCUMENTATION AND RECORDS

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### 5.1 Introduction

In accordance with 10 CFR 830.120, 10 CFR 71, Subpart H and DOE Order 414.1A requirements, a proceduralized document control and records management system is required to support the DOE/NNSA Package Certification and Offsite Transportation Authorization Program and other nuclear weapons program functions. Such a system should establish and maintain sufficient written records that describe the Defense Programs activities in a cost-effective manner and are consistent with the applicable regulations.

Features of the system include limiting access by unauthorized persons; providing protection from misuse or natural disasters; ensuring efficient document issuance, distribution, record storage, retention, and prompt retrieval; as well as providing preservation, or disposition of records according to schedules modeled after the National Archives and Records Administration (NARA) Guide and General Records Schedule (GRS) directives. Retention of records is specified for three years beyond the date when the activity was last performed. Superseded procedures or instructions must be retained for three years after the superseding material is issued.

**NOTE:** A **document** is any recorded information that specifies, describes, defines, reports, or certifies activities, requirements, procedures, or results. Documents include plans for important activities to be accomplished. A document is a working instrument that may be revised and reissued as needed before being declared a quality record. A document is not considered a record until it meets the definition of a record (10 CFR 830.3(a)). A **record** contains information that is retained for its expected future value. Records should be sufficient to support technical and regulatory decisions. Records may be in a variety of forms (e.g., electronic, written or printed, microfilm, photographs, radiographs, optical disks, and etc.).

### 5.2 Documents

Documents are required by DOE/NNSA to control policy and administrative and/or technical information. A document may describe work to be done, data to be used at different locations or by different people, or, in changing situations, data to be controlled from time to time for reference purposes. Documents that will not become records may be managed at the discretion of the responsible manager or supervisor. Documents should be controlled in accordance with written and approved procedures and instructions. Procedures and instructions must ensure that documents, including changes, are reviewed for adequacy and approved for release.

## **A. DOE/NNSA PCD Documents**

### **1. OTC/OTA Documents**

The PCD Manager should maintain a master packaging records file for each packaging OTC and OTA. The master files should include but not be limited to the following documents:

- a. Final packaging SARP or TSRA as appropriate and any subsequent amendment or revisions of the document or the OTC/OTA.
- b. The request for the new packaging.
- c. The packaging production specifications and design drawing package including special fixtures inside the packaging and/or the shipment vehicle.
- d. Packaging specifications for active packaging procurements.
- e. Results of any subsequent reviews of amendments or revisions to SARPs, TSRAs, and packaging or transportation related criteria.
- f. Updated list of users for specific packaging and their authorization for use.
- g. Maintenance, safety, and quality assurance records, including the contractor's QAPP.
- h. Modifications to the package including requests to DOE/NNSA for Quality Category design changes.
- i. Safety Evaluation Report.
- j. Other pertinent information, i.e., loading, unloading, tie-down, vehicle complication documentation, etc.
- k. Documentation of re-certification or stop use.

## **B. Procedures**

1. Approved procedures and instructions should be issued through an approved document control process.
2. Revisions to procedures and instructions should be controlled by the same process used to review and approve the original procedures or instructions.
3. Special process procedures and instructions concerning non-standardized, non-routine work tasks that are expected to be performed once or rarely should be documented in accordance with applicable codes or standards.
4. Procedures should address the following considerations for the control and guidance of work activities:

- a. Acceptance criteria.
  - b. Conditions and requirements as defined by the applicable specifications, codes, or standards.
  - c. Qualification and certification requirements for procedures, specifications, and personnel.
  - d. Equipment or calibration requirements.
  - e. Parameters for which verification and/or documentation is required.
5. Procedures and/or instructions should be prepared for each quality-affecting activity to the level of detail necessary to assure that the activity can be performed as required. Procedures and/or instructions should include or refer to appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities have been completed as specified. Procedures and/or instructions should be uniquely identifiable, retrievable, and reproducible.
6. Procedures should include, but not be limited to, the following stipulations:
- a. Approval signatures and effective date.
  - b. Unique identifier, including revision number.
  - c. Purpose: a short statement of the objective of the procedure or instruction and what it contains.
  - d. Applicability or scope: a concise description of the requirements and to which organization they apply.
  - e. References: identification of the source of requirements.
  - f. Definitions: descriptions of unique acronyms or unique terms. Definitions should be based on standards, codes, regulations, DOE orders, etc.
  - g. Procedure: description of the actions necessary to accomplish the objectives identified in the purpose statement.
  - h. Records: identification of records produced or retained by compliance with the procedure.

### **5.3 Records Maintenance Measures**

(See G-830.120, Para. 4 reference to the NARA and GRS regulations, 10 CFR 830.120(c)(1)(iv), and 10 CFR 71.135)

- A.** At a minimum, these measures should include, but not be limited to, the following:
1. Ensuring that records are legible, complete, and authenticated as the record copy before acceptance.
  2. Identifying and marking (indexing) records, including records released for review.

3. Creating a records index to facilitate retrievability. It should include the record type, unique identifier, record retention time, criteria for disposition, and location of the record within the record system.
4. Acknowledging receipt of record transmittals.
5. Archiving according to the model of the NARA GRS, and in a manner that protects records from detrimental environmental effects.

## **B. Quality Assurance Records**

(See 10 CFR 830.120(c)(1)(iv), G-830.120, Para. 4, with reference to the NARA and GRS regulations; and 10 CFR 71.113)

Sufficient records should be prepared and maintained as work is performed to furnish documentary evidence of the quality of items and of activities affecting quality. The following elements should be included in the contractor's records system

1. Records should be consistent with applicable codes, standards, specifications, and contracts and should be adequate for use in management of the Package Certification and Offsite Transportation Authorization Program and other nuclear weapons safety programs.
2. Records should include the instructions, procedures, and drawings that prescribe quality assurance activities (when completed or superseded), results of reviews, inspections, tests, audits, monitoring of work performance, materials analyses, and facility operating logs.
3. Records should include, as appropriate, closely related data such as qualifications of personnel, procedures, and equipment and other documentation required by the applicable parts of this Guide.
4. Inspection and test records should, at a minimum, identify the date of inspection or test; the inspector or data recorder; the type of observation, the results, the acceptability, and the action taken in connection with any deficiencies noted.
5. Required records should be legible, identifiable, and retrievable.
6. Requirements and responsibilities for record transmittal, retention, and maintenance subsequent to completion of work should be established and documented consistent with applicable codes, standards, and procurement documents.

7. Records that correctly identify the as-built conditions of packages, packaging, and other designated materials should be maintained for at least the life of the item, while the item is stored for future use or while it is in use. Retention times for all records should be specified. These records should include:
  - a. Material certification and test data for traceability and quality verification.
  - b. Reports of inspections, examinations, and test results for conformance verification.
  - d. Drawings, specifications, procedures, and instructions for use in control of configuration.
  - d. Records of nonconformances and their resolution.

### **C. Changes to Records**

Changes to records should be reviewed and approved by the same organizations that performed the original review and approval unless other organizations are specifically designated by an individual with the authority to do so. The reviewing organization should have access to pertinent background information upon which to base its approval, and should have adequate understanding of the requirements and intent of the original record. The changes should include the date and the identification of the person authorized to issue such changes.

## **SECTION 6.0**

### **WORK PROCESSES**

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#### **6.1 Introduction**

This section provides general requirements and guidance for the establishment and execution of the DOE/NNSA PCD responsibilities for the design, fabrication, and use of packaging for the transportation of materials of national security interest. Some activities included are: designing, modifying, fabricating, assembling, installing, inspecting, testing and evaluation, procuring, handling, shipping, documenting, independent review, operating, maintaining, repairing, and application of Quality Assurance requirements identified in DOE Order 414.1A.

#### **6.2 Management Responsibility**

##### **A. Conduct of Work**

DOE/NNSA Service Center management promotes the ISM concept that quality and safety are part of the work process. Employees are properly trained and are knowledgeable in the procedures, instructions, drawings, specifications, and other related administrative and technical documents that control the work. Work processes are conducted according to the applicable requirements established in DOE/NNSA management requirements' documents, including flow down procedures and instructions, which are prepared for the conduct of work activities. Work is then undertaken in accordance with DOE standards, procedures, and instructions.

1. Work should be performed to established technical standards and administrative controls.
2. Work should be performed under controlled conditions using approved instructions, procedures or other appropriate means.
3. Work should be performed in accordance with an established and executed QAPP consistent with DOE Order 461.1A for the activities cited in Section 5.1 above.

##### **B. Identification and Control of Items**

The PCD is not directly involved in the identification and control of items. Refer to Section 3 of this guide for information and control of items guidance that PCD provides to the users of its products and services.

##### **C. Handling, Storing, and Shipping**

The PCD is not directly involved in handling, storing and shipping. Refer to Section 3 of this guide for handling, storing and shipping guidance that PCD provides to the users of its products and services.

#### **D. Control of Engineered Items**

The PCD is not directly involved in the control of engineered items. Refer to Section 3 of this guide for guidance on control of engineered items that PCD provides to the users of its products and services.

#### **E. Control of Commercially Procured Items**

The PCD is not directly involved in the control of commercially procured items. Refer to Section 3 of this guide for control of commercially procured items guidance that PCD provides to the users of its products and services.

#### **F. As Low As Reasonably Achievable**

DOE/NNSA management should ensure that procedures and practices are developed and used to ensure that personnel exposure to radiation is maintained *as low as reasonably achievable* as required in 10 CFR 835.

#### **G. Computer Software Control**

DOE/NNSA PCD does not procure software used in support operations/activities under its cognizance. Refer to Section 3 of this guide for guidance on computer software control for organizations that provide technical computer based support to PCD.

## **SECTION 7.0**

### **DESIGN CONTROL**

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DOE/NNSA PCD does not design any of the hardware or equipment used in the DOE/NNSA Defense Programs packaging program. However, PCD does oversee and enforce design control requirements for the DOE/NNSA certified packages through the package certification process. Refer to Section 3 of this Safety Guide for additional information.

## **SECTION 8.0 PROCUREMENT**

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DOE/NNSA PCD will comply with the DOE prescribed procurement process by ensuring that tasks for technical support services comply with specified SOW requirements. Quality assurance representatives that perform vendor surveillances in support of the DOE/NNSA package certification program will follow acceptable ASME NQA-1, engineering assessments requirements.

## **SECTION 9.0**

### **INSPECTION AND ACCEPTANCE TESTING**

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Inspection and acceptance testing of specified items (i.e., packagings, transport vehicles, aircraft, and prime movers) and processes should be conducted using established written acceptance and performance criteria. Equipment used for inspections and tests should be calibrated and maintained. This criterion is typically not directly applicable to PCD functions and activities as its contractors have the lead responsibility for these functions as dictated by the individual SARPs for each approved packaging.

## **SECTION 10.0 APPRAISALS**

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DOE Order 461.1A assigns DOE/NNSA Headquarters the responsibility for maintaining a comprehensive system of planning, conducting and documenting appraisals of DOE/NNSA contractors, National Laboratories, and Site Offices. PCD supplies members for the DOE/NNSA Headquarters appraisal teams, as requested.

## **SECTION 11.0**

### **DOE/NNSA PCD INDEPENDENT SURVEILLANCES**

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A surveillance system for oversight and/or analyses of packaging and transportation processes is maintained and used by the DOE/NNSA to assist its customers in establishing and maintaining programs and processes that conform to the federal regulatory and DOE Order requirements and promote continuous improvements.

The focus and emphasis of the surveillance may differ depending on the reason(s) for conducting the surveillance. Regulatory compliance is the baseline for any surveillance conducted by DOE. DOE/NNSA PCD performed independent surveillances, in addition to reviewing the organization's compliance with regulatory and DOE Order requirements, focus on identifying areas for program improvement. Management surveillances focus on management issues of the entire program and how well the organizations are working together rather than just compliance issues.

The PCD Manager should:

- A.** Define the scope of each surveillance activity, with the help of the CEs, prior to tasking a team to perform the surveillance; and,
- B.** Ensure that the surveillance team member(s) are sufficiently independent from the subject organization to objectively perform the assigned surveillance (e.g., personnel selected to perform surveillance activities should not have direct responsibilities in the area they are assessing).

Refer to Appendix D of this guide for additional information on PCD performed surveillances.

# **Appendix H**

## **Acronyms and Definitions**

## ACRONYMS AND DEFINITIONS

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AL	Albuquerque
ALARA	As Low as Reasonably Achievable
ANSI	American National Standard Institute, Incorporated
Applicant	A DOE Element that requests DOE/NNSA approval to use certified (OTC) or authorized (OTA) packaging.
Appraisal	A planned and documented investigative evaluation of an item or process to determine the adequacy and effectiveness as well as compliance with established procedures, instructions, drawings, Quality Assurance Program Plans (QAPPs), and/or other applicable documents.
ASME	American Society of Mechanical Engineers
ASTM	American Society for Testing and Materials
Authorized User	A DOE or NNSA contractor that is listed as an Authorized user on the PCD Package Certification and Offsite Authorization WEB Site. To obtain the status of Authorized User, the shipper and receiver must have a copy of the applicable current SARP, SER and OTC and/or OTA, PCD approved packaging procedures, and a QAPP approved by the site's federal management. Similar requirements are required for proposed TSS shipments made under a CofC or CofCA.
BPVC	Boiler and Pressure Vessel Code
CE	Certification Engineer
Certified or Certification	Refers to a written statement signed and dated by a qualified person that confirms a standard of performance as true, accurate or genuine.
CFR	Code of Federal Regulations
CofC	Certificate of Compliance
CofCA	Certificate of Competent Authority
Consignee	Package receiver
Consignor	Package shipper

Corrective Action	Action(s) to correct an identified nonconformance such that, at the completion of the action, the nonconformance no longer exists.
Customer	The DOE/contractor who is the package user (e.g., design agency, or Department of Defense).
Design Owner	The DOE/NNSA contractor that is responsible for the Type B Packaging's design specifications, packaging's design and configuration control, packaging's performance testing and evaluation, packaging's material selection and fabrication, packages acceptance and maintenance procedures, and maintenance of the official records for those responsibilities.
Design Specifications	The specific regulatory requirements, national standards, performance characteristics and operational needs that will ensure that the radioactive material packages shipped in the TSS comply with DOE Orders and regulatory requirements.
Document	Recorded information that describes, specifies, reports, certifies, requires, or provides data or results. A document is not considered a record until it meets the definition of a record. (10 CFR 830.3(a).)
DoD	Department of Defense
DOE	Department of Energy
DOT	Department of Transportation
Electronic Record	Any information that is recorded in a form that only a computer can process and that satisfies the definition of a record. (41 CFR 201-45.201.)
FEA	Finite Element Analysis
Fissile Material	plutonium-239, plutonium-241, uranium-233, uranium-235, or any combination of these radionuclides.
FTU	Flight Test Unit
GRS	General Record Schedule
HAC	Hypothetical Accident Conditions
HAR	Hazards Analysis Report

Hazardous Components	Those parts of nuclear explosives or special assemblies that contain hazardous (other than radioactive) materials, as defined in 49 CFR.
HAZMAT	Hazardous Materials
HE	High Explosives
IAEA	International Atomic Energy Agency
INEEL	Idaho National Engineering and Environmental Laboratory
ISM	Integrated Safety Management
JTA	Joint Test Assembly
LANL	Los Alamos National Laboratory
LLNL	Lawrence Livermore National Laboratory
LTU	Laboratory Test Unit
Major Design Change	Any change to a Quality Category A or B container component
Minor Design Change	Any change to a Quality Category C container component
MCNP code	Monte Carlo Neutral Particle code
NARA	National Archives and Records Administration
NCT	Normal Conditions of Transport
NELA	Nuclear Explosive-Like Assembly, a nuclear weapon program special assembly that meets the definition specified in the <i>Nuclear Explosive-Like Assembly Requirements</i> section of DOE Order 452.2B.
NM	New Mexico
NM/TEC	New Mexico Institute of Mining and Technology
NNSA	National Nuclear Security Administration
Nonconformance	A deficiency in design requirements, characteristics, documentation, or procedures which renders the quality of an item or activity unacceptable or indeterminate. Examples of nonconformance include: out of design tolerance, physical defects, test failures, incorrect or inadequate documentation, and deviation from prescribed procedures.

NRC	Nuclear Regulatory Commission
Nuclear Components	Those parts of nuclear explosives or special assemblies that contain fissile and/or radioactive and other materials.
ORNL	Oak Ridge National Laboratory
OTA	Offsite Transportation Authorization, a DOE/NNSA document , approved and issued by the DOE/NNSA Certifying Official, that authorizes a nuclear weapons-related shipping campaign on a limited basis (i.e., for a specific package and loading configuration, designated routes, and campaign duration).
OTC	Offsite Transportation Certificate, a DOE/NNSA document , approved and issued by the DOE/NNSA Certifying Official, that authorizes (certifies) a specific package (packaging and specified content) for DOE/NNSA radioactive material transportation activities for use on a one-time basis or for up to 5 years.
OST	Office of Secure Transportation
Package	The packaging together with its contents as presented for transport.
Packaging	The assembly of components necessary to comply with the packaging requirements of Title 49 CFR, e.g., marking, labeling, tamper indicator device (TID) sea, radiological surveys, and records. It may consist of one or more receptacles, absorbent materials, spacing structures, thermal insulation, radiation shielding, and devices for cooling or absorbing mechanical shocks.
PRA	Probabilistic Risk Assessment
PSP	Personnel Security Program
PCD	Packaging Certification Division
QA	Quality Assurance

QAPP	Quality Assurance Program Plan. A record which cites the overall criteria, including policies, to be met by the Nuclear Explosive and Weapon Safety Program; defines the staff authority and responsibility; explains how the program functions to accomplish criteria requirements; explains how procedure activities are related to one another; and provides for the performance and appraisal of work.
QC	Quality Control
Qs	Comments/questions developed during the review of a SARP/TSRA/HAR.
Qualified or Qualification	Refers to a person's ability or skill that satisfies a condition or standard to which compliance is required for the performance of a specified activity.
Quality Assurance	Refers to those process or product features which meet customer requirements, and thereby provide process or product satisfaction; and/or freedom from deficiencies in a process or product.
Radioactive Material	Any material having a specific activity greater than 0.002 microcuries per gram.
RAM	Radioactive Material
Record	<p>1) A completed document or other medium which provides objective evidence of an item, service, or process. (10 CFR 830.3(a).)</p> <p>2) "...all books, papers, maps, photographs, photo-negatives, machine readable materials, or other documentary materials, regardless of physical form or characteristics, made or received by an agency of the United States Government under federal law or in connection with the transaction of public business and preserved or appropriate for preservation by that agency or its legitimate successor as evidence of the organization, functions, policies, decisions, procedures, operations, other activities of the Government or because of the informational value of data in them." (44 USC 33010 and DOE G 1324.5B <i>Guide for DOE1324.5B Records Management</i>)</p>

Risk	The combination of the probability of an incident releasing radioactive and/or hazardous materials, and the consequences of the release on the public and the environment, which when taken over all events relating to system operation provide a meaningful picture of the adverse impact.
SA	Special Assembly, a major assembly that may contain nuclear components and/or hazardous components, or no hazardous or nuclear components but still meet the definition of a NELA (See <i>Nuclear Explosive-Like Assembly Requirements</i> section of DOE Order 452.2B) that does not compose a complete nuclear explosive and is not capable of producing a nuclear detonation. Special assemblies include, joint test assemblies, flight test units, laboratory test units and trainers.
SARP	Safety Analysis Report for Packaging, a document that provides a comprehensive technical evaluation of packaging. The SARP consists of sections on general information; structural, thermal, containment, shielding testing, analysis and evaluations; operating procedures; acceptance tests, and maintenance and quality assurance programs. The purpose of the SARP is to demonstrate compliance with the applicable sections of 10 CFR 71 and 49 CFR 100-185. DOE/NNSA uses the approved SARPs as the safety basis certifying Type B packages and issuing OTCs.

SER	Safety Evaluation Report, a document that provides final results of the PCD TSRP's safety evaluation, including its independent review of the SARP and/or TSRA and/or HAR. More specifically, the SER serves the following functions: provides a description of the package design, if applicable; documents the results of the SARP and/or TSRA review and confirmatory analysis, or the results of the analysis of the HAR; confirms that the methodology, assumptions, and technical data used are in compliance with safety standards and regulations; identifies packaging design deficiencies or SARP/TSRA and how they were resolved; documents restrictions on the use of the packaging/shipment that will be repeated in the OTC/OTA; and provides the basis for recommending approval or disapproval of the OTA/OTC.
SG	Safety Guide
SGT	Safeguards Transporter
SNL	Sandia National Laboratories
SNL/NM	Sandia National Laboratories/New Mexico
SME	Subject Matter Expert, an individual who has achieved a senior level status in his or her profession according to the criteria established by the profession, and/or documented knowledge and years of experience.
SNM	Special Nuclear Material
SR	Supplemental Report
SSC	Structures, Systems, Components
SST	Safe-Secure Trailer
Surveillance	The act of monitoring or observing to verify whether an item or activity conforms to specified requirements. (ASME NQA-1-1994.)
TQS	Technical Qualification Standard

TSRA	Transportation System Risk Assessment, a formal documentation that records the hazards, the assessment of the hazards, the analysis method(s), and actual analysis and results used to determine the probability and consequences of undesired but credible events that could pose risks to the workers, public and/or the environment during the proposed offsite transportation of an uncertified package or a special assembly that contains a Type B quantity of radioactive material in a prescribed transportation system and routes.
TSRP	Transportation Safety Review Panel, a committee, chaired by a Federal employee and composed of persons with appropriate expertise, that performs technical reviews to verify compliance with DOE Order 461.1A and makes recommendations for package certifications and offsite transportation authorizations.
TSS	Transportation Safeguards System
Type A package	A packaging that, together with its radioactive contents limited to A <sub>1</sub> or A <sub>2</sub> as appropriate, meets the requirements of 49 CFR 173.410 and 49 CFR 173.412 and is designed to retain the integrity of containment and shielding required by 49 CFR 173 under normal conditions of transport as demonstrated by the tests set forth in 49 CFR 173.465 and 49 CFR 173.466, as appropriate. A Type A package does not require a Competent Authority Approval.
Type AF package	A Type A package that is qualified for packaging and shipping a Type A quantity of fissile material.
Type B package	A Type B packaging that, together with its radioactive content, is designed to retain the integrity of containment and shielding required by 49 CFR 173 when subjected to the normal conditions of transport and hypothetical accident test conditions set forth in 10 CFR 71.

## Verification

The act of reviewing, inspecting, testing, checking, conducting surveillances, auditing, or otherwise determining whether items, processes, or services meet specified requirements. The terms *appraisal* and *verification*, as used in DOE Order 5700.6C and 10 CFR 830.120, are synonymous; their use is determined by who is performing the work. Appraisals are performed by, or for senior management. Verifications are performed by the line organization.

# **Appendix I**

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