



July 27, 2006  
GDP 06-0040

Mr. Jack R. Strosnider  
Director, Office of Nuclear Material Safety and Safeguards  
Attention: Document Control Desk  
U.S. Nuclear Regulatory Commission  
Washington, D.C. 20555-0001

**Paducah Gaseous Diffusion Plant (PGDP)**  
**Portsmouth Gaseous Diffusion Plant (PORTS)**  
**Docket No. 71-0832**  
**Revision to the Radioactive Material Packaging and Transportation Quality Assurance Program (PTQAP)**

Dear Mr. Strosnider:

The United States Enrichment Corporation (USEC) hereby submits Revision 18 (July 26, 2006) of UEO-1041, Radioactive Material Packaging and Transportation Quality Assurance Program (PTQAP). This program is referred to in the NRC Quality Assurance Program Approval for Radioactive Material Packages No. 0832.

Revision 18 to the PTQAP incorporates changes to Sections 2.2.2, 2.3.2, 2.3.3, 2.4.2, 2.5.2, 2.6.2, 2.7.2, 2.8.2, 2.9.2, 2.10.2, 2.10.3, 2.11.2, 2.12.2, 2.12.3, 2.13.2, 2.15.2, 2.16.2 and 2.17.2. These changes were previously submitted for NRC review in our letter dated June 6, 2006 (Reference 1). These changes were approved in Revision 18 to the NRC Quality Assurance Program Approval for Radioactive Material Packages No.0832 via NRC letter dated July 7, 2006 (Reference 2). Revision bars are provided in the right-hand margin to identify changes to the PTQAP. Revision 18 to the PTQAP became effective on July 26, 2006.

Should you have any questions or comments regarding this matter, please contact Mark Smith at (301) 564-3244. There are no new commitments contained in this submittal.

Sincerely,

Steven A. Toelle  
Director, Regulatory Affairs

Mr. Jack R. Strosnider  
July 27, 2006  
GDP 06-0040, Page 2

- References:
1. Letter from Steven A. Toelle (USEC) to Mr. Jack R. Strosnider (NRC), "Paducah Gaseous Diffusion Plant, Portsmouth Gaseous Diffusion Plant, Docket No. 71-0832, Revision to the Radioactive Material Packaging and Transportation Quality Assurance Program (PTQAP)," Letter No. GDP 06-0031, dated June 6, 2006.
  2. Letter from Robert J. Lewis (NRC) to Mr. Steven A. Toelle (USEC), "Quality Assurance Program Approval for Radioactive Material Packages No. 0832, Revision 18", dated July 7, 2006.

Enclosure: UEO-1041, Radioactive Material Packaging and Transportation Quality Assurance Program (PTQAP), Revision 18 (July 26, 2006).

cc: G. Janosko, NRC HQ  
J. Henson, NRC Region II Office  
D. Martin, NRC HQ  
M. Thomas, NRC Resident Inspector - PGDP

**RADIOACTIVE MATERIAL PACKAGING AND TRANSPORTATION  
QUALITY ASSURANCE PROGRAM  
USEC DOCUMENT UEO-1041  
REMOVE/INSERT INSTRUCTIONS  
JULY 26, 2006 – REVISION 18**

<b>Remove Pages</b>	<b>Insert Pages</b>
<b>iii/iv, xi/xii, 3/4, 5/6, 7/8, 9/10, 11/11a, 11b/12, 13/14, 15/16, 17/18, 19/20</b>	<b>iii/iv, xi/xii, 3/4, 5/6, 7/8, 9/10, 11/11a, 11b/12, 13/14, 15/16, 17/18, 19/20</b>

**LIST OF EFFECTIVE PAGES**

<u>Pages</u>	<u>Revision</u>
iii	18
iv	4
v	4
vi	4
vii	4
viii	4
ix	10
x	15
xi	18
xii	16
1	17
2	6
3	18
4	15
5	18
6	18
7	18
8	18
9	18
10	12
11	18
11a	11
11b	11
12	18
13	18
14	18
15	18
16	18
17	18
18	12
19	18
20	18
21	4
22	12
23	11
24	4
25	4
26	4

Blank Page

**Revision Summary Page**

<u>Revision</u>	<u>Revision Summary</u>
16	Revised Section 2.5.2, second paragraph and added a new third paragraph to address the organization change that resulted from combining the Training and Procedures Section with the Production Support Section at PGDP.
17	Revised the Introduction, first paragraph, changing "10CFR 71.12 (c) (2)" to "10 CFR 71.17 (c) (2)." Revised sections 2.6.2 and, first paragraph to address the organization change that resulted from deleting the Plant Services Organization and transferring the document control and records management system to the Production Support Organization at PGDP.
18	Revised Sections 2.2.2, 2.3.2, 2.3.3, 2.4.2, 2.5.2, 2.7.2, 2.8.2, 2.9.2, 2.10.2, 2.10.3, 2.11.2, 2.12.2, 2.12.3, 2.13.2, 2.15.2, and 2.16.2 to minimize the PTQAP dependence on specific organizational titles where possible and to focus on the related quality assurance requirement(s) and where functionally they are to be performed within the organization. Revised Sections 2.6.2 and 2.17.2 to replace "Plant Services" with "Records Management and Document Control" to reflect the specific entity at PORTS responsible for records management and document control.

Blank Page

The PTQAP governs those activities within USEC control and responsibility for the management, operation, maintenance, modification, and new construction of radioactive material packaging and transportation structures, systems, and components (SSCs) of the GDPs to protect the health and safety of the public and workers and for the protection of the environment.

The PTQAP is applicable to packaging and shipment for quantities of fissile material or licensed material in excess of Type A quantity. USEC applies quality assurance in a graded approach commensurate with the importance to safety of these packaging and transportation SSCs. The importance to safety of packaging and transportation SSCs is determined by the packaging design and approval, as reflected in the Safety Analysis Report for Packaging and Packaging Certificate of Compliance.

The quality of existing packaging and transportation SSCs, as well as related activities and services performed prior to the date NRC assumes regulatory oversight was assured by construction, operation, and maintenance procedures and practices employed at that time. These procedures and practices have been validated by more than 40 years of safe operation.

### 2.2.2 Scope

The requirements of the PTQAP apply to activities affecting the ability of radioactive material packaging and transportation SSCs to perform their safety functions. These activities affecting quality include designing, purchasing, fabricating, handling, receiving, shipping, storing, cleaning, erecting, inspecting, testing, operating, maintaining, repairing and modifying. These items are identified as Q items in a controlled document listing provided by the manager responsible for the engineering function. Safety Analysis Reports for Packaging and packaging Certificates of Compliance, as applicable, provide the basis for this determination.

The requirements of the PTQAP are applied in a graded approach to an extent commensurate with the importance to safety. The graded approach methodology for Q items is based on an assessment of the relative importance to safety of specific SSCs, taking into consideration as appropriate:

1. The complexity of the package and component design, fabrication, or uniqueness.
2. The proposed use of the package, its quality history and degree of standardization.
3. The impact of malfunction or failure of the item to safety.
4. The degree to which functional compliance can be demonstrated by inspection or test and the need for surveillance over processes and equipment.

The Paducah Tiger Overpack is the only packaging for fissile materials for which USEC has design responsibility. USEC is a registered user of other packagings shipped or received at the GDPs. Cylinders for shipment of uranium hexafluoride are procured, inspected, handled, and maintained in accordance with the current revision of the Safety Analysis Report (SAR) for the Gaseous Diffusion Plants.

### **2.2.3 Program Implementation**

The PTQAP provides the means of communicating and documenting the quality assurance program goals, objectives, requirements and quality elements for the Q SSCs. The PTQAP is implemented through policies, procedures, instructions, drawings and other appropriate documents consistent with Safety Analysis Reports for Packaging (SARPs), packaging Certificates of Compliance, and regulatory requirements. This program provides measures to ensure activities are planned and accomplished under suitably controlled conditions. The conditions include the use of appropriate equipment, suitable environments, any necessary special controls and the assurance that prerequisites for the activity have been satisfied.

The definitions for terms used in the PTQAP are as provided in Supplement S-1 to ASME NQA-1-1989.

### **2.2.4 Indoctrination and Training**

The indoctrination and training program has been established which provides confidence that suitable proficiency is achieved and maintained in the performance of quality related activities as defined in the PTQAP. Each organization manager is responsible for assuring the necessary indoctrination and training is received by personnel who perform activities which implement the PTQAP. Indoctrination and training sessions objective, content, date and attendance are documented. Personnel who perform activities important to safety receive indoctrination and training commensurate with the skill levels needed prior to engaging in these activities.

Personnel performing inspections of activities affecting safety shall be indoctrinated and trained to assure that suitable proficiency is achieved and maintained. Personnel performing nondestructive examination shall be qualified and requalified in accordance with SNT-TC-1A, 1980 edition. Auditors and lead auditors shall be qualified in accordance with Supplement 2S-3 to ASME NQA-1, 1989.

Training records for personnel who perform activities which implement the PTQAP will be maintained. Periodic requalification is provided for such personnel who are required to maintain their proficiency.

### **2.2.5 Review and Assessment**

Management of those organizations implementing the PTQAP regularly assess the adequacy of that part of the program for which they are responsible and assure its effective implementation in accordance with approved procedures.

The Nuclear Safety and Quality Manager is responsible for the performance of internal and external audits in accordance with the requirements of Section 2.18 of the PTQAP. Audits determine the performance and effectiveness of activities required by the PTQAP and identify the need for any revision to this PTQAP. The result of audits are reported to responsible management as described in PTQAP Section 2.18 and plant procedures.

An assessment of the status, adequacy, and effectiveness of this PTQAP is provided to the USEC Vice President, Operations at least once every 24 months by the NS&Q manager at each GDP. This assessment is developed from such sources as audits, self-assessments, trend data, status reports, etc. Revisions to the PTQAP shall be submitted for approval by NRC in accordance with the provisions of 10 CFR 71.101(c).

## **2.3 PACKAGE DESIGN CONTROL**

### **2.3.1 General**

Packaging design control applies to radioactive material packaging and transportation SSC items, as described below. This system ensures design and design change activities are planned, controlled, and carried out in an orderly manner, with design bases, regulatory requirements, and quality standards correctly translated into design output for procurement and procedural documents. This system provides for verification and checks of the technical adequacy of original and revised design documents.

### **2.3.2 Responsibilities**

The manager responsible for the engineering function is responsible for implementation and execution of the design control system for radioactive material packaging and transportation SSCs.

Design changes and new designs for radioactive material packaging and transportation SSCs are authorized by responsible management and approved by the Plant Operations Review Committee prior to submittal for NRC review and approval, as applicable. Management ensures changes to packaging and transportation SSCs are verified for acceptability and that personnel affected by the changes are adequately trained as described in procedures.

### **2.3.3 Requirements**

Established written procedures for design activities provide measures to ensure the following:

1. The selection and review for suitability of application of materials, parts, equipment and processes essential to the safety functions of the packaging and its components.
2. The identification and control of design interfaces and coordination among participating design organizations.

3. Verification of the adequacy of design by designated individuals other than those who performed the original design.
4. Design changes are subject to design control measures commensurate with those applied to the original design.

In addition, measures are established to ensure:

5. Effective interrelationships among those responsible for preparing design disclosures, conducting independent design analyses, coordinating design interfaces and maintaining lines of communication.
6. The system for the control of design activities applies to the design process, design input, and design verification.
7. Recognized engineering practices are followed where applicable for design drawings, checking methods, reviews and approvals, issuance and distribution of design documents, including revisions and maintaining current configurations.
8. Original and master copies of design documents are controlled and stored for the proper preparation of drawings and specifications.
9. In the absence of appropriate codes or standards used in the design of radioactive material packaging, alternative approaches are identified.
10. Design parameters are considered, reviewed, and approved by the manager responsible for the engineering function to assure the parameters are in accordance with applicable performance codes, standards, and regulatory requirements.
11. Required maintenance, repair, in-service inspection, handling, storage, and cleaning criteria are specified in design documents.
12. Design changes that could result in conditions different than those prescribed on NRC Certificates of Compliance for radioactive material packagings are identified for NRC approval prior to implementation.
13. Design changes that affect radioactive material packaging are incorporated into the packaging inspection criteria.
14. Prototype or sample unit testing are performed under the most adverse design conditions.

## **2.4 PROCUREMENT DOCUMENT CONTROL**

### **2.4.1 General**

The procurement document control system applies to radioactive material packaging and transportation SSC items, as described below. This system ensures that applicable regulatory requirements, technical requirements, and PTQAP requirements are included or referenced in procurement documents for the procurement of items and services. This system also establishes provisions for the preparation, review, approval, and control of procurement documents, including changes thereto.

### **2.4.2 Responsibilities**

The Nuclear Safety and Quality Manager is responsible for review of specifications that include technical and quality requirements for procurement, developed by engineering, prior to use. The Nuclear Safety and Quality Manager is also responsible for preparing and maintaining the approved suppliers list.

The manager responsible for the engineering function is responsible for the preparation and maintenance of design specifications for identifying the technical and quality requirements necessary to ensure item acceptability. In addition, they are also responsible for development of procedures that define these activities, including the criteria for developing the necessary technical and quality requirements for procurement.

The GDP Procurement and Materials Manager is responsible for procurement planning, bid evaluation, and procurement of items and services from suppliers on the Approved Suppliers List, when required.

### **2.4.3 Requirements**

Written procedures are established for the review of radioactive material packaging and transportation SSC procurement documents including changes. These measures ensure the following:

1. Documented review and approval by personnel with access to pertinent information and who have an adequate understanding of the procurement documents to assure appropriate provisions are transmitted to suppliers to ensure items or services will meet specified requirements.
2. Procurement documents specify the applicable criteria of 10 CFR 71 Subpart H and Regulatory Guide 7.10, Revision 1, Section 1.4.2 to be complied with by suppliers and described in their quality assurance programs, with appropriate quality assurance provisions specified for sub-tier suppliers.
3. Procurement documents specify that the provisions of 10 CFR 21 apply where applicable.
4. Procurement documents specify that manufacturers of packaging supply appropriate certifications and any other pertinent document (e.g., certificate of compliance, as-built drawings, photographs, sketches, use and maintenance manuals).
5. Suppliers of non-commercial grade items and services are required by procurement documents to evaluate their lower-tier suppliers that supply Q items or services within the scope of the PTQAP.

## **2.5 INSTRUCTIONS, PROCEDURES, AND DRAWINGS**

### **2.5.1 General**

The system established for instructions, procedures, and drawings applies to radioactive material packaging and transportation SSC items, as described below. Measures are in place to ensure that activities affecting quality are prescribed by documented procedures, drawings, and instruction, as appropriate, and are accomplished in accordance with these documents.

### **2.5.2 Responsibilities**

The Nuclear Safety and Quality Manager is responsible for review of selected procedures for inclusion of quality requirements.

The Training Manager is responsible for the system of preparation, review, approval, and use of procedures and instructions in accordance with the requirements of this PTQAP. (PORTS)

The Production Support Manager is responsible for the system of preparation, review, approval, and use of procedures and instructions in accordance with the requirements of this PTQAP. (PGDP)

The manager responsible for the engineering function is responsible for the system of preparation, reviews, and approval of drawings for SSCs within the scope of the PTQAP.

Organization managers are responsible for developing and approving procedures which control functions or activities within their area of responsibility, as defined in the PTQAP.

All personnel are required to use and adhere to the requirements of applicable procedures, instruction, and drawings for activities within the scope of the PTQAP.

### **2.5.3 Requirements**

Instructions, procedures, drawings and other documents pertinent to radioactive material packaging and transportation SSCs provide measures to ensure activities affecting quality are prescribed, including appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished.

Procedures ensure the following:

1. The requirements for meeting 10 CFR 71.87 are established.
2. Packaging maintenance and repair are prescribed with inspection and hold points incorporated as necessary.
3. Controls for packaging loading and unloading are specified.

4. Prior to shipment, packages are reviewed to ensure Department of Transportation (DOT) compliance.

Activities that require skills normally possessed by qualified personnel (known as skill-of-the-craft) may not require detailed step-by-step delineation in a procedure, but are subject to general administrative procedural controls.

Temporary procedures may be issued when permanent procedures do not exist:

1. to direct operations during testing, maintenance, and modification.
2. to provide guidance in unusual situations not within the scope of permanent procedures.
3. to ensure orderly and uniform operations for short periods when the plant, a system, or component of the system is performing in a manner not covered by existing permanent procedures or has been modified or extended in such a manner that portions of existing procedures do not apply.

Temporary procedures may be used for a period of time which should not exceed 60 days, or a period for which the temporary condition must exist, whichever is greater. These temporary procedures are subject to the same level of review and approval as required for permanent procedures.

## 2.6 DOCUMENT CONTROL

### 2.6.1 General

The document control system applies to radioactive material packaging and transportation SSC items, as described below. The system ensures documents defining the performance of activities affecting quality are controlled to ensure only current and correct information is available at the work location prior to commencing the work.

### 2.6.2 Responsibilities

The Records Management and Document Control Manager (PORTS)/Production Support Manager (PGDP) has the overall responsibility for the development and implementation of the document control system.

Organization managers are responsible for identifying documents to be included in the controlled document system; ensuring instructions, procedures, drawings, and other specified documents are reviewed for adequacy and approved for release; complying with document distribution requirement; and ensuring these documents are maintained and used by personnel performing the prescribed activity.

### 2.6.3 Requirements

The preparation, review, approval, issue, distribution and use of instructions, procedures, drawings and other documents affecting the quality of radioactive material packaging and transportation SSCs, including changes to documents, are provided in accordance with established procedures. In addition to instructions, procedures, and drawings, the following documents are controlled in a similar manner as a minimum:

1. Design documents.
2. Procurement documents.
3. Radioactive Material Packaging and Transportation Quality Assurance Program.
4. Safety Analysis Reports for Packaging.

Procedures establish measures which ensure that documents prescribing activities that affect the quality of radioactive material packaging and transportation SSCs are maintained current, correct, and made available at the work location, as necessary, prior to commencement of work. Controlled documents are adhered to in the performance of work as required by procedures.

Except for minor changes, changes to documents are reviewed and approved by the same organization that performed the initial review and approval or delegated to other qualified organizations as specified in procedures. The reviewing organization has access to pertinent background data or information upon which to base their approval.

Minor changes to documents, such as inconsequential editorial corrections do not require that the revised documents receive the same approval as the original documents. The review and approval for minor changes is specified in procedures.

## 2.7 CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

### 2.7.1 General

The system for the control of purchased items and services applies to radioactive material packaging and transportation SSC items, as described below. The system assures that purchased material, equipment, and services conform to procurement documents.

### 2.7.2 Responsibilities

The Nuclear Safety and Quality Manager is responsible for providing the necessary QA functions to support procurement. These QA functions include review of supplier quality documentation, evaluation of supplier QA capability, supplier audits and annual evaluations, and the development and maintenance of an approved suppliers list. Also the Nuclear Safety and Quality Manager is responsible for audit and/or surveillance of nonconforming items dispositioned "use-as-is" and "repair."

The Nuclear Safety and Quality Manager is responsible for performing supplier source inspection and receipt inspection.

The manager responsible for the engineering function is responsible for assisting the Nuclear Safety and Quality Manager by performing evaluations of supplier technical capabilities and for determining the methods of acceptance to be applied, approval of technical dispositions, and technical evaluation of supplier-generated nonconforming material, equipment, or services. In addition, the manager responsible for the engineering function is also responsible for providing measures which ensure the proper selection, application, methods of acceptance, and use of commercial grade items.

The GDP Procurement and Materials Manager is responsible for purchasing activities and ensuring that items are procured from approved suppliers on the approved suppliers list when required.

### 2.7.3 Requirements

Established written procedures assure that radioactive material packaging and transportation SSC material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These procedures include provisions for the following, as appropriate:

1. Source evaluation and selection.
2. Objective evidence of quality.
3. Source inspection and examination of products upon delivery.

Procedures are established which provide measures to ensure that suppliers of radioactive material packaging and transportation materials, equipment, or services are evaluated for their capability to comply with applicable criteria of 10 CFR 71 Subpart H prior to contract award. This evaluation is based on the following criteria as applicable to the type of procurement; technical considerations; conformance to PTQAP requirements; production capacity; and past performance.

An assessment of the potential supplier's technical and quality capabilities is performed and documented in accordance with one or more of the following:

1. Evaluation of the supplier's history of providing an identical or similar product which performs satisfactorily in actual use. The supplier's history shall reflect current capability.
2. Evaluation of the supplier's current quality records supported by documented qualitative and quantitative information that can be objectively evaluated.
3. A direct evaluation of his facility and personnel and the implementation of the supplier's quality assurance program.

4. Verification that the supplier has a valid NRC Certificate of Compliance and a NRC approved quality assurance program. When using this method, an implementation audit shall be performed in accordance with Section 2.18.3.5.
5. The evaluation of the results of recognized industry shared supplier audits (i.e., third party audits such as the Nuclear Industry Assessment Committee (NIAC) etc.).
6. Verification that the supplier has an applicable valid "Certificate of Accreditation" issued by the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology (NIST). When using this method, an implementation audit shall be performed in accordance with Section 2.18.3.5.
7. The supplier maintains a valid ASME Code certification for the item or service being provided. When using this method, an implementation audit shall be performed in accordance with Section 2.18.3.5.

These procedures ensure that unacceptable conditions identified during the bid evaluation are resolved prior to award, if possible, or a commitment is obtained from the selected supplier to resolve the conditions at a mutually agreeable date during the contract period.

Procedures require that procurement documents identify the required documentation to be furnished by the supplier. This documentation identifies the material or equipment and the codes, standards, and specifications met by the items. This documentation identifies any failure to meet procurement requirements. Procedures establish methods for disposition of nonconforming items and services that do not meet procurement documentation requirements. Evaluation of these items includes adherence to 10 CFR 21 requirements when applicable. Suppliers submittal of nonconformance includes recommended disposition and the technical justification. Records of these supplier submitted nonconformances are maintained.

Blank page

Procedures are established which provide measures for ensuring that material, equipment, and services conform to the requirements of procurement documents prior to installation or use. This information is retained and available for the life of the package to which it applies, to identify that the specific requirements are met. Procedures establish methods for assessing the effectiveness of the control of quality by contractors and subcontractors at specified intervals. These intervals are based on the importance, complexity, and quantity of the product or services.

## **2.8 IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS**

### **2.8.1 General**

The system for identification and control of items applies to radioactive material packaging and transportation SSCs, as described below.

### **2.8.2 Responsibilities**

The manager responsible for the engineering function is responsible for identification, shelf and operating life requirements during the generation of specifications, drawings, procurement or other documents affecting quality.

The Nuclear Safety and Quality Manager is responsible for verifying that items are correctly identified through receipt inspection.

Organization managers are responsible for maintaining and implementing identification, traceability, and shelf life and operating life requirements for items under their jurisdiction.

The GDP Procurement and Materials Manager is responsible for the receipt, delivery, storage and control of materials.

### **2.8.3 Requirements**

Procedures are established for radioactive material packaging and transportation SSCs to assure the following:

Identification of items is maintained by heat or part number, or other appropriate means, either on the item or on records traceable to the item throughout fabrication, installation, and use, to prevent the installation or use of incorrect or defective materials, parts, and components.

## **2.9 CONTROL OF SPECIAL PROCESSES**

### **2.9.1 General**

The system for control of processes affecting the quality of items or services applies to the control of special processes for radioactive material packaging and transportation SSC items, as described below.

## **2.9.2 Responsibilities**

The Nuclear Safety and Quality Manager is responsible for the qualification of NDE personnel and welder/brazer qualification and for providing NDE Level III services for NDE personnel and procedure qualification. This manager is also responsible for performance of audit and/or surveillance of special process activities.

The manager responsible for the engineering function is responsible for determining applicable special processes, providing technical requirements, review and concurrence for special process procedures including the utilization and application of nondestructive examination (NDE) procedures.

Organization managers are responsible for ensuring special processes are accomplished by qualified personnel using approved procedures or documents of a type appropriate to the circumstances.

## **2.9.3 Requirements**

Procedures are established to ensure the following:

1. Radioactive material packaging and transportation special processes are controlled.
2. Special processes are accomplished by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria or other special requirements.
3. Special processes controlled include as a minimum welding, heat treating, and nondestructive testing.
4. Special processes include appropriate acceptance criteria and identify the qualification records to be maintained for procedures, equipment, and personnel.

The required proficiency of personnel performing special processes is based on proof of certification to perform the process, in accordance with the requirements and guidelines of nationally recognized authorities such as the American Society for Nondestructive Testing (ASNT), the American Society of Mechanical Engineers (ASME), or the American National Standards Institute (ANSI). Nondestructive examination personnel qualifications are described in Section 2.2.4 of this document.

## **2.10 INSPECTION**

### **2.10.1 General**

The system for inspection of SSCs applies to radioactive material packaging and transportation SSC items, as described below.

### 2.10.2 Responsibilities

The Nuclear Safety and Quality Manager is responsible for ensuring inspections are performed by qualified personnel and for performance of audit and/or surveillance of inspection activities including qualification of inspection personnel.

The manager responsible for the engineering function is responsible for specifying "hold" and "witness" points for inclusion in applicable work control documents. Such work control documents are developed from approved design documents, which specify the criteria for acceptance of the work.

### 2.10.3 Requirements

Procedures are established to ensure the following:

1. Inspection of radioactive material packaging activities affecting quality by or for the organization performing the activity.
2. Verifying conformance with documented instructions, procedures, and drawings for accomplishing the activity.
3. Inspection is performed by individuals other than those who performed the activity, with examination, measurement, or test of material or processed products performed for each work operation where necessary to assure quality. The qualifications of inspection personnel are described in Section 2.2.4 of this document.
4. Direct inspection is either carried out or indirect control is provided, using monitoring of processing methods, equipment, and personnel. Direct inspection and monitoring are provided when quality control is inadequate without both.
5. If mandatory inspection hold points, which require witnessing or inspecting by a designated individual and beyond which work should not proceed without the consent of its designated representative, are required, the specific hold points must be indicated in the appropriate documents.

When sampling is used to verify the acceptability of a group of radioactive material packaging items, the standard used as the basis for acceptance is identified in the sampling procedure. Where direct inspection is impractical during in-process activities, the process specifications and supporting documents provide for indirect control by monitoring.

The identification of inspection activities and attributes is based on the complexity of the item or activity to be inspected, on mandatory inspections required by codes, standards, regulatory requirements, commitments or on inspection requirements established by the manager responsible for the engineering function. The depth and extent of inspections are determined by the significance of the safety function, and the complexity of the item or activity.

## **2.11 TEST CONTROL**

### **2.11.1 General**

The system for test control applies to radioactive material packaging and transportation SSC items, as described below.

### **2.11.2 Responsibilities**

The Nuclear Safety and Quality Manager is responsible for performance of audit and/or surveillance of test activities including the review of test deficiencies identified as a significant condition adverse to quality.

The manager responsible for the engineering function is responsible for providing technical criteria for testing and the evaluation, and resolution of deficiencies resulting from these tests.

Organization managers are responsible for the conduct of testing of SSCs under their cognizance.

### **2.11.3 Requirements**

Procedures are established to ensure the following:

1. Testing to demonstrate that radioactive material packaging and transportation components will perform satisfactorily in service is identified and performed in accordance with written test procedures.
2. The applicable requirements of 10 CFR Part 71 as well as the requirements and acceptance limits are incorporated into the packaging design documents.
3. Prerequisites are met, adequate test instrumentation is available and used, and the test is performed under suitable environmental conditions.
4. Test results are documented and evaluated to assure the test requirements have been satisfied.

Procedures are established which require that test prerequisites identified in design documents for radioactive material packaging and transportation SSCs are correctly translated into test procedures. These prerequisites include as a minimum instrument calibrations, required monitoring, mandatory hold points, suitable environmental conditions to be maintained, condition of the test equipment, methods for physical identification of test specimens and for documenting or recording test data, and acceptance criteria.

## **2.12 CONTROL OF MEASURING AND TEST EQUIPMENT**

### **2.12.1 General**

The system for control of measuring and test equipment (M&TE) applies to radioactive material packaging and transportation SSC items, as described below. The system ensures that tools, instruments, standards, equipment and other devices used in activities affecting quality are controlled, calibrated and adjusted at specified intervals to maintain accuracy within necessary limits.

### **2.12.2 Responsibilities**

Maintenance management has overall responsibility for the control and calibration of M&TE.

Organization managers are responsible for implementation of the calibration control system for M&TE under their cognizance.

### **2.12.3 Requirements**

Procedures are established to ensure the following:

1. Tools, gauges, instruments and other measuring and testing devices used in radioactive material packaging and transportation activities affecting quality are controlled, calibrated, and adjusted at specified intervals or prior to use to maintain accuracy within necessary limits.
2. In-house reference or transfer standards used in calibrating measuring and test equipment are traceable to nationally recognized standards. If no nationally recognized calibration standard exists, the basis for calibration is documented by the manager responsible for the engineering function or designee.
3. Measuring or test equipment found out of calibration is evaluated to assure the validity of previous inspection or test results and the acceptability of items previously inspected or tested.
4. Measuring and test equipment is handled and stored to maintain accuracy.
5. Records are maintained traceable to the calibrated equipment.

## **2.13 HANDLING, STORAGE, AND SHIPPING CONTROL**

### **2.13.1 General**

The system for handling, storage, and shipping of SSC items applies to radioactive material packaging and transportation SSC items, as described below.

### **2.13.2 Responsibilities**

The manager responsible for the engineering function is responsible for specifying design requirements for handling, storage, shipping, cleaning, packaging and on-site movement of SSC items in specifications, drawings, instructions, procedures, procurement documents, and/or other appropriate documents.

Organization managers have the responsibility for the proper handling and on-site movement of items under their cognizance from the point of issuance through installation and/or use.

The GDP Procurement and Materials Manager has the responsibility for the proper handling, storage, and on-site movement of items under his/her cognizance (i.e., upon receipt, during storage, and to the point of issuance).

The Nuclear Safety and Quality Manager is responsible for selectively verifying that items are correctly handled, stored, and shipped.

### **2.13.3 Requirements**

Procedures are established to ensure the following:

1. Control of the handling, storage, shipping, cleaning and preservation of materials and equipment to be used in radioactive material packaging to prevent damage or deterioration.
2. Special protective environments and specific moisture content and temperature levels are specified and provided when necessary.
3. Special handling equipment is specified and provided when necessary.
4. The methods of controlling stored items are provided.
5. Provisions are established for the use of special shock absorbers or special markings to identify and preserve radioactive material packaging SSCs when necessary.
6. Special instructions for safe opening of a package are sent or made available to the consignee prior to delivery of a package to a carrier for transport.

## **2.14 INSPECTION, TEST, AND OPERATING STATUS**

### **2.14.1 General**

The system for inspection, test, and operating status applies to radioactive material packaging and transportation SSC items, as described below. The controls of the system prevent the inadvertent use of

nonconforming, inoperative, or malfunctioning items and the ready verification that required tests and inspections have been performed.

#### **2.14.2 Responsibilities**

The Nuclear Safety and Quality Manager is responsible for providing a status indicating system for inspections performed.

Organization managers are responsible for the implementation of status indicating systems which are consistent with the requirements of the PTQAP for testing performed under their cognizance.

#### **2.14.3 Requirements**

Procedures are established to ensure the following:

1. Indication of the status of inspections and tests performed upon individual items of the radioactive material packaging and transportation SSCs.
2. Markings such as stamps, tags, labels, routing cards or other suitable means are used to provide for the identification of items that have satisfactorily passed required inspections and tests, to preclude inadvertent bypassing of the required inspections or tests as well as to prevent inadvertent operation.
3. The application and removal of status indicators are controlled.

### **2.15 NONCONFORMING MATERIALS, PARTS, OR COMPONENTS**

#### **2.15.1 General**

The system for the control of nonconforming items, related activities, and services applies to radioactive material packaging and transportation SSC items, as described below. The system establishes requirements for identification of nonconforming items as well as segregation, disposition, and prevention of inadvertent installation or use. Documentation of nonconforming items and notification to affected organizations is provided in accordance with the system.

#### **2.15.2 Responsibilities**

The Nuclear Safety and Quality Manager is responsible for performance of audit and/or surveillance of nonconforming items dispositioned "use-as-is" or "repair," and of the evaluations of 10 CFR 21 nonconforming items.

Personnel participating in quality affecting activities are responsible for reporting and documenting nonconforming items, activities, or services.

The GDP Procurement and Materials Manager is responsible for implementation of the nonconformance control system.

The manager responsible for the engineering function is responsible for providing documentation of disposition of items as "use-as-is" or "repair," and ensuring that as-built records reflect accepted deviations, if required. In addition, the manager responsible for the engineering function is also responsible for the evaluation of nonconforming items which includes adherence to 10 CFR 21.

Plant shift superintendents are responsible for evaluating identified and reported nonconformances for impact on system operability, and to determine if they are reportable to the NRC, when such nonconformances are reported via the problem reporting system.

### 2.15.3 Requirements

Procedures are established to ensure the following:

1. Control of materials, parts, and components that fail to conform to requirements, to prevent their inadvertent use or installation.
2. Nonconforming radioactive material packaging or transportation materials, parts, and components are identified, documented, segregated, evaluated, and dispositioned.
3. Notification to affected organizations and the review of nonconforming items for acceptance, rejection, repair or rework.
4. Nonconforming item reports are analyzed to determine quality trends for appropriate management review and assessment.

Procedures ensure that nonconforming items or services are evaluated to determine whether a particular deviation could create a substantial safety hazard and to determine whether reporting is required in accordance with the provisions of 10 CFR Part 21. Nonconforming radioactive material packaging or transportation items or services reported by suppliers in accordance with the provisions of 10 CFR Part 21 are reviewed and corrective actions are initiated, as appropriate.

Procedures also ensure that nonconforming items and activities are evaluated to determine whether reporting is required in accordance with the provisions of 10 CFR 71.95.

## 2.16 CORRECTIVE ACTION

### 2.16.1 General

The corrective action system for items, activities, and services applies to radioactive material packaging and transportation SSC items, as described below. The system ensures that conditions adverse to quality are identified and corrected as soon as practical. In the case of significant conditions adverse

to quality, the cause of the condition is determined, documented, and reported to management, with corrective action taken to prevent recurrence. Follow-up actions are taken to verify implementation of corrective actions.

### **2.16.2 Responsibilities**

The manager responsible for the regulatory affairs function is responsible for development, maintenance and implementation of the corrective action control system, including escalation of significant adverse conditions for management review. In addition, this manager is also responsible to ensure follow-up action is taken to verify implementation of the corrective action.

The Nuclear Safety and Quality Manager is responsible for audit and/or surveillance of follow-up action taken to verify implementation of corrective action.

Organization managers are responsible for evaluating and performing assigned corrective actions in a timely manner in accordance with procedures. They are also responsible for assuring the identification and documentation of conditions adverse to quality in accordance with applicable procedures.

### **2.16.3 Requirements**

Procedures are established to assure the following:

1. Conditions adverse to quality, including deficiencies, deviations, defective material or equipment and nonconformances, are promptly identified and corrected.
2. Significant conditions adverse to quality, when identified, are analyzed or evaluated to assure the cause of the condition is determined and corrective action taken to preclude repetition.
3. The significant condition adverse to quality, the cause of the condition, and the corrective action taken are documented and reported to responsible levels of management; follow-up action is taken to verify implementation of the corrective action.

## **2.17 QUALITY ASSURANCE RECORDS**

### **2.17.1 General**

The records management system for items, activities, and services applies to radioactive material packaging and transportation SSC items, as described below.

### **2.17.2 Responsibilities**

The Records Management and Document Control Manager (PORTS)/Production Support Manager (PGDP) is responsible for the development, maintenance, and implementation of the records management system.