



February 6, 2012
GDP 12-0003

Ms. Catherine Haney
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)
Docket No. 71-0832
Revision 19 to the Radioactive Material Packaging and Transportation Quality Assurance Program (PTQAP)

Ms. Haney:

The United States Enrichment Corporation (USEC) hereby submits Revision 19 (January 25, 2012) to 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 19 to the PTQAP incorporates changes to Sections 1, 2.1.1, 2.1.2, 2.2.1, 2.2.2, 2.2.5, 2.5.2, 2.6.2, and 2.17.2. These changes were previously submitted for NRC review and approval in our letter dated December 5, 2011 (Reference 1). These changes were approved in Revision 19 to the NRC Quality Assurance Program Approval for Radioactive Material Packages No. 0832 via NRC letter dated January 25, 2012 (Reference 2). Revision bars are provided in the right-hand margin to identify changes to the PTQAP. Revision 19 to the PTQAP became effective on January 25, 2012.

Should you have any questions regarding this matter, please contact me at (301) 564-3250. There are no new commitments contained in this submittal.

Sincerely,

Steven A. Toelle
Director, Regulatory Affairs

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- References:
1. Letter from Steven A. Toelle (USEC) to Ms. Catherine Haney (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 11-0031, dated December 5, 2011.
 2. Letter from Christian Araguas (NRC) to Mr. Steven A. Toelle (USEC), "Quality Assurance Program Approval for Radioactive Material Packages No. 0832, Revision 19", dated January 25, 2012.

Enclosure: UEO-1041, Radioactive Material Packaging and Transportation Quality Assurance Program (PTQAP), Revision 19 (January 25, 2012).

cc: J. Calle, NRC Region II
T. Liu, NRC Project Manager
NRC Senior Resident Inspector – PGDP

Enclosure
GDP 12-0003

UEO-1041
Radioactive Material Packaging and Transportation Quality Assurance Program (PTQAP)
Revision 19
(January 25, 2012)

Radioactive Material Packaging and Transportation Quality Assurance Program

USEC Document UEO-1041

REMOVAL/INSERTION INSTRUCTIONS

Revision 19

(January 25, 2012)

Remove Pages	Insert Pages
Pages iii/iv, xi/xii, 1/2, 3/4, 5/6, 7/8, 9/10, 19/20	Pages iii/iv, xi/xii, 1/2, 3/4, 5/6, 7/8, 9/10, 19/20

LIST OF EFFECTIVE PAGES

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iii	19
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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.
19	Revised Sections 1, 2.1.1, 2.1.2, 2.2.5, 2.5.2, 2.6.2, and 2.17.2 to delete references to Portsmouth/responsibilities and or adapted sentence structure to a singular subject format i.e., Paducah Gaseous Diffusion Plant (GDP) only.

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1. INTRODUCTION

10 CFR 76.60 (g) requires the United States Enrichment Corporation (USEC) to comply with the applicable provisions of 10 CFR 71, "Packaging and Transportation of Radioactive Material." 10 CFR 71.0 (d) subjects the transport of licensed material or delivery of licensed material to a carrier for transport to the quality assurance requirements of Subpart H. 10 CFR 71.17 (c)(2) requires compliance with the applicable requirements of Subpart H. This Quality Assurance Program describes how USEC satisfies the applicable requirements of Subpart H in accordance with 10 CFR 71.101(c).

This document is organized in accordance with the applicable criteria of 10 CFR 71 Subpart H. U.S. Nuclear Regulatory Commission Regulatory Guide 7.10, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material," was used as guidance in developing the Radioactive Material Packaging and Transportation Quality Assurance Program. The PTQAP is applied to the design, procurement, fabrication, assembly, use, maintenance, repair and testing of packing used in the transport of radioactive material in excess of Type A quantities or fissile material.

In accordance with these provisions, this document applies to the Paducah Gaseous Diffusion Plant (GDP).

2. REQUIREMENTS

2.1 ORGANIZATION

2.1.1 Structure

The United States Enrichment Corporation (USEC) is responsible for the design, procurement, fabrication, assembly, use, maintenance, repair, and testing of packaging used in the transport of radioactive material. The USEC organizational structure is described in the Safety Analysis Report (SAR) for the GDP.

2.1.2 Responsibilities

The positions having principal responsibility for activities covered under the scope of the Radioactive Material Packaging and Transportation Quality Assurance Program (PTQAP) are described in the Safety Analysis Report (SAR) for the GDP.

2.1.2.1 *Section deleted*

2.1.2.2 *Section deleted*

2.1.2.3 *Section deleted*

2.1.2.4 *Section deleted*

2.1.2.5 *Section deleted*

2.1.2.6 *Section deleted*

2.1.2.7 *Section deleted*

2.2 QUALITY ASSURANCE PROGRAM

2.2.1 General

The PTQAP complies with the applicable provisions of 10 CFR 71 Subpart H and is established, maintained, and executed as described in this document.

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 GDP 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, Enrichment Operations at least once every 24 months by the NS&Q manager. 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 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.

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 Production Support Manager 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 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 Production Support Manager is responsible for the development, maintenance, and implementation of the records management system.