



July 27, 2012
GDP 12-0026

ATTN: Document Control Desk
Ms. Catherine Haney
Director, Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Paducah Gaseous Diffusion Plant (PGDP)
Docket No. 71-0832
Revision 20 to the Radioactive Material Packaging and Transportation Quality Assurance Program (PTQAP)

Dear Ms. Haney:

The United States Enrichment Corporation (USEC) hereby submits Revision 20 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 20 to the PTQAP incorporates changes to Sections 2.5.2, 2.6.2, and 2.17.2. These changes were previously submitted for NRC review and approval in our letter dated June 29, 2012 (Reference 1). These changes were approved in Revision 20 to the NRC Quality Assurance Program Approval for Radioactive Material Packages No. 0832 via NRC letter dated July 24 2012 (Reference 2). Revision bars are provided in the right-hand margin to identify changes to the PTQAP. Revision 20 to the PTQAP became effective on July 24, 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 12-0022, dated June 29, 2012.
 2. Letter from Eric Benner (NRC) to Mr. Steven A. Toelle (USEC), "Quality Assurance Program Approval for Radioactive Material Packages No. 0832, Revision 20", dated July 24, 2012.

Enclosure: UEO-1041, Radioactive Material Packaging and Transportation Quality Assurance Program (PTQAP), Revision 20 (July 24, 2012).

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

Enclosure
GDP 12-0026

UEO-1041
Radioactive Material Packaging and Transportation Quality Assurance Program (PTQAP)
Revision 20
(July 24, 2012)

**Radioactive Material Packaging and Transportation Quality Assurance Program
USEC Document UEO-1041**

REMOVAL/INSERTION INSTRUCTIONS

**Revision 20
(July 24, 2012)**

Remove Pages	Insert Pages
Pages iii/iv, xi/xii, 7/8, 9/10, 19/20	Pages iii/iv, xi/xii, 7/8, 9/10, 19/20

LIST OF EFFECTIVE PAGES

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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.
20	Revised Sections 2.5.2, 2.6.2, and 2.17.2 to reflect deletion of the Production Support Organization and the reassignment of its former procedures, document control, and records management functions to the Regulatory Affairs Organization.

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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 Regulatory Affairs 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 Regulatory Affairs 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 Regulatory Affairs Manager is responsible for the development, maintenance, and implementation of the records management system.