MID-AMERICA CONVERSION SERVICES
ATKINS, WESTINGHOUSE & FLUOR

DUF6 Depleted Uranium Hexafluoride Conversion Project

Project Quality Assurance Plan

Prepared by: Quality Assurance

Approved by: See DUF6 Form 4320

T. Zack Smith, President & Project Manager

APPROVAL PAGE

Listed below are personnel responsible for the preparation, review, and approval of this plan. Signatures for each have been provided on DUF6 Form 4320, *Document Review & Approval Form*.

LEAD PREPARER	Doug Jones, Paducah QA Engineer
TECHNICAL REVIEWERS:	Keith Hoyer, Paducah Site QA Manager and QA Program Manager
APPROVERS:	Scott Nicholson, Program Director - ESH&QA
	Pete Coutts, Portsmouth Site Plant Manager
	James Barker, Paducah Site Plant Manager
	Sharon Shirley, Program Director - Business Manager & Chief Administration Officer
	Adam Goldberg, Program Director - Chief Engineer
	T. Zack Smith, MCS President and Project Manager

REVISION LOG			
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0	05/07/2017	In accordance with DOE memo PPPO-01-3959684-17, dated 1/31/17, this revision replaced ASME NQA-1 2004/2007a with ASME NQA-1 2008/2009a, addressed other DOE comments, and documents number change from DUF6-MCS-PLN-003 to DUF6-PLN-003.	17, 22, 30, 31, 41, 47, 50, 51, 53, 58, 63, 65, 77, 78, 80, 82, 86, 91, 92, 95-102
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2	12/04/2019	Non-Intent change - Periodic Review	1,3
3	12/23/20	Revised to include new Software Quality Assurance Requirements in Section 19, delete In Process Surveillance in Section 18, refine and clarify the graded approach process, include IPI information in section 12, and make other corrections such as personnel name changes throughout.	All

TABLE OF CONTENTS

ACRONYMS 6

EXECUTIVE SUMMARY 7

1 ORGANIZATION 11

2 QUALITY ASSURANCE PROGRAM 11

3 DESIGN CONTROL 13

4 PROCUREMENT DOCUMENT CONTROL 14

5 INSTRUCTIONS, PROCEDURES, AND DRAWINGS 15

6 DOCUMENT CONTROL 16

7 CONTROL OF PURCHASED ITEMS AND SERVICES 16

8 IDENTIFICATION AND CONTROL OF ITEMS 18

9 CONTROL OF SPECIAL PROCESSES 19

10 INSPECTION 19

11 TEST CONTROL 19

12 CONTROL OF MEASURING AND TEST EQUIPMENT 20

13 HANDLING, STORAGE, AND SHIPPING 21

14 INSPECTION, TEST, AND OPERATING STATUS 22

15 CONTROL OF NONCONFORMING ITEMS 23

16 CORRECTIVE ACTION 24

17 QA RECORDS 24

18 INDEPENDENT ASSESSMENT 25

19 COMPUTER SOFTWARE MANAGMENT 25

20 SUSPECT/COUNTERFEIT ITEMS 37

21 ATTACHMENTS 39

Attachment A, QUALITY ASSURANCE REQUIRMENTS FOR CATEGORY QL3, PRODUCTION SUPPORT AND QL4, GENERAL SUPPORT 40

Attachment B, TERMS AND DEFINITIONS 48
Attachment C, MCS ORGANIZATION 57

ACRONYMS

ASME	American Society of Mechanical Engineers
ASNT	American Society of Nondestructive Testing
ASTM	American Society for Testing and Materials
MCS	Mid-America Conversion Services, LLC
CAS	Contractor Assurance System
CFR	Code of Federal Regulations
CM	Configuration Management
DID	Defense in Depth
DOE	U.S. Department of Energy
DSA	Documented Safety Analysis
DUF6	Depleted Uranium Hexafluoride
EFCOG	Energy Facility Contractors Group
EM	Environmental Management
ESH&QA	Environment, Safety, Health and Quality Assurance
GS	General Support
ICN	Interim Change Notice
IPI	Installed Plant Instrumentation
ISMS	Integrated Safety Management System
M&TE	Measuring and Test Equipment
NARA	National Archive and Records Administration
NDE	Non-Destructive Examination (tests including RT-radiographic; MT-magnetic particle; UT-ultrasonic; PT-liquid penetrant; LT-leak testing; VT-visual testing)
O	Order
OpEx	Operating Experience
P	Policy
PQAP	Project Quality Assurance Plan
PS	Production Support
QA	Quality Assurance
SAT	Systematic Approach to Training
S/CI	Suspect/Counterfeit Item
SME	Subject Matter Expert
SQA	Software Quality Assurance
SQAP	Software Quality Assurance Plan
SS	Safety Significant
SSC	Structures, Systems, and Components
SSEP	Safeguards Security/Emergency Preparedness
TSR	Technical Safety Requirements

EXECUTIVE SUMMARY

This Project Quality Assurance Plan (PQAP) is based on Title 10 Code of Federal Regulations (CFR) 830 Subpart A, *Quality Assurance Requirements*; U.S. Department of Energy (DOE) Order (O) 414.1D Chg. 1, *Quality Assurance*; DOE EM-QA-001, Revision 1, *Environmental Management (EM) Quality Assurance Program*; and the American Society of Mechanical Engineers (ASME) NQA-1-2008 with addenda NQA-1a-2009. (ASME NQA-1a-2009) This PQAP implements the requirements in Part 1 and applicable subparts in Part II of NQA-1a-2009 in a graded approach as described in this PQAP.

To maintain configuration of our consensus standards commitments, DUF6-U-QIP-001, *DUF6 Quality Implementation Plan*, provides a crosswalk from EM-QA-001 to DOE O 414.1D Chg. 1, ASME NQA-1a-2009, and to the DUF6 implementing documents. DUF6-U-QIP-001 is managed as a controlled document and is maintained current with the proper implementing documents.

This PQAP prescribes a comprehensive quality program for work performance during the operation and maintenance of the conversion facilities and the cylinder storage yards at Paducah and Portsmouth. Utilization of this PQAP and its implementing documents is required for continued safety, integrated safety management, and programmatic mission reliability.

The consistent application of quality assurance (QA) is comprised of the QA Policy Statement, this PQAP, and the respective implementing documents (i.e., plans, procedures, instructions technical specifications, and drawings), that are used to minimize the potential of hazards occurring to the public, site personnel, and the environment. ASME NQA-1a-2009, Part III, *Non-mandatory Appendices*, guidance was used in developing implementing procedures.

The DUF6 Program Director - Environment, Safety, Health and Quality Assurance (ESH&QA) is assigned responsibility, authority, and accountability to ensure the development, implementation, assessment, maintenance, and improvement of this PQAP. To ensure this document remains current and continues to address identified controls, this PQAP will be reviewed annually and DOE will be apprised of the results.

This PQAP is implemented in a manner that supports the Integrated Safety Management System and Nuclear Safety Management Program commitments. This PQAP shares the DUF6 management systems approach with the Integrated Safety Management System (ISMS) and thus is a part of the DUF6 commitment to comply with DOE Policy (P) 450.4A, *Integrated Safety Management Policy*. This approach is described in DUF6-PLN-040, *Integrated Safety Management System Plan*. The PQAP shares the DUF6 management systems approach with ISMS in achieving ISMS objectives. These objectives include the following ISMS Guiding Principles and Functions:

- Line management responsibility for safety.
- Clear roles and responsibilities.
- Competence commensurate with responsibilities.
- Balanced priorities.
- Identification of safety standards and requirements.
- Hazard controls tailored to work being performed.
- Operations authorization.
- Worker involvement.
- Define the scope of work.
- Analyze the hazards.
- Develop and implement hazard controls.
- Perform work safely within controls.
- Provide feedback and continuous improvement

Sections 1-18 of this PQAP align with the 18 requirements provided in ASME NQA-1a-2009, Part 1. Section 19 provides the requirements for software management, as described in ASME NQA-1a-2009, Part II, Subpart 2.7, *Quality Assurance Requirements for Computer Software for Nuclear Facility Applications*, and DOE Guide 414.1-4, *Safety Software Guide for Use with 10 CFR 830 Subpart A, Quality Assurance Requirements,* and DOE O 414.1D Chg. 1, *Quality Assurance,* for all other software. Lastly, Section 20 provides the requirements for Suspect/Counterfeit Items, (S/CI) as described in DOE O 414.1D Chg. 1.

Policy Statement from MCS President & Project Manager and Management Team

At DUF6, we will work to achieve our mission by ensuring our actions are in compliance with our Quality Assurance (QA) commitments and procedures to protect our workers, the public, the environment and government assets. This PQAP applies to activities affecting quality (i.e., deeds, actions, processes, tasks, or work), which influence the achievement or verification of our requirements and objectives.

This PQAP defines the actions to be taken by DUF6 management, employees, and our subcontractors during the performance of activities affecting quality. All employees are

responsible for upholding our key principles of procedure compliance, personal accountability, and technical inquisitiveness in our assigned work.

DUF6 is fully committed to meeting and exceeding external and internal customer requirements and expectations. As such, all employees are personally responsible for achieving, maintaining, and improving quality in all aspects of their assigned work.

All employees and subcontractors are given authority commensurate with their responsibilities, including the authority to stop or pause any work that does not conform to established requirements.

This PQAP contains the basic principles found in our nuclear safety culture and shares in our management systems approach with our Integrated Safety Management System.

This PQAP has our complete support and shall be followed at all times. Compliance with the requirements of this PQAP is mandatory and DUF6 is fully committed to it.

Project Quality Assurance Plan Applicability

This Project Quality Assurance Plan implements the applicable requirements of EM-QA-001 and applies to all work performed by DUF6 (e.g., mission, safety and health) in a graded approach as defined in this PQAP. This PQAP also applies to work performed in the DUF4 project, which is being implemented at the Portsmouth DUF6 facility. These requirements are passed down to lower-tier organizations through the sub-contracting process.

Graded Approach Overview

Using the graded approach to quality, this PQAP describes three categories of structures, systems and components (SSC) and activities related to them, at the DUF6 facilities. The graded application of the PQAP requirements to specific activities shall be dependent on the hazards and/or level of risk associated with the activity or SSCs under consideration.

> *Category QL-2 Safety Significant*: Designation for those SSCs, whose preventative or mitigative function, is a major contribution to defense-in-depth and/or worker safety as determined by the DUF6 Documented Safety Analyses (DSA). Although the DUF6 Cylinder Storage Yards and the Conversion Facilities are classified as nuclear hazard category 2 and 3 facilities respectively, which results in the DUF6 Paducah and Portsmouth locations being classified as DOE nuclear facilities, the chemical hazards of the DUF6 Conversion project are the only basis for the inclusion of the safety significant QL-2 classification of SSCs and services related to those SSCs. Safety Significant SSCs are identified in the DUF6 DSAs associated with the Paducah and Portsmouth conversion facilities and cylinder storage yards, and in DUF6-U-PEP-1102, *Grading of Structures, Systems and Components and Identification of Configured Items.* Items or activities classified as QL-2 may include piping, valves, tanks, pumps or other equipment which provide containment for chemical safety and services associated with them.

Category QL-3 Production Support: Designation for those SSCs not classified as Safety Significant, but determined to be necessary to support expected operation of the facility. These SSCs and related activities, which may include waste management driven programs are subject to the requirements of this PQAP in a graded approach as defined in Attachment A. Production Support SSCs are identified in DUF6-U-PEP-1102, *Grading of Structures, Systems and Components and Identification of Configured Items.* SSCs or activities classified as QL-3 may include SSCs such as hydrogen generation, steam boilers, distributer plates, waste management containers and materials etc.

Category QL-4 General Support: Designation for those SSCs not classified Safety Significant or Production Support. These SSCs and related activities, which may include regulatory driven programs are subject to the requirements of this PQAP in a graded approach as defined in Attachment A. QL-4 General Support SSCs are identified in DUF6-U-PEP-1102, Grading of Structures, Systems and Components and Identification of Configured Items. SSCs or activities classified as QL-4 include most of the fire water system, sprinkler heads, potable water system, hoisting and rigging equipment, OSHA related equipment, some laboratory services, etc.

The application of this PQAP to the three project functional classifications cannot be graded to "zero" quality requirements.

Note: Safety Class QL-1 is the designation for those SSCs whose preventative or mitigative function is necessary to limit radioactive hazardous material exposure to the public, as determined by safety analysis. The DUF6 Documented Safety Analyses (DSA) have determined that the DUF6 Conversion Project does not have any Safety Class SSCs.

1 ORGANIZATION

This section identifies and documents the QA Program requirements for the DUF6 organization based on DOE O 414.1D Chg. 1, *Quality Assurance*, Management/Criterion 1 – Program, Assessment/Criterion 10 – Independent Assessment, DOE Order 226.1B, *Implementation of Department of Energy Oversight Policy* to ASME NQA-1a-2009, Part 1 Requirement 1, Organization. DUF6 does not use a graded approach to implement NQA-1a-2009, Requirement 1.

NQA-1, Part 1, Requirement 1 contains basic requirements that the establishment and implementation of the quality assurance program be defined. It includes requirements for organizational structure, functional responsibilities, levels of authority, and lines of communication for activities affecting quality. Requirements for delegation of work and interface control are also defined.

The roles and responsibilities for establishment and implementation of the QA Program are defined along with the levels of authority, lines of communication for activities affecting quality, and interfaces for those managing, performing, inspecting, and assessing work. The MCS President and Project Manager has assigned the ESH&QA Manager to establish, maintain, and provide a single point of responsibility for this PQAP and assess its effective implementation. Day-to-day direction for implementation of the program has been assigned to the QA Program Manager. Details of the organization, including functions and responsibilities, are provided in DUF6's *Project Management Plan*, DUF6-PLN-001 and as described in other sections of this PQAP.

Note: Personnel official position titles and working titles may differ. For example, the Program Manager I, ESH&QA's working title is ESH&QA Manager.

2 QUALITY ASSURANCE PROGRAM

This section identifies and documents the QA Program requirements based on DOE O 414.1D Chg. 1, *Quality Assurance*, Management/Criterion 1 – Program, Criterion 2 – Personnel Training and Qualification, Criterion 3 – Quality Improvement, Criterion 9 – Assessment/Management Assessment; DOE Order 226.1B, *Implementation of Department of Energy Oversight Policy;* ASME NQA-1a-2009, Part 1 Requirement 2, Quality Assurance Program. DUF6 does not use a graded approach to implement NQA-1a-2009, Requirement 2.

NQA-1, Part 1, Requirement 2 contains basic requirements that the documented quality assurance program be planned, implemented, and maintained in accordance with Part 1, or portions thereof. It includes requirements for indoctrination and training, qualification requirements, records of qualification, and records of implementation and training.

The DUF6 QA Program fulfils the above requirements and supports ISMS Performance, Objectives, Measures, and Criteria by providing programmatic controls and assessments ensuring improvements in personnel safety, radiological safety, and environmental performance as described in DUF6-PLN-040, *Integrated Safety Management System Plan*.

DUF6 management ensures that the QA Program is reviewed at least annually and revised as needed, and regularly assessed to assure compliance and effectiveness of quality requirements implementation at a frequency such that all elements of the QA Program are assessed at least triennially.

Responsibilities of DUF6 management are as follows:

- The MCS President and Project Manager has delegated the authority to administer the QA Program described in this PQAP and implementing procedures to the ESH&QA Manager.
- DUF6 managers and supervisors are responsible for establishing effective interfaces and communication processes with both the internal and external organizations.
- The Training Manager is responsible for administering the training and qualification program in accordance with DOE O 426.2, *Personnel Selection, Training, Qualification, and Certification for DOE Nuclear Facilities*, as implemented through DUF6-PLN-027, *Personnel Selection, Training, and Qualification Management Plan.*
- DUF6 functional managers are responsible for ensuring that initial and continuing training and qualification programs, including on-the-job training, are established and maintained for assigned personnel, and assessing the adequacy and effectiveness of training programs for their areas of responsibility.
- DUF6 management is responsible for performing management assessments pertaining to their assigned responsibilities and assigned scope of work. Their participation is essential to the success of the quality improvement process because they are in a position to both evaluate the organization as a total system and to effect needed change.

The American Society for Nondestructive Testing, Recommended Practice No. SNT-TC-1A (2011), *Personnel Qualification and Certification in Nondestructive Testing*, is the required standard for project Non-Destructive Examination (NDE) personnel and activities. Subcontractors performing work under any other standard or different editions of SNT-TC-1A must be approved by the QA Program Manager.

Operations and Maintenance personnel who perform routine operational and maintenance inspection and testing activities are qualified in accordance with DOE O 426.2, *Personnel Selection, Training, Qualification, and Certification Requirements for DOE Nuclear Facilities*, as implemented through DUF6-PLN-027, *Personnel Selection, Training, and Qualification Management Plan.* This provides confidence that suitable proficiency is achieved and maintained in the performance of activities affecting quality as defined in this PQAP.

Lead assessors (referred to as lead auditors in NQA-1a-2009) who organize and direct assessments, report assessment findings, and evaluate corrective actions are qualified and certified in accordance with NQA-1a-2009 requirements. Qualification is based on

communication skills, training, assessment participation, examination, maintenance of proficiency, and requalification. Assessors are provided appropriate training or orientation to develop their competence for performing assessments. Qualification requirements are established for the use of technical specialists.

DUF6 management regularly assesses the adequacy and effective implementation of the QA program.

In addition to the assessment of adequacy and effectiveness of the QA Program, Project Management assesses the performance of their groups to determine how well they meet project and DOE requirements, expectations, mission, and objectives. The purpose of this effort is to identify deficiencies and proficiencies to facilitate continuous improvement. These assessments are generally completed as Management Assessments, in accordance with the management assessment implementing procedure.

The details and implementation of requirements pertaining to management assessments and other assessment processes are performed and documented in accordance with the applicable DUF6 procedure. The coordination and scheduling is documented in DUF6-PLN-130, *DUF6 Oversight Plan*.

The ESH&QA Manager ensures that implementing procedures for management assessments and other assessment processes are maintained and implemented. Project management performs management assessments pertaining to their scope of assigned work. Their participation is essential to the success of the process because they are in a position to both evaluate the organization as a total system and to effect needed change. In some situations, these assessments may be performed by others that are knowledgeable in the subject area and trained in assessment techniques.

3 DESIGN CONTROL

This section identifies and documents the QA Program requirements for design based on DOE O 414.1D Chg. 1, *Quality Assurance*, Performance/Criterion 6 – Design, Criterion 8 – Inspection and Acceptance Testing, and a graded approach to ASME NQA-1a-2009, Part 1 Requirement 3, Design Control. For QL-2 SSCs and activities related to their safety function, DUF6 does not use a graded approach to implement NQA-1a-2009, Requirement 3. For QL-3 and QL-4 SSCs and related activities, see below and Attachment A.

NQA-1, Part 1, Requirement 3 contains basic requirements that the design be defined, controlled, and verified. It establishes requirements for design inputs, design process, design analysis, design verification, change control, interface control, software design control, and documentation and records.

For ASME NQA-1a-2009, Part II, Subpart 2.7 requirements related to the software design process see Section 19 of this PQAP.

The Program Director-Chief Process Technical Officer, Chief Engineer is responsible for maintaining the Technical Baseline and Safety Basis standards for the plants and

ensuring that any changes in the configuration are reviewed and compliant with these requirements.

The design of Safety Significant SSCs is subject to a greater degree of design control and verification than design of Production Support and General Support SSCs. Determination of the required rigor of design control for the DUF6 Conversion Project facilities is based upon DSAs performed in compliance with requirements of 10 CFR 830 Subpart B. These analyses establish:

- The identification and functions of Safety Significant SSCs.
- The safety functions performed by those SSCs.

The responsibility of the Engineering Department is as follows:

- The DUF6 Engineering Department is responsible for implementing design control functions at the plants as they pertain to modification, maintenance, fabrication, and installation of buildings and system components.
- Design activities are performed only through the use of approved and released design documents and work packages as appropriate.
- Project engineering and design personnel are required to perform their work in full compliance with approved plans and implementing procedures.

4 PROCUREMENT DOCUMENT CONTROL

This section identifies and documents the QA Program requirements for procurement document control based on DOE O 414.1D Chg. 1, *Quality Assurance*, Performance/Criterion 7 – Procurement and a graded approach to ASMENQA-1a-2009, Part 1 Requirement 4, Procurement Document Control. For QL-2 SSCs and activities related to their safety function, DUF6 does not use a graded approach to implement NQA-1a-2009, Requirement 4. For QL-3 and QL-4 SSCs and related activities, see Attachment A.

NQA-1a-2009, Part 1, Requirement 4 contains basic requirements that the applicable design bases and other requirements necessary to assure adequate quality shall be included or referenced in documents for procurement of items and services. It establishes requirements for the content of procurement documents, procurement document review, and procurement document changes.

The procurement process is executed in full compliance with applicable NQA-1, DOE orders, DOE Acquisition Regulations, and Federal Acquisition Regulations.

The responsibilities for procurement document control are as follows:

- DUF6 Procurement is responsible for establishing the process for the preparation, review, and issuance of procurement documents.

- Purchase requisition requestors are responsible for providing the scope of work and providing the technical requirements that must be specified including any documentation that must be submitted and approved by DUF6. The appropriate information needed to accept the item or service is identified.
- Purchase requisition requestors, with the assistance and guidance from the Engineering and QA Organizations, are responsible for specifying QA requirements that will be included in the procurement document. This will be based on information, such as quality level, scope, technical requirements, design characteristics, complexity of the item/service, past history, and cost.
- Quality Assurance personnel review purchase requisitions and purchase orders for QL-2 items and services and other specified QL-3 and QL-4 items and services to assure incorporation of quality controls and inspection and acceptance requirements

Project personnel are responsible for requesting items or services that are in full compliance with approved plans and implementing procedures.

5 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

This section identifies and documents the QA Program requirements for instructions, procedures, and drawings based on DOE O 414.1D Chg. 1, *Quality Assurance*, Performance/Criterion, 5 – Work Processes, Management/Criterion 4 – Documents and Records, and a graded approach to ASME NQA-1a-2009, Part 1 Requirement 5, Instructions, Procedures and Drawings. For QL-2 SSCs and activities related to their safety function, DUF6 does not use a graded approach to implement NQA-1a-2009 Requirement 5.

NQA-1a-2009, Part 1, Requirement 5 contains basic requirements that activities affecting quality and services shall be prescribed by and performed in accordance with documented instructions, procedures, or drawings that include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished.

DUF6 has established processes and procedures to meet the above requirements. Responsibility for instructions, procedures, and drawings is as follows:

- DUF6 Program Manager, Operations Paducah, has the responsibility for the establishment of the processes for preparation and approval of procedures.
- Work package instructions are prepared by each site's Work Control organization, in accordance with approved procedures.
- DUF6 Engineering has responsibility for drawings and other design documents.
- Each DUF6 employee and DUF6 subcontractor performing project work is required to do so in full compliance with approved plans, procedures, instructions, and other approved implementing documents. DUF_6 employees

are charged with identifying ways to continuously improve quality and operational performance through worker feedback. Any deviations from prescribed procedural direction require prior approval. The core functions of the project's ISMS are employed during the development and execution of implementing documents.

Assessments evaluate performance in accordance with instructions, procedures and drawings and provide opportunities for improvement.

6 DOCUMENT CONTROL

This section identifies and documents the QA Program requirements for document control based on DOE O 414.1D Chg. 1, *Quality Assurance*, Management/Criterion 4 – Documents and Records and ASMENQA-1a-2009, Part 1 Requirement 6, Document Control. DUF6 does not use a graded approach to implement NQA-1a-2009, Requirement 6.

NQA-1a-2009, Part 1, Requirement 6 contains basic requirements that the preparation, issue, and change of documents that specify quality requirements or prescribe activities affecting quality such as instructions, procedures, and drawings shall be controlled to ensure that correct documents are being employed. It establishes requirements for document control and document changes. Criteria for major document changes and minor changes are defined.

DUF6 uses documents to control policy, administration, work, and technical information. Documents describe work to be done, data to be used, and information to be controlled. In a controlled manner, the Document Control System supplies those documents needed by personnel to safely and correctly perform tasks and carry out their responsibilities. The Document Control System is an integral part of ISMS.

Responsibilities involving Document Control are as follows:

The DUF6 Records Management/Document Control (RM/DC) organization is responsible for implementing the Document Control requirements provided in this section. DUF6 employees are responsible for ensuring that they are working to the correct revision of the controlled document.

7 CONTROL OF PURCHASED ITEMS AND SERVICES

This section identifies and documents the QA Program requirements for procurement of items and services based on DOE O 414.1D Chg. 1, *Quality Assurance*, Performance/Criterion 7 – Procurement, DOE Order 226.1B, *Implementation of Department of Energy Oversight Policy* and a graded approach to ASME NQA-1a-2009, Part 1 Requirement 7, Control of Purchased Items and Services. For QL-2 SSCs and activities related to their safety function, DUF6 commits to NQA-1a-2009, Part 1 requirements, and to alternative approaches as described below, when they provide equivalent and effective control.

NQA-1, Part 1, Requirement 7 contains basic requirements that the procurement of items and services shall be controlled to ensure conformance with specified requirements. It establishes requirements for supplier evaluation and selection, bid evaluation, control of supplier-generated documents, acceptance of items or services, control of supplier non-conformances, and a reference to NQA-1a-2009, Part II, Subpart 2.14, commercial grade items and services, and records.

For engineered equipment, contractual requirements are invoked to assure that use-as-is or repair dispositions for nonconformances identified at a supplier's facility are to be approved by DUF6 before further action is taken (this is not invoked for commercial off the shelf items).

The DUF6 Quality Assurance Program is implemented meeting the above requirements as further described in the following:

NQA-1a-2009, section 200, Supplier Evaluation and Selection, states prior to award of a contract, the Purchaser shall evaluate the Supplier's capability to provide items and services in accordance with the requirements of the procurement documents. The DUF6 Quality Assurance Program includes an evaluation of suppliers' capability to evaluate their sub-tier suppliers. Where adequate capability exists, DUF6 allows approved suppliers of items and services to subcontract performance of portions of their scope to their sub-tier suppliers when working under their DUF6 approved quality program provided that the supplier has flowed down applicable quality requirements to their sub-tier suppliers.

When supplier evaluation is performed of the supplier's technical and quality capability as determined by a direct evaluation of the facilities, personnel, and the implementation of the supplier's quality assurance program, the DUF6 Quality Assurance Program allows the use of remote technology such as virtual meetings, video conferencing, live video streaming of demonstrations and evolutions, electronic sharing of records and documents. The alternate approach is also allowed for Commercial Grade Surveys in the commercial grade dedication process.

The DUF6 program allows for the use of accreditation, certification, and/or license from an independent agency in the supplier evaluation process where suitable confidence exists in the rigor of the accreditation, certification or license. These will be used as evidence to an evaluation per NQA-1a-2009 Part I, Requirement 7, section 200. Examples may include ISO certification, ASME Standards and Specifications, NFPA Standards, etc. The program also allows for the use of supplier evaluations from industry groups including, but not limited to, EFCOG, other DOE Contractors, and MCS parent companies.

The DUF6 program allows for purchase of items and services from approved suppliers. Approval of suppliers is accomplished through evaluation of the proposed supplier's quality program using tailored NQA-1 based checklists. When the supplier's quality program meets applicable requirements on the checklist, the supplier is approved. Where requirements are not met, restrictions or a limited scope are indicated on the DUF6 approved supplier list.

Suppliers with Quality Programs other than NQA-1 (ISO 9001, ISO 17025, etc.) may be approved to supply safety significant items and services if the supplier's history, current quality records supported by documented qualitative and quantitative information, or direct evaluation support supplier qualification. This approach is primarily used for procurement of QL-2 items which provide protection against chemical hazards, not nuclear hazards.

DUF6 meets the requirements of NQA-1a-2009 Part I, Requirement 7, Section 700 and Part II, Subpart 2.14, *Quality Assurance Requirements for Commercial Grade Items and Services.*

DUF6 may use third-party dedication entities in the commercial grade dedication process, such that only a receipt inspection is necessary after procurement of the item. Allowing the use of third-party dedication entities is based on evaluation of the dedication entity to assure capability to perform effective dedication of critical attributes.

8 IDENTIFICATION AND CONTROL OF ITEMS

This section identifies and documents the QA Program requirements for identifying and controlling items based on DOE O 414.1D Chg. 1, *Quality Assurance*, Performance/Criterion 5 – Work Processes, Performance/Criterion 8 – Inspection and Acceptance Testing, and a graded approach to NQA-1a-2009, Part 1 Requirement 8, Identification and Control of Items. For QL-2 SSCs and activities related to their safety function, DUF6 does not use the graded approach to implement NQA-1a-2009 Requirement 8. For QL-3 and QL-4 SSCs and related activities, see Attachment A.

NQA-1a-2009, Part 1, Requirement 8 contains basic requirements that controls be established to assure that only the correct and accepted items are used or installed. It establishes requirements for identification methods and specific requirements for identification and traceability of items, limited life items, and maintaining identification of stored items.

Identification and control of items is a factor in configuration control of installed and replaced items as described in DUF6-PLN-121, *Configuration Management Plan for Operations.*

The responsibility of DUF6 Warehouse/Property/Site Services personnel is as follows:

- Ensuring that items requiring identification and control measures are maintained and issued for test and installation as required by this section.
- Ensuring that item identification and controls are maintained while the items are being stored and maintained until issued for installation.

9 CONTROL OF SPECIAL PROCESSES

This section identifies and documents the QA Program requirements for controlling special processes based on DOE O 414.1D Chg. 1, *Quality Assurance*, Performance/Criterion 5 – Work Processes and ASME NQA-1a-2009, Part 1Requirement 9, Control of Special Processes. DUF6 does not use the graded approach to implement NQA-1a-2009, Requirement 9.

NQA-1a-2009, Part 1, Requirement 9 contains basic requirements that special processes that control or verify quality, such as those used in welding, heat treating, and nondestructive examination, shall be performed by qualified personnel using qualified procedures in accordance with specified requirements. It establishes requirements for process control, special processes, acceptance criteria, special requirements, responsibility, and records.

10 INSPECTION

This section identifies and documents the QA Program requirements for inspection based on DOE O 414.1D Chg. 1, *Quality Assurance*, Performance/Criterion 8 – Inspection and Acceptance Testing, DOE Order 226.1B, *Implementation of Department of Energy Oversight Policy* and a graded approach to ASME NQA-1a-2009, Part 1 Requirement 10, Inspection. For QL-2 SSCs and activities related to their safety function, DUF6 does not use a graded approach to implement NQA-1a-2009 Requirement 10. For QL-3 and QL-4 SSCs and related activities, see Attachment A.

NQA-1a-2009, Part 1, Requirement 10 contains basic requirements that inspections required to verify conformance of an item or activity to specified requirements or continued acceptability of items in service shall be planned and executed. It establishes inspection requirements, hold points, inspection planning, in-process inspection, final inspections, inspections during operations, and records.

Engineering, ES&H and QA are responsible for identifying inspection hold points in appropriate documents at which work shall not proceed without the specific consent of the designated representative. Consent to waive specified hold points are recorded prior to continuation of work beyond the designated hold point.

11 TEST CONTROL

This section identifies and documents the QA Program requirements for testing based on DOE O 414.1D Chg. 1, *Quality Assurance*, Performance/Criterion 8 – Inspection and Acceptance Testing, Assessment/Criterion 10 – Independent Assessment, and a graded approach to ASME NQA-1a-2009, Part 1 Requirement 11, Test Control. For QL-2 SSCs and activities related to their safety function, DUF6 does not use a graded approach to implement NQA-1a-2009, Requirement 11. For QL-3 and QL-4 SSCs and related activities, see Attachment A.

NQA-1a-2009, Part 1, Requirement 11 contains basic requirements that tests required to collect data such as for siting or design input, to verify conformance of an item or

computer program to specified requirements, or to demonstrate satisfactory performance for service shall be planned and executed. It establishes test requirements, test procedures (other than for computer programs), computer program test procedures, test results and test records.

The responsibilities involving Test Control are as follows:

- The Engineering organization is responsible for developing test plans and procedures as appropriate and for verification and acceptance of the test results. Additionally, they evaluate test results to ensure the test requirements have been satisfied and the acceptance criteria are met.
- Plant managers have the responsibility for implementing the test control procedures.
- Operations Operators have the responsibility for conducting testing. Staff assigned to testing responsibilities are required to perform work in full compliance with approved plans and procedures.

For ASME NQA-1a-2009, Part II, Subpart 2.7 requirements related to the software testing process see Section 19 of this PQAP.

12 CONTROL OF MEASURING AND TEST EQUIPMENT

This section identifies and documents the QA Program requirements for control of Measuring and Test Equipment (M&TE) based on DOE O 414.1D Chg. 1, *Quality Assurance*, Performance/Criterion 5 – Work Processes, Criterion 8 – Inspection and Acceptance Testing, and ASME NQA-1a-2009, Part 1 Requirement 12, Control of Measuring and Test Equipment. For QL-2 SSCs and activities related to their safety function, DUF6 does not use a graded approach to implement NQA-1a-2009, Requirement 12.

NQA-1a-2009, Part 1, Requirement 12 contains basic requirements that tools, gages, instruments, and other measuring and test equipment used for activities affecting quality shall be controlled, calibrated at specified periods, adjusted and maintained to required accuracy limits. It establishes requirements for the selection of M&TE, calibration and control including calibration, reference standards, control, application, corrective action, handling and storage, environmental controls, pre-calibration checks, status indication, commercial devices, and records.

For M&TE used to calibrate and/or test QL-2 SSCs, DUF6 fully implements NQA-1a-2009, Requirement 12.

For QL-3 and QL-4 SSCs that are <u>not</u> Installed Plant Instrumentation (IPI), and related activities, see Attachment A.

For IPI see below:

The sections of NQA-1a-2009, Requirement 12, apply to QL-2 IPI, and to QL-3 and QL-4 IPI that are controlled in the DUF6 preventative maintenance program, with the following exceptions:

- Sections 302, and 303.2, do not apply to IPI
- Section 303 applies, except that the frequency of accuracy checks and calibrations of IPI is controlled in the DUF6 preventative maintenance program.
- Section 303.6 applies, except that the calibration status of IPI is maintained and tracked in the DUF6 preventative maintenance program; calibration labels are not applied to IPI.
- Section 402 applies, except that no calibration certificates are generated for IPI.

Control of radiological protection equipment is performed in accordance with the requirements of this PQAP and the radiological control organization plans and procedures. Control of industrial hygiene equipment is performed in accordance with the requirements of this PQAP and the industrial hygiene organization plans and procedures.

Responsibilities for managing the M&TE program reside within the Engineering and Maintenance organizations, and they are as follows:

- Engineering is responsible for specifying the requirements for calibrations.
- Maintenance is responsible for managing the calibration and use of M&TE. iRen is used as a tool to manage the calibration program.

13 HANDLING, STORAGE, AND SHIPPING

This section identifies and documents the QA Program requirements for handling, storage, and shipping based on DOE O 414.1D Chg. 1, *Quality Assurance*, Performance/Criterion 5 – Work Processes and ASME NQA-1a-2009, Part 1 Requirement 13, Handling, Storage, and Shipping. DUF6 does not use a graded approach to implement NQA-1a-2009, Requirement 13.

NQA-1a-2009, Part 1, Requirement 13 contains basic requirements that handling, storage, cleaning, packaging, shipping, and preservation of items shall be controlled to prevent damage or loss and to minimize deterioration. It establishes requirements for special conditions when needed (such as containers, inert gas, moisture levels, temperature, etc.), procedures, tools and equipment, operators, and marking or labeling.

The responsibility for handling, storage, and shipping is as follows: Warehouse/Property/Site Services personnel are responsible for ensuring that these activities are conducted in accordance with established instructions, shipment

instructions, or other pertinent documents. Waste Management and Transportation has responsibility for shipping waste, product and samples for laboratory analysis.

The shipping of waste material is addressed in DUF6-PLN-055, *Waste Certification Program Plan*.

14 INSPECTION, TEST, AND OPERATING STATUS

This section identifies and documents the QA Program requirements for determining inspection, test, and operating status based on DOE O 414.1D Chg. 1, *Quality Assurance*, Performance/Criterion 5 – Work Processes, Performance/Criterion 8-Inspection and Acceptance Testing, and ASME NQA-1a-2009, Part 1 Requirement 14, Inspection, Test, and Operating Status. DUF6 does not use a graded approach to implement NQA-1a-2009, Requirement 14.

NQA-1a-2009, Part 1, Requirement 14 contains basic requirements that status of inspection and test activities shall be identified either on the items or in documents traceable to the items where it is necessary to ensure that required inspections and tests are performed to ensure that items that have not passed the required inspections and tests are not inadvertently installed, used, or operated. It establishes requirements for status, tagging, and markings to prevent inadvertent use.

Systems are in place to assure that the status of items, tests and operating status be discernable at any point to prevent inadvertent installation, use or operation. Status indicators are used for a wide variety of activities such as TSR tests, calibrations, receipt inspections, maintenance, repairs, post maintenance testing, etc. Controls are established for the operability modes on TSR equipment.

DUF6 uses appropriate instructions, procedures, and work packages to authorize and control work and operation of plant equipment. These documents include the required plant configuration for the various modes of operation. As a part of these controls, status indicators are used to ensure that plant equipment will not be inadvertently operated. The responsibilities for application and removal of status indicators are outlined in the governing procedure. As a part of the maintenance or modification process, it is confirmed that plant equipment has been properly inspected and tested prior to relying on the equipment to fulfill its safety function.

The responsibilities involved in the inspection, test, and operating status are as follows:

- DUF6 managers/supervisors are responsible for identifying and implementing any inspection, test, and operating status procedures/instructions that may be necessary.
- Subcontractors, if applicable, are responsible for ensuring that inspection, test, and operating status activities are adequate and conform to direction provided by DUF6. Oversight and direction is provided by the Subcontract Technical Representative (STR) to assure subcontractor's compliance with quality requirements.

15 CONTROL OF NONCONFORMING ITEMS

This section identifies and documents the QA Program requirements for control of nonconforming items based on DOE O 414.1D Chg. 1, *Quality Assurance*, Management/Criterion 3 – Quality Improvement, DOE Order 226.1B, *Implementation of Department of Energy Oversight Policy* and ASME NQA-1a-2009, Part 1 Requirement 15, Control of Nonconforming Items. DUF6 does not use a graded approach to implement NQA-1a-2009, Requirement 15.

NQA-1a-2009, Part 1, Requirement 15 contains basic requirements that items that do not conform to specified requirements shall be controlled to prevent inadvertent installation or use. It establishes requirements for identification, segregation, and disposition of nonconforming items.

Plant equipment, consisting of components or items that do not meet prescribed expectations, are addressed by one of the following methods:

If the discovered deficiency involves installed plant equipment that is repairable/replaceable, corrective maintenance is performed per the work control program.

If the deficiency does not involve a repairable/replaceable item, a Condition Report or Nonconformance Report is initiated. If, during the evaluation of the Condition Report it is determined that the item does not meet specified requirements, a nonconformance report will be initiated and processed per the requirement of this chapter.

The responsibilities involved with control of nonconforming items are as follows:

- DUF6 QA is responsible for establishing and managing the process to control nonconforming items.
- DUF6 Engineering is responsible for dispositioning nonconforming items as specified in the controlling procedure.
- All DUF6 personnel are responsible for identifying items that are not in compliance with requirements using the controlling procedure.

For engineered equipment, requirements are invoked to assure that use-as-is or repair nonconformance identified at a supplier's facility equipment are to be approved by DUF6 before further action is taken (this is not invoked for commercial off the shelf items).

Nonconforming conditions are evaluated and where necessary, the causes of problems are identified and prevention of recurrence is established as a part of corrective action planning describe in section 16 below.

16 CORRECTIVE ACTION

This section identifies and documents the QA Program requirements for corrective action based on DOE O 414.1D Chg. 1, *Quality Assurance*, Management/Criterion 3 – Quality Improvement, Assessment/Criterion 9 – Management Assessment, Assessment/Criterion 10 – Independent Assessment, ASME NQA-1a-2009, Part 1 Requirement 16, Corrective Action and DOE Order 226.1B, *Implementation of Department of Energy Oversight Policy*. DUF6 does not use a graded approach to implement NQA-1a-2009, Requirement 16.

NQA-1a-2009, Part 1, Requirement 16 contains basic requirements that conditions adverse to quality shall be identified promptly and corrected as soon as possible. In the case of significant conditions adverse to quality, the cause of the condition shall be determined and corrective actions taken to preclude recurrence. It establishes requirements for the identification, cause, and corrective action for significant conditions adverse to quality to be documented and reported to appropriate levels of management, and verification of corrective action completion.

DUF6-PLN-145, *DUF6 Contractor Assurance System Description*, describes the framework and integration of DUF6 processes that satisfy CAS requirements of DOE O 226.1B. The document describes our integrated site-wide approach to meeting CAS requirements in support of safe, secure operations and continuous improvement.

17 QA RECORDS

This section identifies and documents the QA Program requirements for QA records based on DOE O 414.1D Chg. 1, *Quality Assurance*, Management/Criterion 4 – Document and Records, DOE O 243.1B, *Records Management Program*; and ASME NQA-1a-2009, Part 1 Requirement 17, Quality Assurance Records. Implementation of these requirements also ensures compliance with the Federal Records Management Program requirements. DUF6 does not use a graded approach to implement NQA-1a-2009, Requirement 17.

NQA-1a-2009, Part 1, Requirement 17 contains basic requirements that quality assurance records shall be established consistently with the schedule for accomplishing work activities. Quality Assurance records shall furnish documentary evidence that items or activities meet specified requirements. It establishes requirements for generation of records, authentication of records, classification as lifetime or nonpermanent, receipt control storage, retention and maintenance.

Responsibility for QA records is as follows: DUF6 RM/DC is responsible for developing and maintaining the process to control QA records. Each person performing project work is required to document his or her performance in full compliance with approved instructions and procedures. Records are to be processed and retained and dispositioned as specified in procedures. Documents are available electronically on the DUF6 network. The details of records control processes are provided in DUF6-PLN-015, *Records Management Plan*.

Records are retained in accordance with the DUF6-PLN-205, *Records Disposition Plan for the DUF6 Project*.

18 INDEPENDENT ASSESSMENT

This section identifies and documents the QA Program requirements for independent assessments based on DOE O 414.1D Chg. 1, *Quality Assurance*, Assessments/Criterion 10 –Independent Assessment, DOE O 226.1B, *Implementation of Department of Energy Oversight Policy,* and ASME NQA-1a-2009, Part 1 Requirement 18, Audits. DUF6 uses the term "independent assessment," and not the term "audit," to define the requirements provided in this section. DUF6 does not use a graded approach to implement NQA-1a-2009, Requirement 18.

NQA-1a-2009, Part 1, Requirement 18 contains basic requirements that independent assessments shall be performed to verify compliance to quality assurance program requirements, to verify that performance criteria are met, and to determine the effectiveness of the program. It establishes requirements for scheduling, preparation, performance, reporting, response, follow-up action, and records.

Independent Assessments are performed to verify compliance to quality assurance program requirements, to verify that performance criteria are met, and to determine the effectiveness of the program. These are performed such that all elements of the PQAP are assessed triennially. Independent Assessments are also performed in other areas to assure safe, compliant and reliable plant operations. In addition to Independent Assessments, Management Assessments are performed as discussed in section 2. A schedule of assessments is issued and revised as necessary to assure comprehensive coverage.

19 COMPUTER SOFTWARE MANAGMENT

This section identifies and documents the requirements for computer software management including safety (QL-2) and non-safety (QL-3, QL-4) software as described here for the DUF6 Conversion Project. DUF6 ensures that the software used (acquired or developed in-house) performs its intended specific function.

DUF6 has established and implemented procedures for defining and controlling work activities involving software. Work processes are implemented for safety and non-safety software to meet the requirements of DOE O 414.1D Chg. 1, *Quality Assurance*, Performance/Criterion 5 – Work Processes, Criterion 6 – Design, Criterion 7 – Procurement, Criterion 8 – Inspection and Acceptance Testing; and the software requirements of ASME NQA-1a-2009, Part I Requirement 3, Design Control (section three of this Plan, *Design Control),* Requirement 11, Test Control (section 11 of this Plan, *Test Control*) and, for Safety Software only, Subpart 2.7, *Quality Assurance Requirements for Computer Software for Nuclear Facility Applications*.

In addition, the requirements of DOE O 414.1D Chg. 1, *Quality Assurance*, Attachment 4, *Safety Software Quality Assurance Requirements for Nuclear Facilities,* apply to safety software.

DEFINITIONS OF SAFETY AND NON-SAFETY SOFTWARE

Safety software, as defined in the DOE O 414.1D Chg. 1, includes the following:

- Safety System Software – Software for a nuclear facility that performs a safety function as part of an SSC and is cited in either (a) a DOE-approved Documented Safety Analysis; or, (b) an approved hazard analysis per DOE P 450.4A and 48 C.F.R. 970-5223.1.
- Safety and Hazard Analyses Software and Design Software – Software that is used to classify, design, or analyze nuclear facilities. This software is not part of an SSC but helps to ensure the proper accident or hazards analysis of nuclear facilities or an SSC that performs a safety function.
- Safety Management and Administrative Controls Software – Software that performs a hazard control function in support of nuclear facility or radiological safety management programs or technical safety requirements, or other software that performs a control function necessary to provide adequate protection from nuclear facility or radiological hazards. This software supports eliminating, limiting, or mitigating nuclear hazards to workers, the public, or the environment as addressed in 10 C.F.R. Parts 830and 835; the DEAR Integrated Safety Management System clause3, and 48 C.F.R. 970-5223.1.

Non-safety Software:

- Software used in GS (non-safety) applications where software failure or application error could result in the potential for high, medium, or low operational risk; or where results are the sole source of quality related information that is provided to external customers.

GRADED APPLICATION OF QA FOR SOFTWARE

DUF 6 uses a graded application of QA for software. Software grading levels are described in terms of consequence and regulatory compliance, based on the intended use of the software. The grading levels are defined as follows:

Level A– This grading level includes safety software applications that meet one or more of the following criteria:

- Software failure that could compromise a limiting condition for operation.
- Software failure that could cause a reduction in the safety margin for a safety SSC that is cited in a DOE-approved DSA.
- Software failure that could cause a reduction in the safety margin for other systems such as toxic or chemical protection systems that are cited in either (a) a DOE-approved Documented Safety Analysis; or, (b) an approved hazard analysis per DOE P 450.4A and 48 C.F.R. 970-5223.1.

- Software failure that could result in a non-conservative safety analysis, design, or misclassification of facilities or SSCs.

Level B – This grading level includes safety software applications that do not meet Level A criteria but meet one or more of the following criteria:

- Safety management databases used to aid in decision making whose failure could impact safety SSC operation.
- Software failure that could result in incorrect analysis, design, monitoring, alarming, or recording of hazardous exposures to workers or the public.
- Software failure that could comprise the Defense in Depth capability for the nuclear facility.

Level C – This grading level includes safety software applications that do not meet Level B criteria but meet one or more of the following criteria:

- Software failure that could cause a potential violation of regulatory permitting requirements.
- Software failure that could affect environment, safety, health monitoring or alarming systems.
- Software failure that could affect the safe operation of an SSC.

Level D – Software used in general service (non-safety) applications where software failure or application error could result in the potential for high impact risk, or where results are the sole source of quality-related information that is provided to external customers.

Level E – Software used in general service (non-safety) applications where software failure or application error could result in the potential for medium to low project risk, but where results are not the sole source of quality-related information that is provided to external customers.

Software that meets any of the following criteria is exempt from the formal software control requirements of this plan.

- "Firmware" or "read only" software, that is integrated into equipment or components in such a way that the source code is not alterable by the user and where functionality of the software is demonstrated through Acceptance and Operational Tests of the equipment or component.

- Single-use spreadsheet applications that are wholly incorporated into technical reports, calculation notes or other documentation, where the calculations, mathematical formulas, and input data can be exactly verified during the technical review of the report. Such calculations are treated as and considered to be manual calculations because the assumptions, formulas, inputs and outputs are verified as part of the calculation package technical review.

- Software applications provided by the supplier where the DUF6 employee uses the application on the internet and where DUF6 does not maintain any records or control any of the processing of the application (i.e., DUF6 is a user site).

- Commercial off-the-shelf (COTS) software used for computer-aided drafting (CAD). This is limited to drafting programs where the generated output is independently verified.

SAFETY SOFTWARE REQUIREMENTS

In addition to using ASME NQA-1a-2009, including Subpart 2.7 to address work processes, additional requirements are imposed by DOE O 414.1D for management of safety software as follows:

- Facility design authority involvement, as applicable, in identifying software specification, acquisition, design, development, verification and validation (including inspection and test), configuration management, maintenance, and retirement of safety software.
- Identification, documentation, and maintenance of a software inventory for safety software to include: software description; software name; version identifier; safety software designation (e.g., safety system software, safety and hazard analysis software and design software, safety management and administrative controls software); grade level designation; specific nuclear facility application used; and the responsible individual.
- Establishment and documentation of grading levels for safety software using the graded approach.
- Using the grading levels established in this PQAP, selection and implementation of the applicable Software QA (SQA) work activities from the list below to ensure that software performs its intended functions. Implementation activities are included below each work activity

a) Software project management and quality planning.

Software project management and quality planning activities are captured in Software Quality Assurance Plans (SQAP). SQAPs describe the required SQA work activities, required documentation, responsible participants, and the methods, controls, reviews, and approvals associated with SQA work activities.

b) Software risk management.

Software risk management focuses on the risks to the successful completion of a new software project or major modification to existing safety software applications. Risks to be addressed are project management risks associated with successful completion of project activities by identification, tracking, and management of risks throughout all phases of the project or

modification, and focusing on risks associated with costs, resources, schedules, and technical aspects.

c) Software configuration management.

Software configuration management provides the process for identifying the version of software products, establishing software configuration baselines of each application, and tracking the status of baseline changes. The software configuration baseline consists of approved configuration items, support software, and associated design, test, and user documentation, based on the classification of the software. Changes to software are systematically proposed, evaluated, documented, and approved to ensure that the impact and rationale for making the change is carefully assessed prior to updating the software baseline.

d) Procurement and supplier management.

Prior to purchasing new or updated safety software/service (Levels A, B, or C), an assessment of the adequacy and effectiveness of a supplier's software QA program is performed in accordance with this PQAP and implementing procedures for the specified capabilities and limitations for intended use of the software/service; or the software/service can be dedicated into safety applications in accordance with this PQAP and implementing procedures. Non-safety software is procured in accordance with Appendix A, section 7 of this PQAP.

e) Software requirements identification and management.

Software requirements are documented either in a Software Requirements Specification (SRS), procurement documents, or the SQAP. Software requirements specify technical and software engineering requirements including security features, identify applicable references that establish test, inspection and acceptance criteria, specify security requirements, and identify the operating system requirements and characteristics.

f) Software design and implementation.

Software design considers the computer's operating environment, includes measures to mitigate consequences of problems identified that can affect the computer program, defines the computational sequence necessary to meet software requirements, and is documented to include, as applicable, numerical methods, mathematical models, physical models, control flow, control logic, data flow, process flow, data structures, process structures and their relations.

g) Software safety analysis and safety design methods.

The development and acquisition of safety software applications requires identification of hazards (i.e., abnormal conditions and events) that have the potential for defeating a safety function and the implementation of design strategies to eliminate or mitigate those hazards. Potential failures are identified

and evaluated for consequences and probability of occurrence. Methods and techniques to mitigate consequences of software failures are described.

h) Software verification and validation.

Verification and validation processes are used to determine if developed software products conform to all design requirements and if software products fulfill their intended use and user expectations. Verification and validation processes evaluate the technical adequacy of the design and ensure internal completeness, consistency, clarity, and correctness of the software design or implementation and verify that software design is traceable to the software requirements. Regression testing, when required, detects unintended adverse effects and ensures that the software still meets the software design requirements.

i) Problem reporting and corrective action.

Software problems and errors are identified in condition reports and the resulting corrective actions are tracked to closure per the implementing procedures of the DUF6 Issues Management program. Corrective actions requiring software modification are controlled by software configuration management requirements in (c) above.

j) Training of personnel in the design, development, use, and evaluation of safety software.

Completion of training, education, and/or qualification requirements for all personnel involved in the development, testing, use and evaluation of safety software (Levels A, B, or C) are documented and reviewed periodically to ensure initial proficiency, maintain proficiency and adapt to changes in technology, methods or job responsibilities. Appropriate training plans are determined for these personnel in accordance with the DUF6 Training and Qualification program. Training of personnel involved in the design, development, test, evaluation, and/or use of software shall be commensurate with scope, complexity, importance of the activities, and the education, experience, and proficiency of the person.

GRADED APPROACH FOR SOFTWARE WORK ACTIVITIES

Appropriate QA controls (SQA work activities) shall be implemented using a graded approach based on the software grade level and applicable software type (i.e., custom developed, configurable, acquired, utility calculations, and commercial design and analysis tools).

For each software type and grade level, implementation of a work activity is defined as Full (F), Graded (G), or Not Applicable (N/A). The following information is provided as a guide in determining actions required for each grading approach.

- "Full" (F) implementation of a particular SQA work activity requires that all essential documentation is completed to the degree necessary to ensure that the life cycle work activity is performed in a traceable, planned, and orderly manner. The intended

method for demonstrating required implementation of the SQA activity must be documented in software project plans.

- "Graded" (G) implementation of a particular SQA work activity adapts the software life cycle to the extent necessary to provide reasonable assurance that the software performs its intended function. Less formality is required in documentation and implementation of the work activity. The intended graded implementation of the SQA activity must be documented in software project plans.
- "Not Applicable" (N/A) applies to work activities that are not required. For example, certain SQA activities are not required when performed by a service supplier. In this case, control of SQA activities of the software is achieved through procurement contracts and specifications.

The responsibilities for computer software management are as follows:

- DUF6 Engineering and Information Technology are responsible for the establishment of computer software management controls.
- All organizations are responsible for implementation of these controls.

The following tables indicate DUF6 implementation of the graded approach (full, graded or N/A as described above) for work activities applicable to safety software documents/products, based on the safety software grade level:

1. Custom Developed Software

SQA Document/Product	Software Grade Level				
	A	B	C	D	E
Software Quality Assurance Plan (SQAP)	Full	Full	Graded	Graded	Graded
Software Risk Evaluation Report (SRER)	Full	Graded	Graded	N/A	N/A
Software Safety Analysis Report (SSAR)	Full	Graded	Graded	N/A	N/A
Software Requirements Specification (SRS)	Full	Full	Full	Graded	N/A
Software Procurement	Full	Full	Full	Graded	Graded
Software Functional Description (SFD)	Full	Full	Full	Graded	N/A
Software User Manual (SUM)	Full	Full	Full	Graded	N/A
Software Verification and Validation Plan (SVVP)	Full	Graded	Graded	Graded	N/A
Software Verifications and Validation Report (SVVR)	Full	Graded	Graded	Graded	Graded
Software Installation and Checkout (SIC)	Full	Full	Full	Graded	Graded
Operations and Maintenance	Full	Full	Graded	Graded	Graded
Software Change Request (SCR)	Full	Full	Graded	Graded	Graded
Problem Reporting and Corrective Action	Full	Full	Full	Graded	Graded
Training	Full	Graded	Graded	Graded	Graded
Retirement	Full	Full	Full	Graded	Graded

2. Configurable Software

SQA Document/Product	Software Grade Level				
	A	B	C	D	E
Software Quality Assurance Plan (SQAP)	Full	Full	Graded	Graded	Graded
Software Risk Evaluation Report (SRER)	Full	Graded	Graded	N/A	N/A
Software Safety Analysis Report (SSAR)	Full	Graded	Graded	N/A	N/A
Software Requirements Specification (SRS)	Full	Full	Full	Graded	N/A
Software Procurement	Full	Full	Full	Graded	Graded
Software Functional Description (SFD)	Graded	Graded	Graded	Graded	N/A
Software User Manual (SUM)	Full	Full	Full	Graded	N/A
Software Verification and Validation Plan (SVVP)	Full	Graded	Graded	Graded	N/A
Software Verifications and Validation Report (SVVR)	Full	Graded	Graded	Graded	Graded
Software Installation and Checkout (SIC)	Full	Full	Full	Graded	Graded
Operations and Maintenance	Full	Full	Graded	Graded	Graded
Software Change Request (SCR)	Graded	Graded	Graded	Graded	Graded
Problem Reporting and Corrective Action	Full	Full	Graded	Graded	Graded
Training	Full	Graded	Graded	Graded	Graded
Retirement	Full	Full	Full	Graded	Graded

3. Acquired Software

SQA Document/Product	Software Grade Level				
	A	B	C	D	E
Software Quality Assurance Plan (SQAP)	Graded	Graded	Graded	Graded	Graded
Software Risk Evaluation Report (SRER)	Full	Graded	Graded	N/A	N/A
Software Safety Analysis Report (SSAR)	Full	Graded	Graded	N/A	N/A
Software Requirements Specification (SRS) or equivalent	Full	Full	Full	Graded	N/A
Software Procurement	Full	Full	Full	Graded	Graded
Software Functional Description (SFD)	N/A	N/A	N/A	N/A	N/A
Software User Manual (SUM)	Full	Full	Full	Graded	N/A
Software Verification and Validation Plan (SVVP)	Full	Graded	Graded	Graded	N/A
Software Verifications and Validation Report (SVVR)	Full	Graded	Graded	Graded	Graded
Software Installation and Checkout (SIC)	Full	Full	Full	Graded	Graded
Operations and Maintenance	Full	Full	Graded	Graded	Graded
Software Change Request (SCR)	Graded	Graded	Graded	Graded	Graded
Problem Reporting and Corrective Action	Full	Full	Graded	Graded	Graded
Training	Full	Graded	Graded	Graded	Graded
Retirement	Full	Full	Full	Graded	Graded

4. Utility Calculation Software

SQA Document/Product	Software Grade Level				
	A	B	C	D	E
Software Quality Assurance Plan (SQAP)	Graded	Graded	Graded	Graded	Graded
Software Risk Evaluation Report (SRER)	Full	Graded	Graded	N/A	N/A
Software Safety Analysis Report (SSAR)	N/A	N/A	N/A	N/A	N/A
Software Requirements Specification (SRS)	Full	Full	Full	Graded	N/A
Software Procurement	Full	Full	Full	Graded	Graded
Software Functional Description (SFD)	Graded	Graded	Graded	Graded	N/A
Software User Manual (SUM)	Full	Graded	Graded	Graded	N/A
Software Verification and Validation Plan (SVVP)	Graded	Graded	Graded	Graded	N/A
Software Verifications and Validation Report (SVVR)	Graded	Graded	Graded	Graded	Graded
Software Installation and Checkout (SIC)	Full	Full	Full	Graded	Graded
Operations and Maintenance	Full	Full	Graded	Graded	Graded
Software Change Request (SCR)	Graded	Graded	Graded	Graded	Graded
Problem Reporting and Corrective Action	Graded	Graded	Graded	Graded	Graded
Training	Full	Graded	Graded	Graded	Graded
Retirement	Full	Full	Full	Graded	Graded

5. Commercial Design and Analysis Software

SQA Document/Product	Software Grade Level				
	A	B	C	D	E
Software Quality Assurance Plan (SQAP)	N/A	N/A	N/A	N/A	N/A
Software Risk Evaluation Report (SRER)	N/A	N/A	N/A	N/A	N/A
Software Safety Analysis Report (SSAR)	N/A	N/A	N/A	N/A	N/A
Software Requirements Specification (SRS)	Full	Full	Full	N/A	N/A
Software Procurement	Full	Full	Full	Graded	Graded
Software Functional Description (SFD)	N/A	N/A	N/A	N/A	N/A
Software User Manual (SUM)	N/A	N/A	N/A	N/A	N/A
Software Verification and Validation Plan (SVVP)	N/A	N/A	N/A	N/A	N/A
Software Verifications and Validation Report (SVVR)	N/A	N/A	N/A	N/A	N/A
Software Installation and Checkout (SIC)	N/A	N/A	N/A	N/A	N/A
Operations and Maintenance	N/A	N/A	N/A	N/A	N/A
Software Change Request (SCR)	Graded	Graded	Graded	Graded	Graded
Problem Reporting and Corrective Action	Full	Full	Graded	Graded	Graded
Training	N/A	N/A	N/A	N/A	N/A
Retirement	N/A	N/A	N/A	N/A	N/A

20 SUSPECT/COUNTERFEIT ITEMS

This section identifies and documents the QA Program requirements provided in IAEA-TECDOC-1169, *Managing Suspect and Counterfeit Items in the Nuclear Industry*, DOE Guide 414.1-2B, Chg. 2 *Quality Assurance Program Guide,* and DOE O 414.1D Chg. 1, *Quality Assurance*.

The responsibility for S/CI is as follows:

- DUF6 Engineering is responsible for evaluating the impact of any S/CI that are found installed and preventing introduction of S/CI by participating in development of appropriate procurement specifications and being involved in maintenance or modification of equipment.
- DUF6 Site QA Mangers are responsible for oversight of S/CI activities and for serving as a point of contact with the Office of Health, Safety, and Security.
- Receiving personnel are responsible for ensuring received items are not or do not contain S/CI.

CONTROL OF SUSPECT/COUNTERFEIT ITEMS

DUF6 project management is committed to effective controls for the prevention, detection, and disposition of S/CI to mitigate any potential safety threat. Controls are established to ensure that items intended for application in conversion project systems and facilities comply with design and procurement documents. DUF6 procedures have been developed and implemented to:

- Maintain current accurate information on S/CIs and associated suppliers.
- Identify, control, and disposition S/CI.
- Report discoveries of and disseminate information about S/CI to DUF6 organizations.

Training of DUF6 personnel on S/CI controls and indicators, including prevention, detection, and disposition, is performed. Training includes managers, supervisors, professional staff, operations and crafts personnel possibly encountering S/CI.

An S/CI is defined as follows: An item which is suspect when inspection or testing indicates that it may not conform to established government or industry-accepted specifications or national consensus standards or whose documentation, appearance, performance, material, or other characteristics may have been misrepresented by the vendor, supplier, distributor, or manufacturer. A counterfeit item is one that has been copied or substituted without legal right or authority or whose material, performance, or characteristics have been misrepresented by the vendor, supplier, distributor, or manufacturer. Items that do not conform to established requirements are not normally considered S/CI if non-conformity results from one or more of the following conditions:

- Defects resulting from inadequate design or production quality control.

- Damage during shipping, handling, or storage.
- Improper installation.
- Deterioration during service.
- Degradation during removal.
- Failure resulting from aging or misapplication.
- Other controllable causes.

As a part of the procurement process, during the selection of suppliers and the purchase of items, the following measures are taken to prevent procurement or use of S/CI:

- Including appropriate technical and quality requirements in procurement documents.
- Accepting only items that comply with purchase requirements, consensus standards, and commonly accepted industry practices.
- Inspection of storage areas for S/CI.

PROCESSES AND PERSONNEL FAMILIARIZATION WITH S/CI PROGRAM

The subject of S/CI is a consideration during the development of DUF6 procedures for various processes (e.g., procurement, supplier evaluation, item receipt, inspection). DUF6 staff involved with the development and implementation of management processes are required to be familiar with S/CI program requirements described in DUF6-related procedures.

IDENTIFICATION OF S/CI

The identification (discovery) of any S/CI in conjunction with the work is documented in accordance with Section 15 of this PQAP and is promptly reported to DOE when S/CI status is confirmed. DUF6 or DUF6 suppliers retain the S/CI until disposition or as otherwise directed by DOE. Items that are installed are evaluated to determine if the safety function of the equipment the items are installed in has been impacted. In addition, the S/CI is evaluated to determine if any other potential hazards exist by remaining installed.

Accurate, up-to-date information on S/CI is maintained, collected, and disseminated. Trend analysis is conducted to improve the S/CI prevention process.

Existing lessons learned reports are reviewed and new lessons learned reports are submitted, as appropriate, for use in improving the S/CI process.

REPORTING S/CI

When an item is determined to be S/CI, DOE is notified in accordance with DOE O 232.2A, Occurrence Reporting and Processing of Operations Information, DOE O 221.1B, Reporting Fraud, Waste, and Abuse to the Office of Inspector General. S/CI are quarantined pending direction from the Inspector General.

21 ATTACHMENTS

- Attachment A, *Quality Assurance Requirements for Category QL3, Production Support and Category QL4, General Support*
- Attachment B, *Terms and Definitions*
- Attachment C, *MCS Organization*

ATTACHMENT A, QUALITY ASSURANCE REQUIRMENTS FOR CATEGORY QL3, PRODUCTION SUPPORT AND QL4, GENERAL SUPPORT

Page 1 of 8

The following applies to those structures, systems, and components (SSCs) and activities identified as QL-3, Production Support and QL-4, General Support.

1 Organization

Requirement 1, Organization, DUF6 does not use a graded approach to implement NQA-1a-2009, Requirement 1.

2 Quality Assurance Program

Requirement 2, Quality Assurance Program, DUF6 does not use a graded approach to implement NQA-1a-2009, Requirement 2.

3 Design Control

Requirement 3, Design Control, For QL-3 and QL-4 SSCs and related activities, Design Control is implemented in a graded approach such that the degree of control is commensurate with the risks and consequences associated with the SSCs and activities. Design Control is applied to configured and non-configured items as described in DUF6-PLN-121, *Configuration Management Plan for Operations*.

Production Support (QL-3), can be either configured or non-configured. Requirement 3, Design Control, of the category QL-2 quality assurance program applies to Production Support (QL-3) Configured. Procedure DUF6-U-PEP-1110, *Operations Design Change Control,* provides direction to meet PQAP requirements.

Production Support (QL-3), Non-configured (PSN) or General Support (QL-4), Non-configured (GSN), are controlled in a graded approach as described in the Configuration Management Plan. Procedure DUF6-U-PEP-1111, *Facility Change Process*, provides direction to meet PQAP requirements.

The Structures, Systems, and Components (SSCs) subject to the Configuration Management (CM) program were selected during design based on their relative importance to safety, safeguards, and security; the magnitude of any hazard involved; operational reliability of the facilities; the particular characteristics of the items; and other relevant factors. SSCs are functionally classified as Safety Class, Safety Significant

(SS), Production Support (PS), or General Support (GS). The DUF6 Conversion Project has no Safety Class SSCs. The remaining functional classifications, SS, PS and GS were/are assigned by using DUF6-U-PEP-1102, *Grading of Structures, Systems and Components and Identification of Configured Items*.

SSCs are further identified based on their configuration status - either "configured" or "non-configured". SSCs identified as functional classification SS were automatically determined to be configured. Items determined to be PS were further analyzed to determine their applicability to the CM program. Those PS SSCs whose failure would adversely impact the availability, reliability, and operability of the process were also placed in the CM program as configured items. SSCs, whose failure do not impact the process, were designated as GS. These SSCs were not identified as configured items; however they are still managed under the CM Program. Design control practices were utilized to provide sufficient change control during design and construction. The Conversion Facility Documented Safety Analyses (DSAs) identified "Additional Protective Features" in DSA Table 4-3. These "Additional Protective Features" were placed in the CMP as configured items.

Following evaluation, components were identified using DUF6-U-PEP-1101, *Component Numbering and Labeling System*, and listed in their respective discipline specialty lists which collectively make up DUF6-G-G-LST-LST, *DUF6 List of Lists*. The component identification number contains several fields, which vary by discipline and component. The last field of the component number identifies the functional classification of the component, as well as whether or not it is a configured item.

Component Identification

Functional Class	Functional Class Designation	Configuration Status	Configuration Designation
Safety Significant	SS	Always configured	C
Process Support	PS	Can be either configured or nonconfigured	C or N
General Support	GS	Always nonconfigured	N

All components for conversion operations and information related to these components have been captured on a Master Equipment List and are managed through the CMP. For cylinder storage yards, all components and information have been captured on DUF6-G-G-LST-002. The Deputy Project Manager controls these lists.

MCS has established a formal change control process with the objective to maintain consistency among design requirements, the physical configuration, and the related facility documentation during conversion operations. The change control process ensures that all changes are properly reviewed and coordinated as follows:

- Changes are identified and assessed
- Changes receive appropriate technical and management review to evaluate the consequences of the change
- Changes are approved or disapproved
- Waivers and deviations are properly evaluated and approved or denied, and the technical basis for the approval is documented
- Approved changes are adequately and fully implemented, or the effects of the partial implementation are evaluated and accepted
- Implemented changes are properly assessed to ensure the results of the changes agree with the expectations
- Documents are revised to be consistent with the changes and the revised documents are distributed to users.

Any DUF6 Conversion Project participant, including members of outside vendors and subcontractors, may request proposed changes to the configuration of the facility SSCs. Once identified, proposed changes within the CM program are reviewed and routed for approval through the change control process per DUF6-U-PEP-1110, *Operations Design Change Control* or DUF6-U-PEP-1111, *Facility Change Process.*

Procedure DUF6-U-PEP-1111, *Facility Change Process,* describes the responsibilities, requirements, and control of performing facility changes at the DUF6 Conversion facilities.

This procedure applies to all Structures, Systems, and Components deemed Production Support Non-configured (PSN) or General Support Non-configured (GSN), which are "non-safety" items that are not relied upon as additional protective safety features in the Conversion Facilities Documented Safety Analysis (DSA).

Facility changes within the scope of this procedure (as a minimum):

- Do not create an Unreviewed Safety Question (USQ) or a Technical Safety Requirements (TSR) violation.
- Do not change configured SSCs, including set points and computer software.
- Does not change a Defense-in-Depth component or function.

- Do not involve a significant level of design and analysis, as determined by the Engineering management.
- Do not install an unproven technology.
- Do not alter the defined engineered design basis of the DUF6 facilities as defined in the appropriate Facility Design Description, System Design Description, and/or System Requirements Document (does not include descriptive information).
- Does not require a design analysis to ensure the design inputs are still met.

The Facility Change Process includes necessary administrative controls and technical reviews to assure effective design control. The facility change documentation is provided to the Change Configuration Control Board for conceptual approval. Operations manager approval is required. Each change is evaluated to determine impact on Design Requirements, currently approved design media, safety basis, design basis, and physical configuration. Technical review is performed in accordance with procedure DUF6-U-PEP-1303, *Technical Review*. Multidiscipline reviews and Unreviewed Safety Question (USQ) review is performed.

System engineers coordinate with the Configuration Specialist and others to red-line drawings. The system engineer (or designee) also provides field oversight for installations by either in-house organizations or subcontractors. The process ensures that drawings, specifications, training materials, etc., are revised.

4 Procurement Document Control

. Requirement 4, Procurement Document Control, for QL-3 and QL-4 SSCs and related activities, Quality Assurance Program Requirements described in NQA-1a-2009 Requirement 4, section 203 - Quality Assurance Program Requirements, section 204 – Right of Access, section 206 – Non-conformances, and section 207 – Spare and Replacement Parts, do not apply to all QL-3 and QL-4 items and service procurements. These requirements may be invoked where added assurance is warranted such as to meet regulatory requirements, safety needs or data quality.

5 Instructions, Procedures, and Drawings

Requirement 5, Instructions, Procedures and Drawings, DUF6 does not use a graded approach to implement NQA-1a-2009, Requirement 5.

6 Document Control

Requirement 6, Document Control, DUF6 does not use a graded approach to implement NQA-1a-2009, Requirement 6.

7 Control of Purchased Items and Services

Requirement 7, Control of Purchased Items and Services, for the procurement of QL-3 and QL-4 items and services the following requirements are applied: (QL-2 controls may also be invoked where added assurance of quality is necessary due to cost, schedule, safety considerations, consequences of failure, effect on mission success, to meet various regulatory requirements, etc.)

Purchase requisitions are prepared for all procurements. They include documents such as statement of work written in accordance with DUF6-U-PEP-1201, *Preparation and Control of Statement of Work*, technical specifications, equipment identification numbers, part number, model number, required codes and standards, drawings; quality assurance requirements, ES&H requirements, waste control documents, budget justification, training; and certification requirements.

The requisition is reviewed and approved to ensure that the special departmental requirements are properly addressed, as applicable (example: IT, ES&H, Waste Management).

Personnel involved in the preparing and reviewing procurement documents are knowledgeable in specifying technical requirements.

QA reviews all requisitions identified as QL-2 and Commercial Grade Dedications as well as QL-3/4 where receipt inspection has been identified in accordance with DUF6-U-QAP-0011, *Quality Assurance Procurement Requirements*. If an item will be manufactured specifically for the DUF6 Project (is not provided as a catalog item), QA ensures Quality Clauses on Non-Conformance Reporting be included in the requisition. QA reviews and approves all non-stock PRs for Special Tools and hoisting and rigging equipment.

Other special reviews and approvals are required to assure that the proper expertise is utilized in the creation of purchase requisitions.

The procurement process provides general policy guidelines for DUF6 procurement personnel responsible for procurement activities, such as material requisitions, solicitation, award, expediting, subcontract management, and administration in accordance with applicable terms and conditions of the MCS Prime Contract. All procurement activities are conducted in accordance with the applicable provisions of the Federal Acquisition Regulation (FAR) and Department of Energy Acquisition Regulation (DEAR). The primary responsibility of the Procurement function for DUF6 is to provide for the purchase of goods and services with the objective that they be available at the time, place, quantity, quality, and price consistent with the needs of the company and in compliance with the MCS Prime Contract DE-EM0004559.

In fulfilling its responsibilities under the Prime Contract, it is DUF6 policy to allow commercially designated goods and services to be procured in a manner similar to that followed by the commercial business sector and consistent with FAR and DEAR Part 12. The guidance contained herein provides the flexibility in adopting the best in commercial procurement practices for the procurement of commercial goods and services. Commercial goods and services are defined as any items, other than real property, that are of a type customarily used by the general public or by non-governmental entities for purposes other than government purposes.

Receipt inspection is not required for all QL-3 and QL-4 items. Receipt inspection is performed on items where they could have a significant impact on environmental, safety, health, regulatory compliance, mission success, etc. Examples of items inspected include hoisting and rigging equipment, specially fabricated items, waste management materials, drums, fall protection, radiation protection and health instruments, M&TE, etc.

8 Identification and Control of Items

Requirement 8, Identification and Control of Items, for QL-3 and QL-4 items and related activities, the need for identification and control of items is evaluated and used where needed or where required by codes, standards, or specifications.

9 Control of Special Processes

Requirement 9, Control of Special Processes, DUF6 does not use a graded approach to implement NQA-1a-2009, Requirement 9.

10 Inspection

Requirement 10, Inspection, for QL-3 and QL-4 items and related activities, the need for inspection is evaluated and used where needed or where required by codes, standards, or specifications.

11 Test Control

Requirement 11, Test Control, for QL-3 and QL-4 items and related activities, the need for test control is evaluated and used where needed or where required by codes, standards, or specifications. QL-2 controls are implemented for QL-3 or QL-4 items and related activities that may affect safety and quality.

12 Control of Measuring and Test Equipment

Requirement 12, Control of Measuring and Test Equipment, DUF6 does not use a graded approach to implement NQA-1a-2009, Requirement 12, except for instrument calibrations in the Radiological Protection, Industrial Hygiene and Waste Management programs, the following requirements apply:

The supplier's calibration facility has been accredited by a nationally recognized organization as having a program meeting the requirements of ISO/IEC 17025*, General Requirements for the Competence of Testing and Calibration Laboratories* and a review of data demonstrates suitable performance,

or,

the supplier's quality program has been evaluated per DUF6-U-QAP-0014 *Supplier Quality Program Evaluation*, to assure it complies with the applicable requirements.

13 Handling, Storage, and Shipping

Requirement 13, Handling, Storage, and Shipping, DUF6 does not use a graded approach to implement NQA-1a-2009 Requirement 13.

14 Inspection, Test, and Operating Status

Requirement 14, Inspection, Test, and Operating Status, DUF6 does not use a graded approach to implement NQA-1a-2009 Requirement 14.

15 Control of Nonconforming Items

Requirement 15, Control of Nonconforming Items, DUF6 does not use a graded approach to implement NQA-1a-2009 Requirement 15.

16 Corrective Action

Requirement 16, Corrective Action, DUF6 does not use a graded approach to implement NQA-1a-2009 Requirement 16.

17 Quality Assurance Records

Requirement 17, Quality Assurance Records, DUF6 does not use a graded approach to implement NQA-1a-2009 Requirement 17.

18 Independent Assessments

Requirement 18, Independent Assessments, DUF6 does not use a graded approach to implement NQA-1a-2009 Requirement 18.

19 Computer Software Management

Requirement 19, Computer Software Management, see section 19 of this PQAP for implementation of the graded approach related to computer software management.

20 Suspect/Counterfeit Items

Requirement 20, Suspect/Counterfeit Items, DUF6 does not use a graded approach to implement the DOE requirements of control of S/CI.

ATTACHMENT B, TERMS AND DEFINITIONS

Page 1 of 9

General Definitions. The following general definitions are used in the implementation of the Project Quality Assurance Plan. Specific Definitions are included at the end of this section for Computer Software and Commercial Grade Items and Services. DUF6 uses the following NQA-1 definitions. Where "this standard" is used in the definition, this is referring NQA-1.

acceptance criteria: specified limits placed on the performance, results, or other characteristics of an item, process, or service defined in codes, standards, or other requirement documents.

audit: a planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents, and the effectiveness of implementation. An audit should not be confused with surveillance or inspection activities performed for the sole purpose of process control or product acceptance. Note: DUF6 uses the terms Independent Assessment in the place of audit and uses assessor in the place of auditor.

audit, external: an audit of those portions of another organization's quality assurance program not under the direct control or within the organizational structure of the auditing organization.

audit, internal: an audit of those portions of an organization's quality assurance program retained under its direct control and within its organizational structure.

Certificate of Conformance: a document signed or otherwise authenticated by an authorized individual certifying the degree to which items or services meet specified requirements.

certification: the act of determining, verifying, and attesting in writing to the qualifications of personnel, processes, procedures, or items in accordance with specified requirements.

characteristic: any property or attribute of an item, process, or service that is distinct, desirable, and measurable.

commercial grade dedication: see specific definitions on page 54.

commercial grade item: a structure, system, component, or part thereof, that affects its safety function, that was not designed and manufactured in accordance with the requirements of this Standard. Note: This definition is applicable to Department of Energy nuclear facilities and activities regulated under 10 CFR 830, Nuclear Safety Management. See also Specific Definitions for Commercial Grade Items and Services below.

commercial grade service: a service that was not provided in accordance with the requirements of this Standard, that affects the safety function of a basic component

computer program: a combination of computer instructions and data definitions that enables computer hardware to perform computational or control functions. Computer programs covered by this Standard are those used for: *(a)* design analysis; *(b)* operations or process control; or *(c)* data base or document control registers when used as the controlled source of quality information for (a) or (b) above. This definition has been copied from ANSI/IEEE 610.12-1990, *Glossary of*

Software Engineering Terminology, with the permission of IEEE. To the extent that computer programs are a physical part of plant systems (e.g., digital reactor protection systems, digital instrumentation) they are included in the term *item*.

condition adverse to quality: an all-inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, defective items, and non-conformances. A significant condition adverse to quality is one that, if uncorrected, could have a serious effect on safety or operability.

configuration: the physical, functional, and operational characteristics of the structures, systems, components, or parts of the existing facility.

configuration item (software): a collection of hardware or software elements treated as a unit for the purpose of configuration control.

configuration management: the process that controls the activities, and interfaces, among design, construction, procurement, training, licensing, operations, and maintenance to ensure that the configuration of the facility is established, approved, and maintained.

corrective action: measures taken to rectify conditions adverse to quality and, where necessary, to preclude repetition.

critical characteristics: important design, material, and performance characteristics of a commercial grade item or service that, once verified, will provide reasonable assurance that the item or service will perform its intended safety function.

design, final: approved design output documents and approved changes thereto.

design authority: the organization having the responsibility and authority for approving the design bases, the configuration, and changes thereto.

design bases: that information which identifies the specific functions to be performed by a structure, system, or component of a facility, and the specific values or ranges of values chosen for controlling parameters as reference bounds for design. These values may be *(a)* restraints derived from generally accepted "state-of-the-art" practices for achieving functional goals; or *(b)* requirements derived from analysis (based on calculations and/or experiments) of the effects of a postulated accident for which a structure, system, or component must meet its functional goals.

design change: any revision or alteration of the technical requirements defined by approved and issued design output documents and approved and issued changes thereto.

design input: those criteria, performance requirements, codes and standards, design bases, regulatory requirements, or other design requirements upon which detailed final design is based.

design output: drawings, specifications, and other documents used to define technical requirements of structures, systems, components, and computer programs.

design process: technical and management processes that commence with identification of design input and that lead to and include the issuance of design output documents.

design review: a critical review to provide assurance that the final design is correct and satisfactory.

deviation: a departure from specified requirements.

document: any written, pictorial, or electronic information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results. A document is not considered to be a quality assurance record until it satisfies the definition of a quality assurance record as defined in this Standard.

document control: the act of assuring that documents are reviewed for adequacy, approved for release by authorized personnel, and distributed to and used at the location where the prescribed activity is performed.

electronic document: a document stored in a form (i.e., magnetic or optical media) that is typically accessible only by a computer.

graded approach: the process of ensuring that the levels of analyses, documentation, and actions used to comply with requirements are commensurate with: the relative importance to safety, safeguards, and security; the magnitude of any hazard involved; the life-cycle stage of a facility or item; the programmatic mission of a facility; the particular characteristics of a facility or item; the relative importance to radiological and non-radiological hazards; and, any other relevant factors.

guidance: a suggested practice that is not mandatory in programs intended to comply with this Standard. The word *should* denotes guidance; the word *shall* denotes a requirement.

inspection: examination or measurement to verify whether an item or activity conforms to specified requirements.

inspector: a person who performs inspection activities to verify conformance to specific requirements.

item: an all-inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, or unit.

measuring and test equipment (M&TE): devices or systems used to calibrate, measure, gage, test, or inspect in order to control or acquire data to verify conformance to specified requirements.

nonconformance: a deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate.

objective evidence: any documented statement of fact, other information, or record, either quantitative or qualitative, pertaining to the quality of an item or activity, based on observations, measurements, or tests that can be verified.

Owner: the organization legally responsible for the construction and/or operation of a nuclear facility including but not limited to one who has applied for, or who has been granted, a construction permit or operating license by the regulatory authority having lawful jurisdiction.

procedure: a document that specifies or describes how an activity is to be performed.

procurement document: purchase requisitions, purchase orders, drawings, contracts, specifications, or instructions used to define requirements for purchase.

Purchaser: the organization responsible for establishment of procurement requirements and for issuance or administration, or both, of procurement documents.

qualification, personnel: the characteristics or abilities gained through education, training, or experience, as measured against established requirements, such as standards or tests, that qualify an individual to perform a required function.

qualified automated means: automated methods of controlling or monitoring processes that have been demonstrated to produce required quality within controlled limits.

qualified procedure: an approved procedure that has been demonstrated to meet the specified requirements for its intended purpose.

quality assurance (QA): all those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service.

quality assurance record: a completed document that furnishes evidence of the quality of items and/or activities affecting quality. Types of record media may include paper, electronic (magnetic or optical), or specially processed media such as radiographs, photographs, negatives, and microforms. The term *record*, as used throughout the Standard, is to be interpreted as quality assurance record.

quality standard: a code or standard that provides design inputs, acceptance criteria, or other criteria necessary to assure the quality of the designated item.

receiving: taking delivery of an item at a designated location.

repair: the process of restoring a nonconforming characteristic to a condition such that the capability of an item to function reliably and safely is unimpaired, even though that item still does not conform to the original requirement.

rework: the process by which an item is made to conform to original requirements by completion or correction.

right of access: the right of a Purchaser or designated representative to enter the premises of a Supplier for the purpose of inspection, surveillance, or quality assurance audit.

safety function: the performance of an item or service necessary to achieve safe, reliable, and effective utilization of nuclear energy and nuclear material processing.

service: the performance of activities such as design, fabrication, inspection, nondestructive examination, repair, or installation.

shall: see *guidance*.

should: see *guidance*.

software: computer programs and associated documentation and data pertaining to the operation of a computer system. Note: This definition has been copied from ANSI/IEEE 610.12-1990,

Glossary of Software Engineering Terminology, with the permission of IEEE. See Specific Definitions for Computer Software

special process: a process, the results of which are highly dependent on the control of the process or the skill of the operators, or both, and in which the specified quality cannot be readily determined by inspection or test of the product.

Supplier: any individual or organization who furnishes items or services in accordance with a procurement document. An all-inclusive term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, consultant, and their sub-tier levels.

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

testing: an element of verification for the determination of the capability of an item to meet specified requirements by subjecting the item to a set of physical, chemical, environmental, or operating conditions.

traceability: the ability to trace the history, application, or location of an item and like items or activities by means of recorded identification.

use-as-is: a disposition permitted for a nonconforming item when it has been established that the item is satisfactory for its intended use.

verification: the act of reviewing, inspecting, testing, checking, auditing, or otherwise determining and documenting whether items, processes, services, or documents conform to specified requirements.

waiver: documented authorization to depart from specified requirements.

Specific Definitions for Computer Software

The following definitions apply specifically to computer software:

acceptance testing, also known as *software validation:* the process of exercising or evaluating a system or system component by manual or automated means to ensure that it satisfies the specified requirements and to identify differences between expected and actual results in the operating environment.

baseline: a specification or product that has been formally reviewed and agreed upon, that thereafter serves as the basis for use and further development, and that can be changed only by using an approved change control process.

configuration management (software): the process of identifying and defining the configuration items in a system (i.e., software and hardware), controlling the release and change of these items throughout the system's life cycle, and recording and reporting the status of configuration items and change requests.

configuration item: a collection of hardware or software elements treated as a unit for the purpose of configuration control. Note: This definition has been copied or adapted from ANSI/IEEE Std. 610.12-1990, *Glossary of Software Engineering Terminology*, with the permission of IEEE.

control point: a point in the software life cycle at which specified agreements or control (typically a test or review) are applied to the software configuration items being developed, e.g., an approved baseline or release of a specified document or computer program.

error: a condition deviating from an established baseline, including deviations from the current approved computer program and its baseline requirements.

operating environment: a collection of software, firmware, and hardware elements that provide for the execution of computer programs.

regression testing: selective retesting to detect errors introduced during modification of the computer program or to verify that the modified computer program still meets its specified requirements. Note: This definition has been copied or adapted from ANSI/IEEE Std. 610.12-1990, *Glossary of Software Engineering Terminology*, with the permission of IEEE.

software design verification: the process of determining if the product of the software design activity fulfills the software design requirements.

*software development cycle:*1 the activities that begin with the decision to develop a software product and end when the software is delivered. The software development cycle typically includes the following activities: *(a)* software design requirements, *(b)* software design, *(c)* implementation, *(d)* test, and *(e)* sometimes installation.

software engineering: (a) the application of a systematic, disciplined, quantifiable approach to the development, operation, and maintenance of software; that is, the application of engineering to software *(b)* the study of approaches as in (a). Note: This definition has been copied or adapted from ANSI/IEEE Std. 610.12-1990, *Glossary of Software Engineering Terminology*, with the permission of IEEE.

software life cycle: the period of time that begins when a software product is conceived and ends when the software is no longer available for use. The life cycle typically includes a concept phase, requirements phase, design phase, implementation phase, test phase, installation and checkout phase, operation and maintenance phase, and, sometimes, retirement phase. These phases may overlap or be performed iteratively, depending on the software development approach used. Note: This definition has been copied or adapted from ANSI/IEEE Std. 610.12-1990, *Glossary of Software Engineering Terminology*, with the permission of IEEE.

software tool: a computer program used in the development, testing, analysis, or maintenance of a program or its documentation. Examples include comparators, cross-reference generators, compilers, CASE (Computer Aided Software Engineering) tools, configuration and code management software, decompilers, disassemblers, editors, flowcharters, monitor test case generators, and timing analyzers. Note: This definition has been copied or adapted from ANSI/IEEE Std. 610.12-1990, *Glossary of Software Engineering Terminology*, with the permission of IEEE.

system software: software designed to enable the operation and maintenance of a computer system and its associated computer programs. Note: This definition has been copied or adapted from ANSI/IEEE Std. 610.12-1990, *Glossary of Software Engineering Terminology*, with the permission of IEEE.

testing (software): the process of *(a)* operating a system (i.e., software and hardware) or system component under specified conditions, *(b)* observing and recording the results, *(c)* making an evaluation of some aspect of the system, (i.e., software and hardware) or system component in order to verify that it satisfies specified requirements and to identify errors.

test case: a set of test inputs, execution conditions, and expected results developed for a particular objective, such as to exercise a particular program path or to verify compliance with a specific requirement.

test plan (procedure): a document that describes the approach to be followed for testing a system or component. Typical contents identify the items to be tested, tasks to be performed, and responsibilities for the testing activities.

Specific Definitions for Commercial Grade Items and Services

The following definitions apply specifically to commercial grade items and services:

basic component: a structure, system, component, or part thereof that affects its safety function, that was designed and manufactured in accordance with the requirements of this Standard, or commercial grade items which have successfully completed the dedication process.

commercial grade item: a structure, system, or component, or part thereof, that affects its safety function, that was not designed and manufactured in accordance with the requirements of this Standard. Note: This definition is applicable to Department of Energy nuclear facilities and activities regulated under 10 CFR 830, Nuclear Safety Management.

commercial grade service: a service that was not provided in accordance with the requirements of this Standard that affects the safety function of a basic component.

critical characteristics: important design, material, and performance characteristics of a commercial grade item or service that, once verified, will provide reasonable assurance that the item or service will perform its intended safety function.

dedicating entity: the organization that performs the dedication process. Dedication may be performed by the manufacturer of the item, a third-party dedicating entity, or by the facility.

dedication: an acceptance process performed in accordance with this Standard to provide reasonable assurance that a commercial grade item or service will perform its intended safety function and, in this respect, is deemed equivalent to an item or service designed and manufactured or provided under the requirements of this Standard. This assurance is achieved by identifying the critical characteristics of the item and verifying their acceptability by inspections, tests, or analyses performed by the purchaser or third-party dedicating entity after delivery, supplemented as necessary by one or more of the following: commercial grade surveys; product inspections or witness at hold-points at the manufacturer's facility, and analysis of historical records for acceptable performance. In all cases, the dedication process must be conducted in accordance with the applicable provisions of Part I.

equivalency evaluation: a technical evaluation performed to confirm that a replacement item (not identical to the original) can satisfactorily perform its intended functions, including its safety functions.

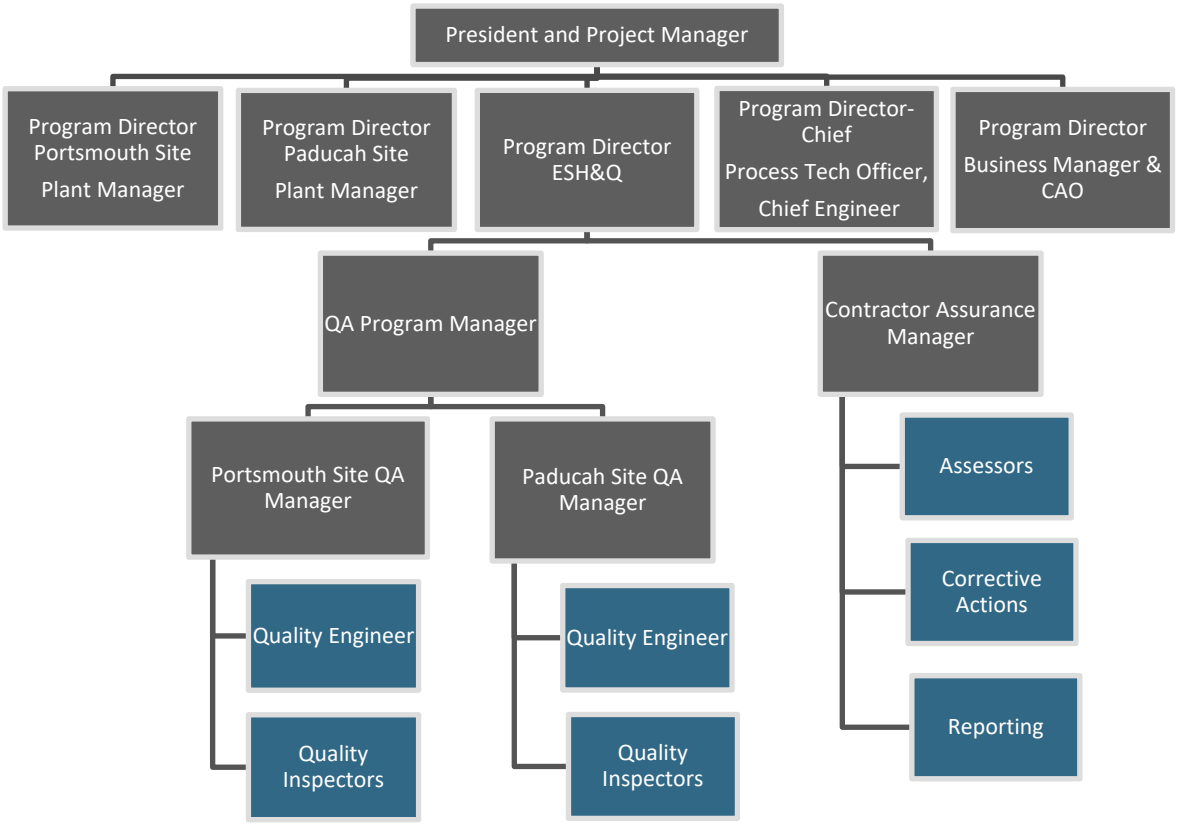
equivalent replacement: a replacement item not physically identical to the original. These replacement items require an equivalency evaluation to ensure that the intended functions, including its safety function, will be maintained.

identical item: an item that exhibits the same technical and physical characteristics (physically identical).

like-for-like replacement: the replacement of an item with an item that is identical.

ATTACHMENT C, MCS ORGANIZATION

Page 1 of 3



Responsibilities and Reporting Relationships

The President and Project Manager has overall responsibility for the *Organization* structure, responsibilities, and reporting relationships.

Site *Quality Assurance* Managers perform or oversee the following:

- Development of QA Program requirements that are responsive to DOE orders, national consensus standards, and project needs for mission success.
- Review of documents to ensure incorporation of quality requirements.
- Independent Assessments to determine compliance and effectiveness of quality program implementation.
- Approve suppliers' quality capabilities.
- Receipt inspection to assure purchased items comply with quality and technical requirements.
- Inspection of plant equipment to assure compliance with technical requirements.

- Maintain cognizance of plant activities to assure comprehensive QA oversight and consultation with senior managers.

Site QA Managers are organizationally independent with reporting relationships to the Program Director - ESH&QA. To preserve independence and objectivity QA managers do not engage in managing functional areas of plant operations. The QA Program Manager serves as a single point of contact for Quality Assurance matters.

The Contractor Assurance manager is responsible for event reporting, managing the corrective action program, performing assessments of safety programs, and maintaining the comprehensive assessment plan and schedule for all assessment activities.

Engineering Managers at each site report to the Program Director - Chief Process Technical Officer, Chief Engineer, and are responsible for implementing the *Design Control* Requirements.

The Supply Chain Manager reports to the Program Director - Business Manager & CAO, and is responsible for implementing *Procurement Document Control* requirements.

Work control managers, reporting to Program Director - Site Plant Managers; the RM/DC Manager, reporting to the Program Director - Business Manager & CAO; Procedures staff - reporting to Program Manager - Operations Paducah, and Engineering Managers share responsibility for implementing *Instructions, Procedures, and Drawings* requirements.

The RM/DC Manager is responsible for the *Document Control* program.

The Supply Chain Manager, Site Quality Assurance Managers, and Engineering Managers share responsibility for implementing *Control of Purchased Items and Services* requirements.

Warehouse/Property Supervisor, reporting to the Supply Chain Manager is responsible for the *Identification and Control of Items*.

Engineering Managers are responsible for *Control of Special Processes*.

Quality Assurance Managers and Engineering Managers are responsible for *Inspection*.

Engineering Managers and Plant Managers have responsibilities in implementing *Test Control* requirements.

Maintenance Managers, reporting to Program Director - Site Plant Managers, are responsible for the *Control of Measuring and Test Equipment* program.

ATTACHMENT C, MCS ORGANIZATION

Page 3 OF 3

Warehouse/Property Supervisor and Waste Management and Logistics have responsibilities for *Handling, Storage & Shipping*.

Implementation of *Inspection, Test, and Operating Status* requirements occurs on a broad spectrum and is accomplished by a number of DUF6 managers and supervisors.

The process for the *Control of Nonconforming Items* is a responsibility of Site Quality Assurance managers with disposition being provided by Engineering Managers.

The *Corrective Action Program* is a responsibility of the Contractor Assurance Manager and involves the participation of most all project members.

The Records Management Document Control Manager is responsible for *QA Records* program.

Independent Assessment is a shared responsibility between Site QA Managers and the Contractor Assurance Manager.

The IT Manager, reporting to the Program Director - Business Manager & CAO, is responsible for the *Computer Software Management* program.

The program for *Suspect/Counterfeit Items* is under the control of Site Quality Assurance Managers.

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