CP2-QA-1000/FR4A

Quality Assurance Program Description for the Paducah Gaseous Diffusion Plant, Paducah, Kentucky

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Quality Assurance Program Description for the Paducah Gaseous Diffusion Plant, Paducah, Kentucky

Date Issued—September 2023

U.S. DEPARTMENT OF ENERGY
Office of Environmental Management

Prepared by
FOUR RIVERS NUCLEAR PARTNERSHIP, LLC,
managing the
Deactivation and Remediation Project at the
Paducah Gaseous Diffusion Plant
under Contract DE-EM0004895

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Total Pages: 110

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APPROVALS

Quality Assurance Program Description
for the Paducah Gaseous Diffusion Plant,
Paducah, Kentucky

CP2-QA-1000/FR4

September 2023

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REVISION LOG

REVISION NUMBER	DATE	DESCRIPTION OF CHANGES	PAGES AFFECTED
FR0	10/03/2017	Initial Release by FRNP	All
FR1	10/17/2018	Annual update review, includes editorial updates, clarifications, and improvements	All
FR1A	12/11/2018	Resubmittal to address concerns related to Section 1.4 Graded Approach; Minor updates to organization chart, references, and for consistency throughout.	All
FR2	09/26/2019	Annual update review, includes editorial updates, clarifications, and improvements.	All
FR2A	07/27/2020	Resubmittal to address concerns related to controls for software quality assurance. Other changes to include language to resolve action items.	All
FR3	09/27/2021	Annual update with minor corrections and changes to align with DOE Order 414.1 Admin Change 1, *Quality Assurance.*	All
FR4	9/22/2022	Annual update with minor changes. Updated references to DOE Order 414.1D, Chg 2 (LtdChg), *Quality Assurance*.	All

REVISION NUMBER	DATE	DESCRIPTION OF CHANGES	PAGES AFFECTED
FR4A	9/25/2023	Correction to minor format error. Add reference to Electronic Information System Requirements per CP2-RD-0002. Other clarifications, corrections and updates that do not reduce or change commitments (FRNP-23-7642).	15, 20-22, 29, 31, 32, 40, 42, 43, 59, 62, 65, 68, 82, 88, 91, 94, 99, 102, 104, 105

CONTENTS

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FIGURE

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ACRONYMS

ANSI	American National Standards Institute
ASL	approved suppliers list
ASME	American Society of Mechanical Engineers
CAS	contractor assurance system
CFR	*Code of Federal Regulations*
CGI	commercial grade items
CoC	certificate of conformance
COTS	commercial off-the-shelf
CPAP	contractor performance assurance program
DOE	U.S. Department of Energy
DOECAP	DOE Consolidated Audit Program
EIS	electronic information system
EM	environmental management
EMS	environmental management system
FAM	functional area manager
FRNP	Four Rivers Nuclear Partnership, LLC
HSS&Q	health, safety, support, and quality
IEEE	Institute of Electrical and Electronics Engineers
IH	industrial hygiene
ISM	Integrated Safety Management
ISMS	Integrated Safety Management System
IT	information technology
JHA	job hazard analysis
M&O	management and operating
M&TE	measuring and test equipment
MA	management assessment
NCR	nonconformance report
NCSE	nuclear criticality safety evaluation
NDA	nondestructive assay
NDT	nondestructive testing
NIC	NNSS Waste Acceptance Criteria Implementation Crosswalk
NM	nuclear material
NMC&A	Nuclear Materials Control and Accountability
NNSS	Nevada National Security Site
NQA	nuclear quality assurance
NTS	noncompliance tracking system
O	order
OREIS	Oak Ridge Environmental Information System
ORPS	Occurrence Reporting and Processing System
PAAA	Price-Anderson Amendments Act
PEMS	Project Environmental Measurements System
PGDP	Paducah Gaseous Diffusion Plant
PPPO	Portsmouth/Paducah Project Office
QA	quality assurance
QAP	quality assurance program
QAPD	quality assurance program description
QAPP	quality assurance project plan
QC	quality control

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QL	quality level
QSNDA	quality system for nondestructive assay
R2/A2	roles, responsibilities, authorities, and accountabilities
S&M	surveillance and maintenance
S/CI	suspect/counterfeit item
SC	safety class
SME	subject matter expert
SMO	sample management office
SQA	software quality assurance
SS	safety significant
SSC	structure, system, and component
TSR	technical safety requirement
USQ	unreviewed safety question
V&V	verification and validation

EXECUTIVE SUMMARY

INTRODUCTION

The Four Rivers Nuclear Partnership, LLC, (FRNP) team serves as the prime contractor to the U.S. Department of Energy (DOE) to achieve the goals for deactivation and remediation of the Paducah Gaseous Diffusion Plant (PGDP) facilities and prepare the facilities for surveillance and maintenance (S&M). The site is located on a federal reservation west of Paducah, KY, and south of the Ohio River. PGDP is situated on 3,556 acres. The extent and nature of support provided by FRNP to DOE at PGDP, as well as the terms and conditions under which FRNP provides support, are defined in Deactivation and Remediation Project Contract DE-EM0004895.

The performance work statement describes the objectives and programmatic requirements for the contractor to deactivate and remediate PGDP facilities. The FRNP performance work statement includes activities to perform uranium removal, perform technetium-99 treatment, and continue optimizing facility systems/structures to minimize short-term and long-term S&M costs. In addition, FRNP will continue to implement the Environmental Remediation Program as described in the Site Management Plan under the Federal Facility Agreement for the Paducah Site. To accomplish this work, FRNP will utilize established management systems that work together to ensure worker safety and delivery of quality products and services to DOE.

The management programs and implementing documents used by FRNP are described in this Quality Assurance Program Description (QAPD).

PROGRAM BASIS

This QAPD is written to meet the Quality Assurance (QA) requirements of the Contract specifying delivery of a QA Program and Implementation Plan, which imposes Title 10 *CFR* Part 830, Subpart A, *Quality Assurance* (for nuclear and radiological facilities), and DOE Order (O) 414.1D, Chg 2 (LtdChg), *Quality Assurance*, (for all FRNP activities) as the primary QA criteria. The Contract also requires the FRNP QAPD to be consistent with the DOE Office of Environmental Management QA program, EM-QA-001, Rev. 1, which requires a program description and implementation plan. The American Society of Mechanical Engineers (ASME) Nuclear Quality Assurance (NQA)-1-2008, *Quality Assurance Requirements for Nuclear Facility Applications* (with Addenda through 2009), is the nuclear consensus standard and implementing framework for this QAPD. These requirements outline criteria for managing, performing, and assessing quality in an integrated cost-effective manner. Nuclear facilities are defined in DOE-STD-1027, *Hazard Categorization and Accident Analysis Techniques*. The QAPD also encompasses implementation of management systems that form the safety basis for the former uranium enrichment facilities.

As directed by the EM-QA-001, Rev. 1, this QAPD is based on Parts I and applicable Part II requirements of ASME NQA-1-2008 (with Addenda through 2009). Parts III and IV also were considered during the development of this QAPD and implementing documents. Parts III and IV serve as guidance in the application of Part I and II requirements where they are applicable. Guidance from Parts III and IV will be used when a clear benefit can be realized for DOE. Each section of the description identifies the applicability of Part I and II requirements.

Appendix A, "Applicability Matrix," and Appendix B, "Performance Implementation Matrix," serve in conjunction with the QAPD as the implementation plan. These matrices identify the relationship between the ten QA criteria identified in DOE O 414.1D, Chg 2 (LtdChg); applied ASME NQA-1-2008 (with

Addenda through 2009) Part I and II Requirements; EM-QA-001, Rev. 1, requirements, and Integrated Safety Management System (ISMS) core functions and guiding principles relative to the performance documents that implement those requirements.

OBJECTIVES OF THE QUALITY ASSURANCE PROGRAM

FRNP and DOE objectives are aligned closely to promote and ensure quality while realizing the improvements and optimization that DOE expects. Implementation of this QAPD is an integral part of ensuring that FRNP meets the objectives outlined below.

- Protect workers, the public, and the environment from site hazards while striving for a goal of zero accidents;
- Safely, securely, compliantly, and cost-effectively perform S&M and utility operation and maintenance under DOE safety basis;
- Protect the interests of DOE and FRNP with respect to compliance with federal, state, and local laws; public and worker safety; preservation of the environment; and the implementation of safeguards and security;
- Provide value to DOE through continuous cost and process improvements and optimization for deactivation activities;
- Promote economy and continuity of effort by providing on-time results within cost; and
- Seek innovative means to continuously improve products and services furnished by FRNP.

REVIEW AND APPROVAL

This QAPD is reviewed annually and is revised, as needed, to maintain compliance with regulations and to accommodate changes to the Contract as required by the DOE Portsmouth/Paducah Project Office (PPPO). These changes may include scope changes, DOE O and Directive changes, or changes in applicable national consensus standards. A summary of the annual review will be submitted to PPPO; if changes are more than editorial, a revised QAPD also will be submitted. QAPD revisions are considered approved after 90 days from submittal, if no formal accept/reject response is provided by PPPO.

1. PROGRAM

1.1 PROGRAM DESCRIPTION

The Four Rivers Nuclear Partnership, LLC, (FRNP) Quality Assurance Program Description (QAPD) describes a Quality Assurance Program (QAP) that is planned, implemented, and maintained in accordance with the Contract, as identified in the Program Basis above. The QAP is a management system that addresses three major elements: managing, performing, and assessing the quality and the adequacy of work performed under this Contract. The management element includes programs that establish organizational structures and responsibilities, as well as management processes, including planning, scheduling, and resource considerations (described in Criterion 1). This management element also includes personnel training and qualifications, quality improvement, and management of documents and records (described in Criteria 2-4). The performance element includes work process, design, procurement, and inspection and acceptance testing activities required to plan and to perform work in a manner that meets Contract requirements (described in Criteria 5-8). The assessment element includes independent assessments, management assessments (MAs), surveillances and self-assessments (described in Criteria 9–10). These elements provide for the planning and accomplishment of activities affecting quality under suitably controlled conditions; for indoctrination, training, and qualification, as necessary; and for regular assessment of the adequacy and effective implementation of the QAP.

Performance documents necessary to implement requirements for the QAP and the applicable quality assurance (QA) requirements mandated by regulations and the FRNP Contract are contained in project execution and support organization performance documents (e.g., procedures, policies, and directives). Each project execution organization and support organization identifies and describes its functional responsibilities and interfaces within its implementing programs, plans, procedures, work instructions, and other controlled documents. These documents are supplemented by other related cross-functional level documents and lower-tier implementing procedures and work documents to provide the details necessary for proper implementation of requirements. As documents and procedures are revised, the affected functional organization(s) reviews and provides comments on the changes. Approved changes are incorporated into lower-tier documents and/or subcontract language, thus ensuring alignment of lower-tier documents and subcontract language with the instructions in the cross-functional documents, the U.S. Department of Energy (DOE) Contract, and applicable regulatory requirements.

While two separate sets of implementing documents might seem appropriate to implement this QAP, one set to address work affecting nuclear safety and the specific application of Nuclear Quality Assurance (NQA)-1 and a separate set to address all other work where nuclear safety is not at risk and NQA-1 would not apply, FRNP has prepared one set. FRNP implementing procedures have been prepared to comply with NQA-1 requirements, where applicable and are implemented with a graded approach, as discussed in Section 1.4 of this QAPD, to address the spectrum from full NQA-1 application to little or no application of NQA-1. Little or no application of NQA-1 does not mean “graded to zero,” but rather proper application of DOE Order (O) 414.1D, Chg 2 (LtdChg), without NQA-1 requirements. Determination of the proper graded approach to be applied is the responsibility of the management requesting or directing the work to be performed and the services or items to be procured, with the full knowledge and understanding of any potential nuclear safety implications. Procedures on graded approach and quality level (QL) determination provide the guidance and direction for making decisions that affect the applicability of NQA-1.

The assessment element verifies implementation and compliance of the management and performance elements through the use of self-assessments, MAs, surveillances, and independent assessments. Implementing procedures for the assessment processes prescribe planning, conducting, and coordinating the assessment and oversight of both FRNP (including teaming partners) and FRNP subcontract activities.

The assessment functions are comprised of independent assessments conducted by internal FRNP or external team's independent of work actually being performed; MAs conducted by or on behalf of the organization manager; surveillances by or for quality and self-assessments by the implementing organization or an invited independent organization.

Issues identified by assessments, as well as many other sources such as work control, performance observations, etc., are documented, and screened for any required reporting, to include Occurrence Reporting and Processing System (ORPS) and potential Noncompliance Tracking System (NTS) reporting. The issue or event is analyzed for cause(s), utilizing the graded approach based upon relative risk. Remedial, corrective, and preventive actions, as appropriate, are developed and tracked to closure. Analyses are conducted on a periodic basis to identify trends for management action. Data from these processes are evaluated by functional organizations to identify opportunities for improvement and communicate lessons learned.

Software Quality Assurance (SQA) requirements are included in this QAPD (refer to Section 12) to implement the requirements from DOE O 414.1D, Chg 2 (LtdChg)and the American Society of Mechanical Engineers (ASME) NQA-1-2008 (with Addenda through 2009), Parts I and II, and also the guidance from EM-QA-001 Rev. 1 and DOE G 414.1-4, *Safety Software Guide for Use with 10 CFR Part 830, Subpart A, Quality Assurance Requirements and DOE O 414.1C,*), *Quality Assurance*. The FRNP SQA program provides controls for the acquisition, design, development, verification and validation (V&V) (including inspection and testing), configuration management, maintenance, operation, and retirement of software, firmware, and process control devices utilized by FRNP employees or subcontractors in support of FRNP operations or mission objectives. SQA controls are implemented according to a risk-based, graded approach, within the given requirements, via the implementing procedure, CP3-QA-1002, *Software Quality Assurance*.

This QAPD also includes a program of suspect/counterfeit item (S/CI) controls (refer to Section 11) to ensure that items intended for use on-site comply with design and procurement documents. The fundamental controls of the S/CI program are intended to identify, control, and disposition items which could create potential hazards when used in safety systems and applications. FRNP uses available resources within the government and industry to identify and prevent S/CI from entering into use on this project. FRNP disseminates relevant information on S/CIs to field organizations and contractors.

The primary objectives for FRNP are to perform facility deactivation, decontamination, and decommissioning, to implement processes to remediate and disposition specific areas of the site (land sites, groundwater, and surface water), to characterize waste materials and to operate site waste storage facilities to include waste management and disposition. Included within the objectives are groundwater environmental remediation actions, material disposition, facilities disposition, soils remediation, surface water remediation, waste disposition options project, polychlorinated biphenyl remediation activities, environmental monitoring and reporting, management of burial grounds (i.e., containment cells) and project support. Site waste management and remediation processes also include overall implementation of the operable unit strategy in accordance with the Site Management Plan; the Paducah Federal Facility Agreement; CP2-WM-0001, *Four Rivers Nuclear Partnership, LLC, Paducah Deactivation and Remediation Project Waste Management Plan*; and CP2-QA-2500, *Four Rivers Nuclear Partnership, LLC, Paducah Deactivation and Remediation Project Nevada National Security Site Waste Acceptance Criteria—Implementation Crosswalk (NIC) for the Paducah Gaseous Diffusion Plant Paducah, Kentucky* (NNSS NIC). Where necessary, Quality Assurance Project Plans (QAPPs) may be developed to document and support quality requirements specific to a defined project.

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Implementation plan for the QAPD is identified in Appendix B, "Performance Implementation Matrix," which includes the specific performance documents used to implement requirements identified in this

QAPD; the QA requirements that form the basis of the QAPD; the Integrated Safety Management System (ISMS) Core Functions and Guiding Principles, as implemented in the ISMS Description; and the Waste Management requirements identified in the Waste Management Plan and the NIC. The implementation matrix does not address government furnished products or services provided by others.

The QAPD described herein will be implemented by all FRNP personnel who contribute to the Paducah Deactivation and Remediation Project. Teaming partner organizations, subcontractors, staff augmentation, and suppliers who provide support to FRNP relative to the scope of the Contract will implement the QAPD described herein unless an alternative means of compliance is established by a FRNP approved teaming agreement, purchase order, or subcontract, such as an approved subcontractor quality program. Flow down of QAPD requirements to FRNP subcontractors is discussed in Section 5.1 of this document.

In the event of a conflict between this QAPD and any standard or regulation cited in the Contract, the standard or regulation cited in the Contract prevails. When conflicts between this QAPD and lower-tiered documents occur, including QAPPs, the requirements of this QAPD govern. Any conflicts involving interpretation of the requirements in this QAPD are to be resolved by the FRNP QA/Quality Control (QC) Program Manager (also may be referred as the Quality Manager or QA Manager in other procedures).

1.2 ORGANIZATION AND RESPONSIBILITIES

The FRNP functional organization, shown in Figure 1, is comprised of a Program Management office, Program Execution organizations, and the Enabling Services organizations. The Program Manager has overall responsibility for the Project and is supported in the program management role by the Deputy Program Manager/Chief Operating Officer. The following program execution and enabling services senior managers report to the Program Manager: Technical Programs; Technical Services; Environmental Services; Site Operations, Stabilization and Deactivation; Waste Management; Health, Safety, Support, and Quality (HSS&Q); Safeguards and Security; Planning and Optimization; and Business Services. In addition, the areas of Project Management, Employee Concerns, Legal/General Counsel, and Prime Contracts report directly to the Program Manager. Supporting the senior managers are the functional area managers (FAMs) and project execution managers necessary to ensure full contract compliance and who are the primary program implementing leaders. In addition, the QA/QC Program Manager and the Contractor Performance Assurance Program (CPAP) Manager each have a direct reporting relationship with the HSS&Q Director for any quality concerns or Contractor Assurance System (CAS) concerns, respectively. Figure 1 represents the reporting structure in FRNP at the time of QAPD approval; however, changes might occur in the future as experience necessitates. Unless such changes impact the QAP performance, these changes will not force a special update to this description document.

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A

Senior managers are responsible and accountable for the achievement of Contract milestones through management system implementation. These personnel are empowered to control project resources within their respective organizations and together have overall responsibility for project planning and execution. Senior managers have direct and immediate responsibility for the safe performance of project activities under their direction, including field implementation of Quality and Integrated Safety Management (ISM) requirements.

Each of the senior managers provides direct oversight and supports task teams to facilitate effective integration of functional programs and processes. Senior managers, FAMs, and project execution managers who work for them are responsible for their designated subject matter areas and are committed to ensuring that each area has input from those personnel with sufficient knowledge of the structure, system, and component (SSC) or process to be designated as subject matter experts (SMEs). FAMs also are responsible for the development, oversight, and maintenance of their function-specific implementing documents and

processes to ensure complete and accurate flow down of Contract requirements. These responsibilities and requirements are included in operating procedures and other work control documents, which are used by workers and subcontractors, under the direction of the project execution managers, to perform daily activities.

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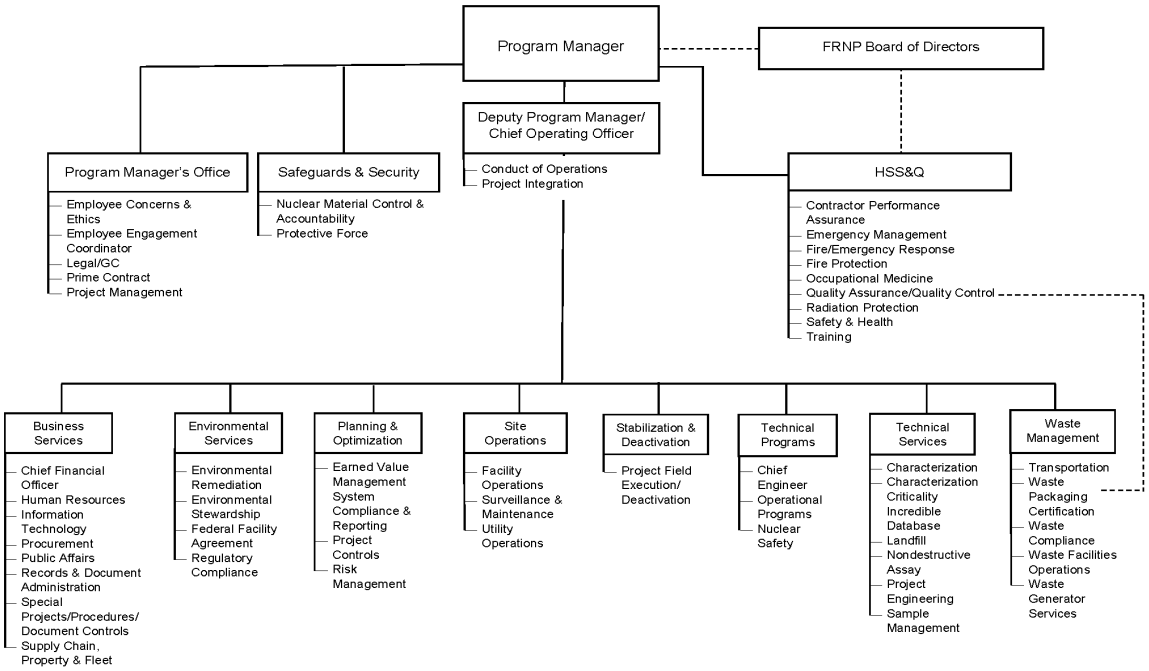

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Figure 1. Functional Organizational Chart

FRNP project execution managers and FAMs are responsible for the planning and successful execution of line and support work. Managers develop task-specific execution plans, procedures, specifications, work documents, and subcontracting requirements necessary to perform task activities and oversight to confirm that activities comply with the specified requirements. Task teams ensure the necessary task-specific execution plans, procedures, specifications, work documents, and subcontractor requirements are incorporated into the work activity control documents. Frontline supervisors have the responsibility to execute the work activity documents in the field. Workers and supporting personnel participate in work planning meetings and are responsible to execute work plans or procedures safely and consistently in order to obtain a quality product or service. All personnel are responsible to provide feedback to their supervisor/manager as part of continuous improvement and lesson learned processes as required by ISM. Feedback is captured in accordance with CP3-QA-3011, *Feedback and Continuous Improvement Program.* This procedure ensures feedback is documented, evaluated, communicated, and applied to promote continuous improvement in all aspects of work, especially for worker safety.

It is the role of management to establish and cultivate principles that integrate quality requirements into daily work. Management, from the Program Manager to the supervisors, is responsible for leadership and commitment to quality achievement and improvement within a framework of public, worker, and environmental safety. Management retains the primary responsibility and accountability for the scope and implementation of the quality management system and ensures that the QAPD is implemented effectively. It is the responsibility of each FRNP employee to perform individual tasks that comply with the quality program per specific implementing performance documents.

1.2.1 Quality Responsibilities

Each individual is responsible for the quality of his or her work, for identifying nonconforming items and activities, and for safely complying with requirements in performance documents. Individuals, who are responsible for producing an item or performing an activity, work under the direction of their immediate management, who has direct and final responsibility for the quality of the item, activity, or service. These individuals are responsible for reviewing item reliability; process implementation, documentation, and other quality-related information; and then analyzing data to identify items and processes needing improvement. The identified items are reported to management as opportunities for improvement. Additionally, procedure CP2-TS-1000, *Roles, Responsibilities, Authorities, Accountabilities for the Paducah Gaseous Diffusion Plant, Paducah Kentucky*, describes roles and responsibilities; expands the guiding principle into a roles, responsibilities, authorities, and accountabilities (R2/A2) document; and integrates R2/A2 into the overall FRNP approach to manage environmental, safety, and health at Paducah Gaseous Diffusion Plant (PGDP).

Independent verification of activities affecting quality is assigned to individuals or organizations that do not have direct responsibilities for performing the work. They will have sufficient authority, access to work areas, and direct access to responsible levels of management, including sufficient independence from cost and schedule, to be able to do the following:

- Identify quality problems and recommend solutions to resolve identified problems;
- Verify implementation of solutions;
- Verify that nonconforming conditions and unsatisfactory conditions are dispositioned according to approved procedures and that further processing, delivery, installation, or use is controlled until proper disposition has occurred; and
- Have direct access to the levels of management required to resolve identified problems.

Specific roles and responsibilities of key organizations and personnel associated with implementing the QAPD are as follows.

All FRNP Staff, Including Managers

- Complete reading, indoctrination, training, qualification, and/or certification necessary to perform daily work activities.
- Implement and adhere to those plans and procedures that apply to daily work activities.
- Ensure quality of the work performed, report issues, and identify improvement opportunities that support safety and project mission.
- Pause/stop work immediately when involved in or observing work activities that jeopardize or compromise safety and health of workers or the public, environment, or quality.

Program Manager

- Approve overall policy and management direction for the QAPD.
- Approve allocation of resources to implement quality requirements.
- Approve the revision and annual update of the QAPD.
- Extend and support a direct line of communication to the QA/QC Program Manager for all quality-related concerns.

Managers

- Provide necessary resources for their organizations to implement quality requirements, as applicable.
- Provide integration, coordination, and oversight of activities under their purview.
- Implement integrated site meetings, on an agreed frequency and schedule to enhance communication between site prime contractors and DOE representatives.
- Establish and cultivate principles that integrate quality requirements into daily work.
- Demonstrate commitment and leadership to achieve quality through active involvement in implementing the requirements of the QAPD.
- Incorporate applicable quality requirements into documents that govern work, activities, and the procurement of items and services.
- Ensure effective implementation of the QAPD for assigned activities, including continuous improvement.
- Assess the implementation of the QAPD for assigned activities through effective self-assessment.
- Provide resources to correct identified quality problems in a timely manner based on prioritized impacts to facility safety and process reliability.

Health, Safety, Support, and Quality Director

In addition to the general responsibilities as a senior manager, this position is specifically responsible for the following.

- Establish direction and guidance for defining, implementing, and maintaining the QAPD.
- Review and concur with revisions and annual updates of the QAPD.
- Resolve quality-related problems not resolved at a lower or peer organization level.

QA/QC Program Manager

In addition to the responsibilities as FAM covering QA and QC, this position also is responsible to do the following job functions.

- Develop, coordinate, maintain, and approve the QAPD and applicable quality performance documents.
- Provide for independent verification of quality achievement by persons not directly responsible for performance of the work.
- Serve as the interface with Site DOE Facility Representatives and Portsmouth/Paducah Project Office (PPPO) Quality organization on quality-related matters.
- Advise senior management regarding actual and potential issues related to quality that may affect the organization's ability to accomplish its mission or that may impact workers, the public, or the environment.
- Establish, in coordination with the responsible implementing organizations, controls to ensure that conditions not in compliance with quality requirements are identified, controlled, and promptly corrected.
- Serve as the chair of the Material Review Board for resolution of nonconformance reports.
- Provide assistance, indoctrination, and training in quality practices, procedures, and regulations to project personnel, and subcontractors when applicable.
- Coordinate the annual QAPD review to assess the overall implementation and effectiveness of the QAP and QAPD on an annual basis.
- Support the evaluation and resolution of project wide quality issues or quality issues that cross project boundaries.
- Assign Quality staff, matrixed to project execution organizations and independent of the work being performed, to verify quality achievement.
- Assign Quality staff, independent of the work being performed, necessary to support the evaluation of vendor/subcontractor QA programs and plans for work that will be performed under FRNP for the project.
- Assign Quality staff, independent of the work being performed, necessary to evaluate and approve vendors/suppliers/subcontractors that supply items/materials/services to the project.

- Provide an interface/avenue for project quality functions to communicate with senior management for issues that cannot be resolved within project or functional boundaries.

- Ensure that laboratory and disposal facilities utilized have completed DOE Consolidated Audit Program (DOECAP) audits and results from these audits meet overall quality standards, or have been otherwise qualified under the FRNP QAPD.

- Ensure the preparation and maintenance of quality records, including those documenting the indoctrination, training, qualification and certification of personnel involved in the verification of quality.

- The QA/QC Program Manager is a member of the Executive Review Board (ERB) whose purpose is to oversee and monitor effectiveness of programs and processes associated with safety management programs, QA programs, ISMS/environmental management system (EMS) implementation activities, and the Price-Anderson Amendments Act (PAAA) program. The ERB is chaired by the Deputy Program Manager and co-chaired by the Program Manager. This membership provides direct interface with program management related to quality concerns.

Contractor Performance Assurance Program Manager

- Manage implementation of the FRNP CAS in compliance with the Contractor Requirements Document of DOE O 226.1B, *Implementation of Department of Energy Oversight Policy*.

- Manage the independent assessment/audit function.

- Support organizational MA and self-assessment activities.

- Provide analysis of and report on the key performance indicator and performance objectives, measures, and commitments information to senior management on a project defined schedule.

- Facilitate/lead the evaluation and resolution of project-wide quality issues or quality issues that cross project boundaries. Facilitate the reporting of qualifying events or conditions to the DOE ORPS and NTS.

1.2.2 Stop Work Authority

FRNP authority to stop/pause work extends to all personnel and subcontractors to prevent any work, activity, or process that jeopardizes or compromises personnel or public safety and health, quality, or has the potential to cause significant environmental impact. Stop work authority is one of the mechanisms used to ensure that planning or scheduling considerations do not degrade safety, quality, or environmental performance. Prior to restart of work after a work stoppage due to safety, quality, or environmental hazards or concerns, appropriate measures will be taken to eliminate or mitigate the hazard or concern, and prepare for activity restart as determined by procedure CP3-HS-2009, *Stop/Suspend Work*. Additional measures may be necessary as identified in Section 3, Quality Improvement.

1.3 MANAGEMENT SYSTEMS INTEGRATION

1.3.1 Integration of the Quality, Safety, and Environmental Management Systems

The QAPD is one of several management systems used by FRNP to ensure that work is accomplished safely and in an environmentally responsible manner. The safety management system described in DOE Policy 450.4A, Change 1, *Integrated Safety Management Policy*, provides the framework that FRNP uses to promote effective achievement of performance objectives through implementation of the safety management system policy guiding principles. One of the principal objectives of a quality management system is to support the achievement of safety and environmental management (EM) objectives. Accordingly, the effort dedicated to achievement and assurance of quality must be substantially consistent with the effort to accomplish work safely and in an environmentally responsible manner.

The *Integrated Safety Management System Description*, CP2-HS-1000, describes the safety management system objectives and the strategy for achieving these objectives within the Project. The Project ISMS is based on the seven Guiding Principles and five Core Functions outlined in DOE P 450.4A, *Integrated Safety Management Policy*. The Guiding Principles and Core Functions of ISMS found in DOE P 450.4A, change 1, also are recognized in EM-QA-001, Rev. 1, Section 7.0, as a basis for integration between the QAPD and the ISMS at the requirements level. Appendix B, Performance Implementation Matrix, recognizes the relationship among the ISMS functions and principles, applicable elements of the QAPD, and the associated implementing procedures.

FRNP is committed to performing work in a manner that is compliant with environmental requirements (e.g., regulations, permits), environmentally sustainable, and in conformance with DOE O 436.1, *Departmental Sustainability*; Executive Order 13423, *Strengthening Federal Environmental, Energy, and Transportation Management.;* and Executive Order 13834, *Efficient Federal Operations.* To satisfy this commitment, FRNP requires adherence to and implementation of requirements (e.g., deactivation-related) in CP2-ES-0100, *Four Rivers Nuclear Partnership, LLC, Sustainability Plan at the Paducah Gaseous Diffusion Plant,* and CP2-ES-0101, *Environmental Management System for the Deactivation and Remediation Project, Paducah Gaseous Diffusion Plant, Paducah, Kentucky*. These documents describe the methods and processes used to implement the EM program, which assures that EM and safety requirements are integrated properly to achieve objectives and ensure that applicable ISM principles, functions, and safety culture focus areas are incorporated into work control documents. This integration is in accordance with the DOE Guide (G) 450.4-1C, *Integrated Safety Management System Guide,* recommendation that the EMS be integrated with the site's ISM system.

1.3.2 Integration of the QAPD and the Contractor Assurance System

This QAPD incorporates elements of the CAS, as required by DOE O 226.1B, *Implementation of Department of Energy Oversight Policy*, Attachment 1, according to a graded approach. For FRNP, the CAS is implemented primarily through the *Contractor Performance Assurance Program Description,* CP2-QA-3000. In order to achieve the objectives outlined in DOE O 226.1B, alignment between the processes used to implement the CPAP and those processes used to implement the QAPD is necessary to assure consistency and continuity in the integrated management system approach.

Appendix B identifies the primary procedures used within the Project to address QAPD requirements and some of the CPAP requirements from DOE O 226.1B referenced in the QA Criteria. Appendix B does not identify all procedures used to implement the CPAP within the PGDP Deactivation and Remediation Project. For a more comprehensive understanding of procedures used by FRNP in implementing the CPAP within FRNP, refer to the *Contractor Performance Assurance Program Description,* CP2-QA-3000.

1.4 GRADED APPROACH

Consistent with 10 *CFR* Part 830.7, *Graded Approach*, FRNP applies the Quality requirements of 10 *CFR* Part 830, Subpart A, using a graded approach. This approach imposes a level of control and oversight commensurate with the likelihood and consequences of failure or occurrence of an adverse event. FRNP grades the level of analysis, documentation, and actions necessary to comply with a QAPD requirement through the assignment of a specific QL. Varying levels of rigor accompany the QLs as control measures in meeting program requirements. The graded approach may not be used in implementing the unreviewed safety question (USQ) process or in implementing technical safety requirements (TSRs).

The graded approach process applies the methodology described in DOE-STD-1073-2016, *Configuration Management*, with respect to the assignment of grade levels to facilities and programs. DOE-STD-1073-2016 also provides guidance on grading based on changes in lifecycle considerations, changes related to programmatic and technical concerns, and changes based on remaining lifetime. With deactivation and remediation of PGDP, the basis for Quality oversight has changed, much as the likelihood and consequences of failure or occurrence of an adverse event has changed. While the nuclear component of any risk analysis remains, the failures and adverse events due to a nuclear SSC event or concern have changed. This change in risk and consequence analysis is reflected in the FRNP graded approach.

The graded approach is implemented uniformly on a project-wide basis in management systems and implementing documents. Plans and procedures with necessary risk, safety, and hazard analysis adjustment(s) remain consistent as they identify the items, activities, and importance relevant to public and worker health and safety and protection of the environment. CP3-QA-1001, *Graded Approach*, incorporates the management system requirements, whereas CP3-EN-0400, *Quality Level Determination*, addresses QLs. At no time does FRNP grade any item, service, activity, or process that supports nuclear activity work at the site to zero.

The QL of some items is derived specifically from existing documents (default values in procurement procedures or designations of items within the Documented Safety Analysis). For the majority of other Project items and services, the QL will be assigned case-by-case. Quality requirements are based on the level of rigor required for the activity in accordance with the criteria established for Levels 1, 2, 3, and 4 activities and as defined in CP3-EN-0400 with Level 1 being the most stringent and Level 4 being the least stringent level of rigor. This latter level does not mean graded to zero.

Items and activities affecting quality with nuclear safety impact are controlled under national consensus standard, NQA-1a, 2009, and are categorized as QL-1 or QL-2, unless otherwise stated in this section, with the following noted.

QL-1 items and activities include the following:

- Safety Class (SC) items are QL-1. However, there are no items or activities that meet the Documented Safety Analysis requirement for QL-1 or SC, and none are anticipated.

QL-2 items and activities include the following:

- Safety Significant (SS) items with a specified safety function from the documented safety analysis and associated quality-affecting activities;

- Safety-related items or NCSE-credited design features and activities with a specified safety function from nuclear criticality safety evaluations, and associated activities affecting quality;

- Safety Software (i.e., all Level A, and new Level B, safety software) and new software graded at Level C if the Level C software failure could affect safe operation of an SSC (i.e., SC, SS, active design feature, passive design feature, or safety-related item in a nuclear criticality safety evaluation), or if software failure could cause a potential violation of radiological-related regulatory-permitting requirements; and associated activities affecting quality. Existing QL-3 Level B and C software that would be QL-2 software, if new (i.e., was grandfathered at QL-3 under previous QAPD revisions), will be upgraded to QL-2 at its next software revision; and

- Other items and associated activities affecting quality required by other drivers that specify compliance with NQA-1.

QL-3 items and activities include the following:

- Existing QL-3 Level B and C Software that would be QL-2, if new (i.e., grandfathered at QL-3 under previous QAPD revisions), will be upgraded to QL-2 at its next software revision. Software graded at Level C will be QL-3 for those applications where software failure would NOT affect safe operation of an SSC (i.e., SC, SS, active design feature, passive design feature, or safety-related item in a nuclear criticality safety evaluation), and where software failure would NOT cause a potential violation of radiological-related regulatory-permitting requirements; and associated activities affecting quality;

- Items or activities used to store or dispose of hazardous waste;

- Installed pressure safety vessels and relief devices and activities that involve their code compliance (e.g., inspection);

- Items and activities where failure would expose workers to chemical or radiological hazards above the permissible exposure limit with health consequences or potential severe injury or illness;

- Items and activities where failure would result in off-site spread of contamination or ecological damage resulting in regulatory violations; and

- Items and activities where other drivers or regulations require independent inspection.

QL-4 items and activities include the following:

- Items and activities that are not in QL-1, QL-2, or QL-3 categories and are commercial quality with low risk. Examples include standard personal protective equipment; specialized personal protective equipment that is maintained with “prior to use” guidelines or inspection; nonnuclear calibration and measuring services, etc.

  Procurement and receipt of radiological control instruments that are not used for QL-2 applications. These instruments are accepted through the radiological control program that incorporates the applicable instrument standards.

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The requirements of consensus standard NQA-1a, 2009 are applied on a graded approach to support the specified safety function of safety-related items or NCSE-credited design feature, and in accordance with the NQA-1 definition of commercial grade item and commercial grade service, with respect to initial dedication or acceptance. Potentially, some lower QL items and activities (i.e., QL-3 or QL-4) that would not otherwise be required to meet NQA-1 requirements (i.e., does not have a specified nuclear safety function), may warrant and be provided the additional controls of NQA-1 on an as needed bases.

The term "not grade to zero" applies to all items and activities including those that are not nuclear safety related. QL-4 is the lowest QL and is subject to the "not grade to zero" philosophy. The application of requirements that extend to QL-4 includes DOE O 414.1D, Chg 2 (LtdChg), Criteria 1–10, such as on-site use of the issues management process; use of standard work practices or manufacturer's instructions within a controlled program (e.g., ISMS effectively covered); suspect counterfeit item controls; and software controls. For example, equipment (e.g., devices and instruments) that is not used for NQA-1- related purposes, but is used for process monitoring or data collection, is exempt from the more stringent measuring and test equipment (M&TE) criteria of NQA-1a 2009. However, this equipment is subject (on a graded approach) to DOE O 414.1D, Chg 2 (LtdChg) criteria for such instruments being calibrated and maintained.

The FRNP graded approach criteria defined in CP3-QA-1001 includes guidance for levels of risk; consequence categories; consequence levels; and probabilities of failure as part of the consideration for graded approach applications. Integrated consideration of the risk, consequence of failure and probability of failure guidance is available through matrices in the procedure, if needed.

Formalized processes exist for most applications to address consistently and continually the graded approach (e.g., work control, performance document development, QL determination). The graded approach procedure guidance provides for evaluation of the following:

- Relative importance of the item or activity to safety, safeguards, security, waste management, waste transportation, and other mission objectives;
- Importance of data generated by the item or service;
- Magnitude of any hazard involved as identified, analyzed, and controlled in the facility safety basis documents (e.g., Documented Safety Analysis for nuclear safety);
- Life-cycle stage of the facility/SSCs/activity or project; impact/likelihood/consequences on the programmatic mission of the facility/activity or project;
- Complexity or uniqueness of products or services involved;
- Environmental consequences and level of resource protection required; and
- Relative risk, based upon the above evaluation guidance.

1.5 INTERFACE CONTROL

Where more than one functional organization is involved in the execution of activities, the responsibilities, interfaces, and authorities of each organization are clearly defined and documented through respective organization plans and procedures (e.g., Work Planning and Control, Procurement, etc.). This includes external interfaces between organizations and the internal interfaces within organizational units, and changes thereto. FRNP utilizes integrated site meetings on an agreed frequency and schedule to enhance communication among site prime contractors and DOE representatives. This interaction allows enhanced planning and efficiency of operations among these groups.

1.6 SPECIAL PROGRAM REQUIREMENTS

Depending on the quality requirements for specific programs, projects, and functions, additional QA Plans may be required. When necessary, these will be developed using an applicable graded approach to provide supplemental project or function-specific guidance for those activities [e.g., waste management plan and quality system for nondestructive assay (QSNDA) plan]. Subordinate quality plans will be based on this QAPD, and are implemented in support of and under this QAPD. Those subordinate plans will be prepared, reviewed, approved, and distributed in accordance with the requirements stated in Section 5 of this QAPD.

1.6.1 Environmental Data Operations

Environmental data operations are managed under the overall FRNP scope of operations and activities. FRNP understands ultimate success of an environmental program or project depends on the quality of the environmental data collected and used in the decision-making process.

FRNP recognizes the unique quality-related requirements of data collection activities and will implement plans to meet regulatory, DOE Order, and permit requirements. At PGDP, where there are multiple DOE contractors; FRNP, as the deactivation and environmental remediation and waste management contractor, is designated as the lead coordinating contractor in maintaining a sitewide EMS (i.e., CP2-ES-0101, *Environmental Management System for the Deactivation and Remediation Project, Paducah Gaseous Diffusion Plant, Paducah, Kentucky*) that accounts for site operations as stated in DOE O 436.1, *Departmental Sustainability*.

The Environmental Monitoring Plan, Environmental Radiation Protection Program Plan, and/or Sampling and Analysis plans establish the frequency of sample collection, reporting, and quality criteria. Additionally, procedures will be implemented to ensure that quality assured data are generated by each given project. Data will be assessed and validated in accordance with approved procedures and the appropriate plan.

1.6.2 Sampling and Data Management

In accordance with the Contract, sampling and data management activities are required to be performed for work associated with deactivation and remediation activities. The FRNP Sample Management Office (SMO) is required to collect, evaluate, and manage the characterization data generated during Contract performance, including performing sampling and analysis of media, managing samples and analytical data, and validating analytical data; maintain, input, create reports, and complete the other activities necessary to manage environmental data generated by FRNP activities. FRNP is required to ensure the data is current, complete, and compliant with Contract requirements. This includes utilizing site databases [e.g., Oak Ridge Environmental Information System (OREIS), Geographical Information System, Paducah Project Environmental Measurement System (PEMS)] or other databases included as part of a regulatory agreement(s) and performing activities per the appropriate regulatory requirements to ensure project objectives are met. Applicable implementing procedures provide specific requirements and guidelines for sampling and data management activities.

1.6.3 Waste Packaging and Transportation

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FRNP waste packaging and transportation activities will be conducted in accordance with this QAPD and CP2-WM-0001, *Four Rivers Nuclear Partnership, LLC, Paducah Deactivation and Remediation Project Waste Management Plan*, with approved implementing procedures governing activities.

Chg A

Specific project/campaign waste packaging and transportation QA plans may be developed. These QAPPs for waste packaging and transportation would further describe the QA requirements for projects or campaigns where certificate packaging or unusual and unique shipments are required. Approval of waste packaging and transportation QA plans will be generated as required by DOE O 460.1D, *Hazardous Materials Packaging and Transportation Safety*. If a specific project/campaign packaging and transportation plan requires use of a Type B or fissile material packaging with a Certificate of Compliance subject to packaging with a DOE Certificate of Compliance, FRNP will submit the specific QAPP to the DOE EM Headquarters Certifying Official for approval.

1.6.4 Nuclear Materials Control and Accountability

FRNP is required to manage all nuclear materials (NMs) associated with the Contract requirements including compliance with DOE O 410.2, Admin Chg 1, *Management of Nuclear Materials*, and DOE O 474.2, Admin Chg 4. CP2-SS-3000, *Nuclear Materials Control and Accountability Plan for the Paducah Gaseous Diffusion Plant, Paducah, Kentucky*, defines the Nuclear Materials Control and Accountability (NMC&A) program to control and account for NMs for operation, NM remediation, deactivation, decommissioning, decontamination, or demolition of PGDP. The NMC&A plan documents the approach for accountability of NM at the site based on-site material holdings (Category IV, Attractiveness Level E), and Security Protection Level 4 requirements. The plan provides a process for implementing the requirements of DOE O 474.2, Admin Chg 4, *Nuclear Material Control and Accountability*. The plan documents the NMC&A program objectives for program management, material control, measurement, material accounting, and physical inventory of NM.

1.6.5 Nondestructive Assay

The Nondestructive Assay (NDA) program establishes requirements for definition and documentation of quality objectives, policies, systems, and plans. The NDA program also establishes its commitment to good and professionally accepted NDA characterization practices and standard of service. The NDA organization implements the requirements of CP2-ND-1001, *Quality System for Nondestructive Assay Plan*, within its management and control systems. Requirements of the QSNDA Plan flowdown into implementation procedures.

1.7 DISCUSSION OF SPECIFIC NQA-1 REQUIREMENTS IN CRITERION 1

Appendix B identifies the portions of NQA-1 addressed in Criterion 1. Requirement 1/100 and 200 are described in Section 1.2. This section includes the responsibilities for establishment and implementation of the QAP, including the structure, functional responsibilities, levels of authority, and lines of communication for activities affecting quality. The application of graded approach throughout the QAP is described in Section 1.4. Requirement 1/300, Interface Control, is discussed in Section 1.5. Requirement 2/100, requiring a documented QAP that provides for the planning and accomplishment of activities affecting quality, is addressed in the Program Basis and Section 1.1. While the latter section indicates this program provides for indoctrination, training and qualification of personnel, these topics are specifically addressed in Criterion 2. Records of qualification and quality records are discussed in more detail in Criterion 4. The QAP provides for regular assessment of the adequacy and effective implementation of the QAP through provisions in the Contractor Assurance Program in accordance with requirements of DOE O 226.1B.

1.8 CONCLUDING SUMMARY FOR SECTION 1 OF THE QAPD

Section 1 of the QAPD, in conjunction with the graded approach rationale of Section 1.4 of the QAPD, is the FRNP plan description for how the management/program criterion of DOE O 414.1D, Chg 2 (LtdChg) is accomplished. This includes (a) establishing the FRNP organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work; and (b) establishing FRNP management processes, including planning, scheduling, and providing resources for the work.

2. PERSONNEL TRAINING AND QUALIFICATION

FRNP training program consists of several methods of training necessary to provide an understanding of the fundamentals, basic principles, systems, procedures, and emergency responses involved in an employee's work assignments. This enables efficient appropriate indoctrination, training, qualification, and, where applicable, certification of personnel performing or managing activities affecting quality. A systematic and graded approach is applied to the training and qualification programs by developing upon the basis of federal, state, and local laws that apply to the work; the specific DOE standards that apply to the work, the plans and procedures the work must be performed in accordance with; the hazards involved; the complexity of the operation, skills, and experience necessary to accomplish the work; and the risk associated with operation of the facility. The training program is tailored to ensure employees and subcontractors are trained, qualified, and certified (where required) commensurate with their responsibilities (ISM Guiding Principle #3, Competence Commensurate with Responsibilities).

Confidence that quality has been achieved in all instances relies, in part, on the knowledge and skill of personnel who perform the work and those personnel who verify the work meets requirements; therefore, it is essential that training and/or qualification needs are identified and completed prior to performing work. CP2-TR-0100, *Training Program for the Paducah Gaseous Diffusion Plant Paducah, Kentucky,* establishes the primary process and corresponding responsibilities for training and qualification of Project personnel. Other implementing procedures are utilized in support of CP2-TR-0100 to ensure personnel are competent in their responsibilities relative to performing work.

2.1 QUALIFICATION OF PERSONNEL

Personnel are trained and qualified commensurate with their responsibilities to ensure that they are capable of performing their assigned work. Management establishes initial and continuing training and qualification requirements with supporting processes for specific job categories. Management also verifies the training, qualification, and where appropriate, proficiency of personnel prior to assigning a task or activity. The qualification of personnel supports the quality program, the ISM core functions, and satisfies the third ISM guiding principle to ensure personnel have the competence commensurate with their responsibilities.

The qualification of personnel is accomplished by consideration of experience, education, training, and where appropriate, by demonstration and testing to verify acquired skills. Training programs consist of a combination of classroom, on-the-job training, and simulator or laboratory training, as it applies to position and/or task requirements. Other training delivery methods include, but are not limited to, lectures, seminars, computer-based training, and structured self-study activities.

Personnel performing work that requires special skills or abilities may be required to be certified (e.g., QC inspectors). If required, these personnel initially demonstrate proficiency and periodically must demonstrate maintenance of proficiency. The initial and periodic demonstration along with the certification documentation is collected and maintained as a quality record.

Training and qualification programs for personnel are developed and implemented in a manner consistent with the hazards and the risks associated with the operation of the facility or activity using the established graded approach. Qualification and certification programs are reviewed by management and are maintained to reflect changes to the facility, operational procedures, quality requirements, and regulations, as well as applicable industry operating experience. Programs are structured to be in compliance with contractual and DOE O requirements for training and qualification of managers, operators, technicians, and maintenance personnel. NQA-1 Requirements 2/300 and 302 for inspection personnel, which require written procedures for the qualification of inspection personnel, are addressed in FRNP procedure CP3-QA-2006, *Inspection Personnel Training Qualification and Certification*. NQA-1 Requirements 2/300 and 301 for nondestructive testing (NDT) personnel are addressed in FRNP procedure CP3-QA-1039, *Written Practice for Nondestructive Testing Personnel Certification*. This procedure establishes the FRNP criteria for selection, training qualification, examination, certification, proficiency, evaluation and recertification of NDT personnel according to American Society of Nondestructive Testing SNT-TC-1A, 1980 and interpretations from 1976 through 2014. The procedure contains requirements for NDT Level I, II, and III personnel, including maintenance requirements for the qualification and certification documents and records, in accordance with NQA-1 Requirements 2/400 and 500. Additionally, NDT Level I, II, and III personnel are qualified according to the visual testing requirements of the ASME Boiler and Pressure Vessel Code. Assessor qualification requirements are implemented under the CP2-TR-0100, *Training Program for the Paducah Gaseous Diffusion Plant Paducah, Kentucky*, in conjunction with CP3-QA-1008, *Assessor Qualification, Training and Certification*. The latter procedure meets the expectations of NQA-1 Requirements 2/303-305 for assessors when performing independent assessments (CP3-QA-1004, *Independent Assessment Program*); supplier evaluations (CP3-QA-2001, *Approved Supplier Selection, Evaluation, Approved Supplier Maintenance*); surveillances (CP3-QA-2002, *Surveillance*) when performed as an independent oversight; and effectiveness reviews as part of the Issues Management process (CP3-QA-3001, *Issues Management*). CP3-QA-1008 defines the FRNP requirements for qualifying and documenting the qualifications of audit/assessment (referred to hereafter as assessment) personnel. Assessment personnel requiring documentation of qualifications include auditors/assessors (referred to hereafter as assessors) and lead assessors. The terms Assessor and Lead Assessor, as applied to independent oversight, are used in lieu of Auditor and Lead Auditor. The procedure also addresses the maintenance of qualification records in accordance with CP3-RD-0010, *Records Management Process*.

2.2 TRAINING

Initial training programs are established for all personnel, particularly those personnel performing functions associated with safety-related structures, systems, and components or other identified quality affecting activities to develop or enhance their knowledge and skills to perform job assignments. These programs are structured for specific position needs. Examinations and/or operational evaluations on material included in the training programs are administered and documented.

Continuing training programs are recognized to maintain and enhance the knowledge and skills of all personnel. DOE guidance is used to develop continuing training programs that maintain job proficiency as well as continuously improve the knowledge and skills of personnel. These programs are structured for specific position and/or task needs.

Continuing training can include items such as training in significant facility system operational changes, applicable procedure changes, applicable industry operating experience, selected fundamentals with emphasis on knowledge and skills necessary to assure safety, and other training as needed to correct any identified performance problems.

CP2-TR-0100, *Training Program for the Paducah Gaseous Diffusion Plant Paducah, Kentucky* and CP2-TR-0102, *Paducah Deactivation and Remediation Project Training Implementation Matrix*, define and describe the application of selection, qualification, certification, and training requirements of DOE O 426.2, Admin Chg 1, *Personnel Selection, Training, Qualification, and Certification Requirements for DOE Nuclear Facilities*. These define the organization, planning, and administration of the program and set forth the responsibility, authority, and methods for conducting training. Procedures are provided to implement the requirements of the Training Program.

2.3 INDIVIDUAL/POSITION TRAINING PLANS

Training and qualification plans establish standards used to conduct training and qualification programs. Training and qualification plans describe what individuals are to be trained on in order to perform a job and to maintain performance. Training and qualification plans also may identify improvement and developmental opportunities. Various sources of training are considered. For Quality positions, including management positions, the training and qualification requirements are defined and documented in accordance with CP2-TR-0100, *Training Program for the Paducah Gaseous Diffusion Plant Paducah, Kentucky,* and CP2-TR-0102, *Paducah Deactivation and Remediation Project Training Implementation Matrix.*

2.4 INSTRUCTORS

Instructors are qualified appropriately for the specific training tasks, whether on-the-job performance or classroom based in accordance with CP2-TR-0100, *Training Program for the Paducah Gaseous Diffusion Plant Paducah, Kentucky*. The instructor training is based, in part, on the results of instructor evaluations and also any needs for training on new methods and equipment. Instructors possess the technical knowledge, experience, and development and instructional skills commensurate with the subject material and the level of instruction needed.

2.5 CERTIFICATION OF PERSONNEL

Personnel performing work that requires special skills or abilities may be required to be certified (e.g., QC inspectors, welders, and auditors/assessors). If required, these personnel initially demonstrate proficiency and periodically must demonstrate maintenance of proficiency, which is documented and maintained as a QA record in accordance with NQA-1 Requirements 2/400 and 500. The initial and periodic demonstration documentation is collected and retained. FRNP also utilizes a certification program for certain positions to meet the requirements of DOE O 426.2, Admin Chg 1, for personnel performing or supporting applicable nuclear facility operations tasks. More specific certification details and the conditions under which they are accepted are included in CP2-TR-0100, *Training Program for the Paducah Gaseous Diffusion Plant Paducah, Kentucky*, and supporting procedures.

2.6 DISCUSSION OF SPECIFIC NQA-1 REQUIREMENTS IN CRITERION 2

Appendix B identifies the portions of NQA-1 requirements addressed in Criterion 2. This criterion includes the provision for indoctrination, training, and qualification of personnel per Requirement 2/100 (b). A general description of the indoctrination, qualification, training, and certification provisions in the FRNP QAP is provided in Sections 2.1 through 2.5 per NQA-1 Requirements 2/200 (including 201 and 202) and 300. Specific qualification requirements for personnel performing nondestructive examination inspection and tests, per NQA-1 Requirements 2/301 and 302, are addressed in Section 2.1, Lead Auditors, Auditors and Technical Specialists, per NQA-1 Requirements 2/303 through 305, are discussed in Section 2.1, using the terms Assessor and Lead Assessor. Records of Qualification and Records (NQA-1 Requirements 2/400 and 500) are discussed in Criterion 4.

2.7 CONCLUDING SUMMARY FOR SECTION 2 OF THE QAPD

Section 2 of the QAPD, in conjunction with the graded approach rationale of Section 1.4 of the QAPD, is the FRNP plan description for how the management/personnel training and qualification criterion of DOE O 414.1D, Chg 2 (LtdChg) is accomplished. This includes: (a) train and qualify personnel to be capable of performing their assigned work; and (b) provide continuing training to personnel to maintain their job proficiency.

3. QUALITY IMPROVEMENT

This QAPD establishes and implements processes to detect and prevent quality problems. These processes provide for the prompt identification and control of items, materials, services, and processes that do not meet established requirements, including nonconforming items, noncompliant conditions (issues), procedural noncompliance, and opportunities for quality improvement. The issues management process includes identification of problems, the required remedial and corrective measures, and the actions necessary to minimize recurrence. A graded approach is applied in the development of corrective actions and causal analyses based on the significance of the observed condition. The issues management process forms a comprehensive and structured system of problem identification, categorization, and resolution that applies to all FRNP personnel and applicable subcontractors. FRNP uses issue categorization, tracking, and trending activities to disclose potential repetitive and programmatic issues.

The Nonconformance Control system implements processes for identifying and controlling nonconforming items or materials and provides controls for the identification, documentation, segregation, evaluation, and

disposition of the nonconforming items. The overall goal is quality improvement—the identification and resolution of problems and nonconformances before they affect quality and the prevention of use of nonconforming items.

The FRNP Laboratory QAP also addresses the corrective action process as it pertains to analytical laboratory activities through references to this QAPD and applicable implementing procedures. QAPPs, where needed, also will reference this QAPD and its implementing procedures.

3.1 ISSUES MANAGEMENT SYSTEM

Document reviews, inspections, self-assessments, management and independent assessments, surveillances, trend analysis, and similar processes that are part of the QAPD each serve as a means whereby performance problems, nonconforming items, negative or adverse trends, and other circumstances requiring corrective action ("issues") can be identified. Once issues are discovered, they are formalized, documented, and entered into the issues management system. FRNP has multiple procedures with mechanisms for the identification of issues and reporting methods such as procedures CP3-QA-3001, *Issues Management*, and CP3-QA-2005, *Nonconformance Control*. Appendix B includes procedures that lead to entry of issues into the issues management system. Implementation of the issues management procedure provides the appropriate steps to address and resolve the problem identified. CP3-QA-3001 implements FRNP practices for corrective action management described in CP2-QA-3000, *Contractor Performance Assurance Program Description*, to meet the requirements of DOE O 414.1D, Chg 2 (LtdChg), Attachment 2, Criterion 9, and NQA-1 Requirement 16.

Specifically, CP3-QA-3001, *Issues Management*, is the process for managing and tracking issues and resulting corrective actions identified in the normal course of assessments, self-evaluations, and other reviews of project or functional activities as a result of required reporting. The issues management database is used to support and assist in tracking identified issues and actions to closure. The issues management procedure applies to FRNP issues and corresponding actions and is applicable to on-site subcontractor issues and corresponding actions identified through the following source activities, as a minimum (this is not an all-inclusive listing):

- Oversight source documents such as those issued by external reviews (e.g., DOE and state and federal regulatory agencies);
- Screening for reporting into NTS and ORPS, as described in CP3-QA-3004, *Evaluation and Reporting of Potential PAAA/WSH Noncompliances,* and CP3-QA-3005, *Occurrence Reporting,* respectively;
- FRNP independent audits/assessments/surveillances, MAs, and self-assessments;
- Issues associated with nonconformance reports (NCRs);
- Safety evaluation reports (e.g., conditions of approval, updates to safety basis documents, and other related documents);
- Management commitments and management concerns; and
- Process improvements.

All personnel are responsible for reporting problems. Management is responsible for ensuring that issues are entered into the issues management database and evaluated for disposition; screened for DOE

occurrence (e.g., ORPS) and regulatory noncompliance reportability (e.g., PAAA, NTS); corrective actions are developed and implemented as required; and Lessons Learned are documented and disseminated when appropriate.

Issues are screened and categorized to determine their significance. The screening will determine if issues have a serious effect on safety, the capability to prevent or mitigate the consequences of accidents that could have significant off-site consequences, or seriously jeopardize the ability to complete the site mission.

Consistent with the application of a graded approach, the extent and rigor of causal analysis for issues is commensurate with the significance of the issue. Formal causal analysis or apparent cause determination will be performed based on significance determination. Persons leading the formal causal analyses are trained in the appropriate causal analysis methodology used in accomplishing the analysis.

Management directs the performance of extent-of-condition reviews when an issue is determined to be significant, programmatic issues are identified, or at management's discretion. This review is a focused effort to determine the potential for the issue to exist elsewhere (e.g., in other activities, equipment, processes, operations, or organizations). When identified, corrective actions are to be broad enough to address such similar conditions. In cases where a significant causal factor is identified, an extent-of-cause review may also be conducted.

Corrective actions are intended to correct the item, service, or condition and minimize the risk of recurrence of the issue. Corrective actions are developed in accordance with CP3-QA-3001, *Issues Management*, and/or CP3-QA-2005, *Nonconformance Control*, and are implemented in a graded manner depending on the significance of the issue. Corrective action plans specify discrete actionable actions, action owners, action due dates for completion, and required verifications to be performed for the completed actions (e.g., verification task required for conditions adverse to quality and not for routine process improvements).

Lessons learned and operating experience information are gathered and shared in accordance with CP3-QA-3002, *Operating Experience/Lessons Learned (OE/LL)*, and used in work planning to enhance safety, quality, and economy of operations.

Corrective action status through closure is tracked in accordance with CP3-QA-3001, *Issues Management*. Effectiveness evaluations—conducted by qualified personnel after corrective actions for an issue have been implemented and experience gained since implementation—typically are conducted for significant deficiencies, and when requested by management or the issue owner.

3.2 MANAGEMENT INVOLVEMENT

Line management has the primary responsibility for the implementation of quality improvement activities, including event investigation, causal analysis, and corrective-action determination; Quality personnel provide support and oversight of these processes. Responsible management is notified immediately during the course of assessments when significant issues are identified, in those cases where the assessment was not management conducted.

The CPAP organization performs trending and analysis as part of the issues management process (includes NCR related issues) and submits data quarterly, as a minimum frequency, and reports to FRNP management for review in accordance with CP3-QA-3009, *Trend Analysis*. This enhances feedback opportunities and promotes continuous improvement at the site. Senior management reviews the trending information for performance status to determine if further actions or more specific information is required and for

evaluation of adverse trends. Additional reporting is performed as directed by senior management in accordance with DOE O 232.2A, *Occurrence Reporting and Processing of Operations Information*.

3.3 NONCONFORMING ITEM IDENTIFICATION

Items or materials that do not conform to requirements are to be evaluated and controlled to prevent inadvertent installation or use. Potential nonconforming items or materials are marked, tagged, and/or segregated upon identification and, if not found by Quality personnel, then brought to the attention of Quality personnel, who will verify the nonconformance and ensure that the nonconforming condition is documented on an NCR. Upon verification and documentation of the nonconforming condition, the item or material continues to be controlled to ensure that those items or materials are not used until a disposition has been approved and implemented. Boundary flagging may be used in lieu of QA hold tags, where individual tagging is not practical. Quality personnel are responsible for reviewing and verifying closure information for nonconforming conditions and removing tags segregating the item or materials. Implementing procedure CP3-QA-2005, *Nonconformance Control*, defines the process used to control the identification, disposition and handling of nonconforming items. The Material Review Board reviews NCRs, to determine the organization responsible for dispositioning the NCR and to address issues identified in the reports. Nonconforming items or materials that are identified as S/CI are controlled in accordance with procedure CP3-QA-1006, *Suspect/Counterfeit Items*. NCRs are communicated to the waste certification official to allow tracking of NNSS applicable corrective actions.

Engineering evaluates nonconforming conditions and provides documented technical justification commensurate with the original corresponding design requirements (i.e., review and approval), as necessary (e.g., for QL-1 and QL-2 use-as-is and repair dispositions), for items or materials that have a material or functional nonconforming condition relative to applicable specifications, i.e., characteristic, documentation or procedural requirements. Where evaluation is more complex, it is documented using procedure CP3-EN-0215, *Engineering Evaluations*. Technical justification is included with NCR documentation for evaluations less complex in nature. Personnel designated to perform evaluations to determine proper disposition are required to have the competence in the area being evaluated, understanding of the requirements, and access to background information to make the correct decisions. An appropriate disposition could include use-as-is or repair [either of these dispositions require written engineering technical justification for acceptance (i.e., constitutes a change in acceptance criteria and engineering justification is required)], rework (no engineering technical justification required as the item is reworked to meet the acceptance criteria), or reject. For items not yet installed (e.g., items detected during receiving inspection), the documented technical justification determines if the original functional and safety requirements for SSC are compromised. For items installed within nuclear facility SSCs, the Plant Shift Superintendent is informed immediately and evaluations are performed by the appropriate functional areas/execution organizations to determine the extent that the operating process can be placed into a safe configuration. Nonconformances to design requirements are dispositioned based on design control measures comparable to those applied to the original design. Reworked items are reinspected to the original acceptance criteria.

Nonconforming items identified at receipt inspection may require notification from the procurement organization to the vendor/supplier of the nonconforming condition. If the identified problems are severe, repetitive, or related to critical items, corrective action may be pursued with the vendor.

3.4 DISCUSSION OF SPECIFIC NQA-1 REQUIREMENTS IN CRITERION 3

Appendix B identifies the NQA-1 requirements addressed in Criterion 3. Personnel who perform evaluations and determine the disposition for nonconforming items, materials, and services are required to have competence in the specific area being evaluated, adequate understanding of the requirements against which the evaluation is performed, and access to the background information needed to make proper judgments and decisions. The training and indoctrination requirements, including documented records, for these personnel are addressed in Criterion 2 and are in conformance with NQA-1 Requirements 2/100(b), 200–202), and 500. Specific qualification of inspection and test personnel who identify the nonconformances are discussed in Section 2.1 of Criterion 2 and also are described in Criterion 8. The control of nonconforming items, materials, or services is addressed in Section 3.3 in conformance with NQA-1 15/100–405. Section 3.1 describes the FRNP Issues Management approach and corrective action management in conformance with NQA-1 Requirement 16.

3.5 CONCLUDING SUMMARY FOR SECTION 3 OF THE QAPD

Section 3 of the QAPD, in conjunction with the graded approach rationale of Section 1.4 of the QAPD, is the FRNP plan description for how the Management/Quality Improvement criterion of DOE O 414.1D, Chg 2 (LtdChg) is accomplished. This includes: (a) establish and implement processes to detect and prevent quality problems; (b) identify, control, and correct items, services, and processes that do not meet established requirements; (c) identify the causes of problems, and include prevention of recurrence as a part of corrective action planning, and (d) review item characteristics, process implementation, and other quality related information to identify items, services, and processes needing improvement.

4. DOCUMENTS AND RECORDS

The FRNP QAP addresses the preparation and use of documents and records for many different disciplines and across most functional areas. Policy CP2-OP-1102, *Performance Document Program*, establishes requirements that control the development, receipt, unique identification, review, approval, distribution, change or revision, and use of documents to prescribe processes, specify requirements, and establish design. CP2-RD-0001, *Records Management Plan*, describes FRNP processes for the identification, capture, maintenance, use, control, and disposition of records created, received, and managed under the Contract. The documents and records prepared, used, and maintained by FRNP also provide an evidentiary basis for oversight of the QAP and other management systems within FRNP in accordance with requirements of DOE O 226.1B. The following sections describe various types of documents and records and how they are managed and used by FRNP.

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4.1 DOCUMENTS

FRNP manages and controls work using approved performance documents. Performance documents include plans, policies, procedures, program description documents, program requirement documents, guides, and work control documents that define the management systems, programs, and processes established by FRNP. Processes documented in performance documents implement the requirements of this QAPD, other management system descriptions, and applicable requirements mandated by law and the Contract to provide the detail necessary for proper implementation of the quality program using a graded approach.

Performance documents are drafted, reviewed, approved, and controlled in accordance with the following procedures: CP3-OP-0002, *Developing and Maintaining Performance Documents*; CP3-OP-0025, *Document Control Process*; and CP3-SM-1101, *Work Package Development*. Each of these documents identifies the individuals responsible for the preparation, review, approval, and distribution of documents controlled by each of the processes. Additional requirements for the development and control of activity-level work are described in Section 5.

Periodic review and revision of the content of performance documents regularly is necessary for continuous improvement efforts. Changes are accomplished using a structured, controlled effort that includes reviews conducted by the affected functional groups, SMEs, and execution organizations. Changes include non-intent changes and intent changes. A non-intent change is inconsequential change involving correction of grammar, spelling without changing meaning; update of organizational titles without change of responsibilities; update of numbers or titles of reference documents; update of contact information; renumbering of steps; reformat or change of forms where form intent is unchanged; changes to appendices marked "Example," "Sample," or exhibits that are clearly intended to be representative only; or minor clarifications without add/delete of steps, sequence, or scope as defined within CP3-OP-0002. Intent changes are defined as anything beyond non-intent. The review and approval requirements for non-intent changes and for intent changes also differ. Intent change reviewers are selected based on scope of change according to a matrix in the procedure and include USQ or have documented USQ exemption. Approvers are selected based on a responsibility matrix in procedure. Non-intent change reviewers include the SME, criticality safety (for documents that implement Nuclear Criticality Safety requirements or could impact a fissile material operation), and waste certification official if applicable, and USQ or have documented USQ exemption. Approvers are the same as for intent change.

The Document Control group is responsible for aiding in the development of performance documents and providing approved documents for use. Performance documents and forms that are approved for use are controlled and made available for use by personnel on a continuing basis either via intranet electronic and/or hard copy distribution. It is the individual's responsibility to verify that the version he or she is using is the current revision of performance documents at the time of use of any copy printed from the Web site.

Controlled copy distribution of these documents is performed according to approved procedures. Paper copies issued as controlled copy distribution are assigned a unique control number and tracked as to whom they were issued. Upon revision of controlled documents, all controlled copy holders are provided with instructions to replace outdated copies and place the current copy into use.

All quantitative project documents generated by FRNP are the property of DOE PPPO. Such documents may be distributed to state agencies, federal agencies, other regulatory agencies, and citizen's groups in accordance with DOE approvals, policies, and guidelines.

Review intervals are established for each plan and procedure as a measure to ensure the plans and procedures in use reflect the most current contract standards, requirements, and business practices.

4.2 RECORDS

Records provide a basis for planning, measuring performance, repeating work in near duplicate form, resolving quality problems, and providing insight to the effort to improve quality. Records are a basis for verifying, and thereby demonstrating that QAPD objectives have been achieved. The requirements for records are specified in several QAP areas, such as indoctrination and training, design, procurement, process control, inspection, testing, QA, and auditing and oversight, including issue management and corrective action. The generation of these records is specified in performance documents specific to the respective areas. The authentication, classification, receipt control, and maintenance of records by FRNP

are described in CP2-RD-0001, *Records Management Plan*, and CP3-RD-0010, *Records Management Process*. The controls described in these documents conform with several contractual requirements, namely, 36 *CFR* Chapter XII, Subchapter B, *Records Management*; 36 *CFR* 1236, *Electronic Records Management*; DOE O 243.1C, *Records Management Program*; and ASME NQA-1-2008, *Quality Assurance Requirements for Nuclear Facility Applications*, Requirement 17, *Quality Assurance Records*. Chg A

CP2-RD-0001, *Records Management Plan*, defines the process and corresponding responsibilities for managing records produced under the contract and is supported by implementing work performance procedures. These procedures address the complete life cycle of records, consisting of three stages: creation or receipt; maintenance or use; and disposition, which include and address the specific tasks of records generation, authentication, classification, and maintenance via the applicable implementing procedures.

FRNP personnel and subcontractors are responsible for the preparation, custody, and transfer of the records produced by their effort while records are in their custody. Completed records will reflect accurately the work performed, be legible, and be traceable to the applicable work.

Records that are generated by and contained in an electronic information system (EIS) are controlled per the requirements of CP2-RD-0002, *Electronic Information System Requirements*. The EIS requirements document describes the requirements and processes employed by FRNP to capture records from EISs. An EIS is an information system (computer software) that contains and provides access to computerized federal records and other information. The EIS plan provides guidance on incorporating records management requirements into the process of any software deployed by FRNP through the SQA process to ensure that records management controls are planned and implemented into all EISs. Chg A

Following generation and use, the records management organization receives records from functional organizations, projects, and subcontractors and uses developed indexes and categories to enter these records into the records storage system. Several types of records are retained under the records management system including: QA records, classified records, vital records, official use only records, and unclassified controlled nuclear information records. In addition, the overall records management process is established to ensure that sufficient records are maintained to preserve the technical and nuclear basis documentation.

QA records are those that furnish evidence of the quality of items and/or activities affecting quality. QA records require additional classification as lifetime or nonpermanent and have additional requirements under NQA-1, which are reflected in records management procedures (e.g., CP3-RD-0010, *Records Management Process*).

- **Lifetime QA Records:** Denotes safe operation of an item; significant value in maintaining, reworking, repairing, replacing, or modifying the item; significant value in determining the cause of an accident or malfunction of an item; and/or provide required baseline data for in-service inspections. Lifetime records are associated with items and should not be confused with the National Archives and Records Administration definition of permanent.

- **Nonpermanent QA Records:** Provide evidence that an activity was performed in accordance with applicable requirements, but does not need to be retained for the life of an item because they do not meet the criteria for lifetime records. Nonpermanent records are those associated with "activities."

Records actively needed to support the scope are maintained by the records management organization according to approved procedures until they reach an inactive state. At that time, the records management organization coordinates transfer of inactive records to the DOE assigned site Infrastructure Contractor who is responsible for the final storage and disposition of records at the site. Prior to transfer to the infrastructure

contractor, records will be protected from loss, damage, deterioration, and through implementation of one or a combination of the following means of storage, as directed in records management procedures:

- Records placed in locked or controlled access areas; and either
- Two-hour fire-rated cabinet, plus adequate smoke detection or fire suppression systems and reasonable safeguards against theft, water damage, and insect or rodent infiltration; or
- Maintain duplicate records in identified storage area in a separate location; duplicate records storage areas must be removed sufficiently from one another to eliminate circumstances where a single adverse event can damage records held at both locations; or
- Duplicate information in another record medium that is stored in a separate location.

When temporary storage of QA records (such as for processing, review, or use) is required, the storage facility or container provides the procedurally specified fire rating, unless dual storage requirements are met.

4.3 DISCUSSION OF SPECIFIC NQA-1 REQUIREMENTS IN CRITERION 4

Appendix B identifies the NQA-1 requirements addressed in Criterion 4. Document and record requirements described above and in the implementing documents listed in Appendix B address most of the QAP areas covered by NQA-1. Specifically, the following document and record requirements are addressed by this criterion: Implementation records of indoctrination and training, including qualification and requalification records for Assessor and Lead Assessor (Auditor and Lead Auditor) as well as inspection and test personnel are maintained per NQA-1 Requirements 2/400 and 500. Requirements for documentation and records that support designs and design input are prepared and maintained to satisfy NQA-1 Requirements 3/100, 200 and 900. Procurement documents are prepared and reviewed, including changes to the documents, to satisfy NQA-1 Requirements 4/300 and 400. Instructions, procedures, and drawings are prepared, used, and maintained to prescribe activities affecting quality and services to satisfy NQA-1 Requirement 5/100. Document control, described in Section 4.1, addresses NQA-1 Requirements 6/100-302. Records established and maintained as a result of the purchase of items and services are controlled by the processes described in Section 4.2 to address NQA-1 Requirement 7/400 and 800. Records of personnel, processes, and equipment used for special processes are maintained as described in Section 4.2 to satisfy NQA-1 Requirement 9/400. Inspection and test records that cover item inspection, date of inspection, inspector, type of inspection, and results and actions taken to address nonconformances, if any, are established and maintained in accordance with FRNP implementing documents to satisfy NQA-1 Requirement 10/800. Test results and records, where developed and maintained by FRNP implementing documents, satisfy NQA-1 Requirements 11/500-602. M&TE records are established and maintained as required by NQA-1 Requirements 12/400-402. QA records are generated, authenticated, classified, controlled, stored, and maintained, as described in Section 4.2, and satisfy NQA-1 Requirement 17/100-800. Audit records, including plans, reports, replies, and corrective action documentation, are maintained to satisfy NQA-1 Requirement 18/800.

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4.4 CONCLUDING SUMMARY FOR SECTION 4 OF THE QAPD

Section 4 of the QAPD, in conjunction with the graded approach rationale of Section 1.4 of the QAPD, is the FRNP plan description for how the Management/Documents and Records criterion of DOE O 414.1D, Chg 2 (LtdChg) is accomplished. This includes: (a) prepare, review, approve, issue, use, and revise

documents to prescribe processes, specify requirements, or establish design; and (b) specify, prepare, review, and maintain records.

5. WORK PROCESSES

5.1 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

FRNP self-performs a substantial amount of work to support the scope of the project and also subcontracts work to other companies. After the work is categorized, then both self-performed and subcontracted work are performed to established technical standards, administrative controls, and other hazard controls adopted to meet regulatory or contract requirements using approved instructions, procedures, drawings, and work documents or other appropriate mechanisms. Repetitive work is controlled through the use of approved procedures and work documents, while nonrepetitive work is controlled through the use of task-specific work instructions (work documents) such as those prepared for deactivation and maintenance activities. Other hazard controls are adopted primarily through implementation of the Job Hazard Analysis (JHA) process (CP3-HS-2004). JHAs are developed, approved and maintained in a controlled database for use on repetitive and nonrepetitive work. The document control program is discussed in Section 4, Documents and Records.

The work control program has been established to incorporate the ISMS core functions and guiding principles, EMS, worker safety, and applicable QA criteria; and to address the necessary requirements for all authorized work. The procedures are developed to ensure compliance of the integrated program requirements for worker safety, security, quality standards, and client expectations are incorporated into standards, work instructions, and technical requirements at all organizational levels through the activity level. The contract requires FRNP to perform stabilization and deactivation activities for facilities in order to place them in a safe configuration for long-term surveillance and maintenance (S&M). Deactivation activities address the control of NMs and hazardous/nonhazardous contaminants being prepared for storage and/or removal from PGDP. These requirements are met through the work planning and control program for each category of work and includes the evaluation of risk and complexity to determine the work package planning and approval controls.

A graded approach is used in the development of work control documents and implementation of quality and safety requirements. The work process graded approach is based on the complexity and risk for environmental and safety consequences, and programmatic effects. The graded approach determines the level of detail in work control documents and extent of involvement of organizations in reviewing, approving, and monitoring work control documents.

The work control program requires project team members involved with the performance of work to be involved in the work planning process to the greatest extent possible, including the identification and development of hazard controls through the JHA process and utilization of the Hazard Identification Checklist. Personnel with work approval authority review the scope of work requests and provide approval prior to work commencement. These work documents specify the necessary administrative controls, including applicable permits or formal agreement conditions, and quality inspections. The work control program provides for work and job planning functions that require preparation, review, and approval of work documents prior to initiation of work. Work documents contain (or incorporate through reference) all documents needed to perform work safely and successfully. Work documents also specify applicable post-modification or functional acceptance tests and acceptance criteria. The program also requires individuals to verify they are working to the latest approved revision of procedures and controlled work documents.

Documents used to define and perform work must comply with the requirements of applicable technical standards, vendor manuals, safety basis documents, codes, specifications, subcontract terms and conditions, and other technical requirement documents. Performance documents used to accomplish work are developed using technical, health, safety, environmental, and quality requirements. These documents also define requirements for review, by the implementing organization or team (e.g., Business Services and HSS&Q) or other affected organizations, prior to approval. Personnel reviewing these documents are selected by their organizations based on qualification, knowledge, experience, and competency in their area of responsibility.

When work is subcontracted, the quality implementation requirements are addressed by requiring subcontractors either to perform work under the QAPD and to FRNP-generated work control documents or to develop the necessary FRNP approved documents, plans, and procedures to perform their work scope and to address the requirements. Depending upon the subcontractor owned plans and documents involved, DOE prior approval will also be required prior to on-site use (e.g., work under subcontractor worker safety and health plan), as necessary. Programmatic requirements imposed on the subcontractor are defined by the subcontract language.

5.2 IDENTIFICATION AND CONTROL OF ITEMS

FRNP identifies and controls items under interdepartmental procedural guidance to ensure their proper use. FRNP also implements procedurally controlled methods (e.g., CP3-QA-2004, *Material Receipt Inspection*) to maintain items to prevent damage, loss, or deterioration. Items include materials, equipment, components, appurtenances, assemblies, modules, parts, structures, subsystem units, subassemblies, and systems. Material identification and traceability requirements are based on the specificity of the material identification, the end use, and the consequences of failure. Item identification is maintained and replaced, as necessary, to prevent loss due to degradation or weathering.

Identification of items is maintained, in accordance with implementing FRNP procedures, either on the item or in documentation traceable to the item. Item identification and traceability are implemented using the established graded approach criteria. When required, either by subcontract terms and conditions or FRNP procedures, items are identified from initial receipt or fabrication up to and including installation or use. Physical identification is used to the maximum extent possible. When physical identification on the items is impractical or insufficient, physical segregation or other effective means are used. Procedures are established to ensure that, when items having identification or traceability requirements are subdivided or sampled, identification will be transferred to each part, container of parts, or sample at the time of subdividing or sampling.

Controls are established and implemented to ensure only correct and accepted items are used and installed. Where specified, items having a limited shelf life, operating life, or cycle are controlled to preclude use when such limits are exceeded.

In addition to the above, controls for potentially hazardous items or materials (e.g., chemicals or similar) are managed under separate FRNP program requirements, which the HSS&Q organization will provide oversight of through the integrated assessment and surveillance program.

5.3 CONTROL OF SPECIAL PROCESSES

Certain processes require a greater extent of control than others either because the quality of work produced is highly dependent on the skill and abilities of the operator and/or because quality cannot be verified readily

by inspection or testing of the final product. Such special processes may be controlled by instructions, procedures, drawings, checklists, travelers, or other appropriate means. Measures to ensure special processes produce high quality results include qualification of the procedure or methodology that the process is based on, as well as qualification of the personnel using the process or equipment used in the process. Methods used to accomplish qualification may vary according to the special process involved, but, in all cases, these methods will be consistent with the standards that apply according to the Contract. Conditions necessary for accomplishment of the special process will also be addressed. Heat-treating, nondestructive examination or testing, brazing, and welding operations are considered special processes. Any other processes that are to be considered special processes (beyond those cited previously) will be identified by the HSS&Q Director, and qualification requirements for personnel, procedures, or equipment will be established and documented in referenced procedures or instructions when needed to describe the control of those processes.

Engineering defines the codes/standards, including acceptance criteria, for the control of special processes for subcontracted work. Where codes/standards do not exist for the control of special processes, FRNP includes the necessary controls, such as qualification requirements for personnel, processes or equipment, in prepared or referenced procedures or instructions. Subcontractor submittal of implementing procedures (e.g., welding and nondestructive examination procedures) and personnel qualifications (e.g., American Welding Society Certified Welding Inspector) are used to verify the existence of qualified procedures and personnel. These submittals will be reviewed for acceptance by designated SMEs from Engineering, Quality, and other appropriate functional areas. Heat treatment charts, welding procedures, welder's qualifications, welding records, and nondestructive examination results are examples of submittals and/or deliverables that demonstrate or certify conformance to the technical or quality requirements for special processes. The records and documents for currently qualified personnel, processes, and equipment associated with these special processes are maintained in accordance with Section 4, "Documents and Records."

5.4 CONTROL OF MEASURING AND TEST EQUIPMENT

NQA-1 defines M&TE as "devices or systems used to calibrate, measure, gage, test, or inspect in order to control or acquire data to verify conformance to specified requirements." M&TE plays an important role in achieving and ensuring quality in the execution of project activities. The information resulting from the use of M&TE often is used as a basis for decision making in terms of characterization of safety or environmental hazards, acceptance of data or materials, acceptance of items and services, project readiness, and/or the status of operating systems. FRNP implements the M&TE program through formalized procedures to ensure the information produced by M&TE is accurate and reliable within prescribed tolerances on an ongoing basis. CP3-SM-0017, *Measuring and Test Equipment*, describes how M&TE standards and calibrated instruments, maintained by the PGDP S&M Organization, Calibration Facility, are purchased, calibrated, used, and controlled. CP3-HS-2038, *Industrial Hygiene Measuring and Test Equipment Program*, provides controls for calibrating and maintaining Industrial Hygiene (IH) equipment that is relied upon for IH monitoring or data collection and establishes controls for the implementation of the IH M&TE, where applicable. CP4-QA-2133, *Metrology Measuring and Test Equipment Calibrations and Certifications*, provides the instructions and describes the documentation requirements for the inspection, calibration, and certification of QC Metrology M&TE. CP3-SM-0017 provides the FRNP processes to control M&TE application; actions for correcting M&TE if lost, damaged, or out-of-calibration; handling and storage; environmental conditions for use and calibration; performing and recording results of pre-calibration checks; and maintaining calibration status and traceability of calibration records. CP4-QA-2133 identifies prerequisite requirements to ensure pre-calibration checks on standards, inspect for damaged M&TE, and ensure proper control of the temperature and humidity. M&TE records and maintenance history files are maintained in accordance with Section 4, "Documents and Records."

M&TE is identified, handled, stored, transported, and used in accordance with the manufacturer's recommendations. A tracking system is used to maintain information related to each M&TE item and calibrated M&TE is available for use on project activities. The M&TE tracking system identifies the item number, the calibration interval, last calibration date, calibration due date, and other pertinent information. CP3-SM-0017, *Measuring & Test Equipment*, requires the FRNP Calibration Facility to perform a self-assessment of Control of M&TE at a minimum of every 3 years according to CP3-QA-1003, *Management and Self-Assessment*. The same procedure also requires the performance of an annual inventory check for active M&TE devices in the MetTeam database and assigned locations. If any M&TE device is found to be lost, damaged, use log lost, or previous use indeterminate, an issue is filed through the CP3-QA-3001, *Issues Management*.

The Laboratory QA Program also addresses control of M&TE as it pertains to analytical laboratory activities through references to this QAPD and its implementing procedures. QAPPs, where needed, also will reference this QAPD and its implementing procedures.

FRNP or subcontractors that use M&TE are required to establish and implement work processes based on an Engineering evaluation to ensure equipment is of the proper type, range, and accuracy, and that such equipment is calibrated based on technical standards and maintained to ensure that data quality and process capabilities continue. Other equipment not relied upon for NQA-1 purposes, but that is relied upon for process monitoring or data collection must be calibrated and maintained. When working under FRNP, subcontractors either are to perform work under this QAPD or to address these requirements via a FRNP approved quality program, as stated under the subcontractor quality requirements flow down and quality program approval requirements of this document.

M&TE is stored in an environment that conforms to the manufacturer's or supplier's recommendations. If the manufacturer or supplier does not specify storage conditions, then storage conditions are specified by the designated FRNP M&TE SME.

Calibrations of M&TE are discussed in Section 8.2, "M&TE."

Equipment, such as installed plant instrumentation used for process monitoring or data collection, is calibrated and maintained using applicable FRNP program or process procedures.

5.5 HANDLING, STORAGE, AND SHIPPING

Controls for handling, storing, shipping, cleaning, and preserving items to prevent damage, loss, or deterioration are defined in subcontract terms and conditions or in relevant procedures (e.g., CP3-PR-3001, *Warehouse Operations and Receipt of Material*, and CP3-QA-1007, *Procurement Quality Assurance*), as appropriate. The control levels for storing and shipping are based on requirements in DOE Orders, standards, and directives, national consensus standards, FRNP procedures, subcontract language, or in technical documents, if no standards exist.

Marking and labeling of items for packaging, shipping, handling, and storing are required and controlled to adequately identify, maintain, and preserve the integrity and applicable traceability of items, including indicating the need for special environments, tools or equipment, controls, or safety handling requirements or procedures. Instructional documents for handling, storage, and maintenance of engineered items (subject to design or specification requirements) require engineering approval prior to use. These documents are processed as submittals or deliverables for subcontracted work. For off-site transportation, these requirements are defined in procedures (e.g., CP3-PR-3001 and CP3-QA-1007) and/or subcontract terms and conditions.

5.6 INSPECTION, TEST, AND OPERATING STATUS

FRNP or subcontractor managers who perform operations, support, testing, and/or environmental functions are required to maintain physical status indicators and supporting documentation for the work processes under their control. Procedures are developed to specify the content, application, update, and removal of physical status indicators. Where it is necessary, the responsible FRNP or subcontractor managers are required to ensure that required inspections and tests are performed, and that items that have not passed the required inspections and tests are not inadvertently installed, used, or operated. Status is maintained through indicators such as physical location and tags, markings, stamps, inspection records, or other suitable means. The authority for application and removal of tags and markings, labels, and stamps is specified via the implementing procedure(s). Status indicators also provide a method of indicating the operating status for systems and components of the nuclear facility, such as tagging valves and switches to prevent inadvertent operation. CP3-OP-0015, *Control of Equipment and System Status*, identifies the authority for identifying and making changes to the status of safety-related systems or other equipment critical to the operation of the project/facility as the facility manager. The project site maintains a formal lockout/tagout program to help protect workers while enabling safe, controlled work on de-energized systems.

In accordance with CP3-QA-2005, *Nonconformance Control*, NCRs are generated for items that do not conform to quality, design requirements, or that fail quality inspection or testing. Nonconforming items are segregated and/or tagged, using a QC hold tag, to preclude inadvertent use or the bypassing of required tests until such time that an approved engineering disposition is determined. The item owner is responsible for ensuring that untagged/segregated items are identified adequately and for implementing actions necessary to prevent unauthorized use of the items. Rejected items are made unavailable for use, except according to established procedures or as specifically defined in the disposition of the NCR. When the disposition of the NCR is completed satisfactorily, QC hold tags are authorized for removal. All QC hold tags and/or any segregation boundary flagging associated with the NCR are removed. Nonconformances are managed under the Nonconformance Control program to ensure that actions are appropriately documented and tracked to closure, and that adverse trends are appropriately analyzed.

5.7 SAMPLE MANAGEMENT OFFICE

FRNP through the SMO is responsible for managing sample data by processing sample data requests, assisting procurement to establish analytical laboratory contracts, generating statements of work to comply with QAPP requirements and/or projects expressed needs, managing sample chain of custody and sample labeling through PEMS, overseeing sample collection, monitoring progress of data deliverables, running queries for screening purposes to verify FRNP received data requested, integrating with the project team on data assessment and verification, and contract third party V&V as needed. The SMO is required to utilize OREIS for uploading sample data information, and the PPPO Environmental Geographic Analytical Spatial Information System for uploading sample data for public and regulatory viewing. The SMO is required to ensure sample residuals are returned or disposed of by the on-site laboratory and/or all contracted analytical laboratories. In addition, the SMO is responsible for continuing environmental monitoring of all remediated site areas for Comprehensive Environmental Response, Compensation, and Liability Act actions, upkeep of the 400 plus monitoring wells, managing the water policy, and all Geographic Information System needs. Implementing procedures provide specific requirements and guidelines for SMO processes. Applicable SQA controls are implemented as further described in Section 12 of this QAPD.

5.8 DISCUSSION OF SPECIFIC NQA-1 REQUIREMENTS IN CRITERION 5

Appendix B identifies the NQA-1 requirements addressed in Criterion 5. NQA-1 Requirement 5/100 addresses the use of instructions, procedures and drawings for the control work processes in Section 5.1. The identification and control of items during work processes are described in Section 5.2 per NQA-1 Requirements 8/100-303. The control of special processes as required by NQA-1 Requirements 9/100-400 is discussed in Section 5.3. The control of M&TE per NQA-1 Requirements 12/100-402 is described in Section 5.4. The handling, storage and shipping of items, including marking and labeling, for work processes are described in Section 5.5 per NQA-1 Requirements 13/100-600. Inspection, test and operating status methods and requirements used during work processes are discussed in Section 5.6 as required by NQA-1 Requirement 14/100. In addition to these NQA-1 Part I requirements, Part I Introduction and several Part II Subpart requirements are identified in Appendix A and in Appendix B for Criterion 5, based on the inclusion in EM-QA-001, *EM Quality Assurance Program*, or the applicable relationship to Part I requirements. The Part I Introduction, which is specified in EM-QA-001, is included in Appendix B to address the applicability and responsibility requirements for application of NQA-1 requirements. This part also addresses the terms and definitions used throughout the NQA-1 requirements, and therefore, the QAPD descriptions. NQA-1 Part II Requirement, Subpart 2.2 supplements the requirements of Part I Requirement 13 as described in Section 5.5 and invoked in implementing procedures for items related to uranium processing or handling. Part II Requirement, Subpart 2.4 supplements the requirements of Part I Requirement 14 as described in Section 5.6 and invoked in implementing procedures for uranium processing facility maintenance as related to deactivation activities. Part II Requirement, Subpart 2.7 is included based on EM-QA-001 and supplements the SQA discussion in Section 12 of this QAPD. Part II Requirement, Subpart 2.18 supplements Part I Requirement 9 for the control of special processes as the requirements relate to the maintenance of nuclear facilities.

5.9 CONCLUDING SUMMARY FOR SECTION 5 OF THE QAPD

Section 5 of the QAPD, in conjunction with the graded approach rationale of Section 1.4 of the QAPD, is the FRNP plan description for how the Performance/Work Processes criterion of DOE O 414.1D, Chg 2 (LtdChg) is accomplished. This includes: (a) perform work consistent with technical standards, administrative controls, and other hazard controls adopted to meet regulatory or contract requirements using approved instructions, procedures, or other appropriate means; (b) identify and control items to ensure proper use; (c) maintain items to prevent damage, loss, or deterioration; and (d) calibrate and maintain equipment used for process monitoring or data collection.

6. DESIGN

6.1 GENERAL

The design process covers development of design inputs/outputs, technical review, and approval of design based on a graded approach. Change control, along with development of specifications, drawings, and calculations, are in separate procedures. Design inputs/outputs are identified and documented on a graded approach, based on the level of complexity. The Chief Engineer serves as the Design Authority and has delegated Design Authority also to Engineering Manager(s)/Lead(s). The origin of design input is the responsibility of a designated responsible engineer. The design input is specified to the level of detail necessary to permit the design activities to be performed in a compliant manner. A consistent basis is used for making design decisions and design adequacy is verified by individuals other than those who prepared the original design. Design changes and revision control are governed by control measures commensurate

with those applied to the original design, and as procedurally specified. Items and processes are designed using sound engineering, scientific principles, and appropriate standards. The following are the primary engineering documents that implement these processes.

- CP2-EN-0201, *Configuration Management Program Description*
- CP3-EN-0203, *Design Change Process*
- CP3-EN-0224, *Configuration Management System (CMS) Control*
- CP3-EN-0207, *Facility Change Process*
- CP3-EN-0209, *Plant Drawings*
- CP3-EN-0307, *Engineering Procurement Specification*

Engineering procedures have been established and implemented to perform and control a range of items and operations supporting the Project, including the design of SSCs. FRNP Engineering and other design-related procedures ensure that each final design:

- Is traceable/relatable to the design input criteria by documentation in sufficient detail to permit independent design verification;

- Specifies required inspections and tests and includes or references appropriate acceptance criteria;

- Identifies systems, assemblies, and/or components that are part of the item being designed; and

- Ensures the final approved design package is intended for field implementation.

When a design-related scope of work is to be performed by subcontractors, the quality and technical requirements with the appropriate level of rigor and oversight are contractually flowed down to subcontractors through the subcontract language.

6.2 DESIGN PROCESS

Design activities are performed in a graded approach using hazard classifications based on safety basis calculations of potential risk to on- and off-site individuals. If no safety basis hazard classification exists, then design procedures grade requirements based on the nature of the design and the significance of the SSC being considered. Various elements of the QAPD and administrative controls are applied according to these hazard classifications throughout the life of the design. Requirements for determining the design basis include the following:

- Basic function and performance requirements
- Safety basis requirements and their effect on the design
- Computer systems and applicable software programs
- Environmental conditions
- Material requirements
- Codes, standards, and regulatory requirements
- Interface requirements
- Operational, maintenance, constructability, and redundancy requirements
- Fire protection, safety, quality, and reliability requirements

The design inputs are specified to the level of detail necessary to permit design activities be carried out in a correct manner and to provide a consistent basis for making design decisions, accomplishing design

verification measures, and evaluating design changes. Design inputs are based on regulatory requirements, contractual obligations, applicable codes and standards, and customer expectations. Design requirements typically are verified as technically correct and complete before procurement/construction and, in all cases, prior to relying on the SSC to perform its safety function. Design inputs may include design bases; environmental, safety, health, and quality considerations; life cycle performance parameters; applicable codes, standards, and procedures; and reliability requirements. Requirements typically are contained in design criteria documents and functional performance requirements. These requirements/specifications are incorporated into applicable design documents.

The design process is controlled to ensure that design input requirements (e.g., codes, standards, quality requirements) are translated properly and correctly into design outputs such as calculations, drawings, test/inspections plans, maintenance requirements and specifications. NQA-1 related design analyses are documented such that the analyses clearly define the relationship between design input, the engineering standards used, mathematical models and formulas used, and the conclusions drawn from the analyses.

Design analyses are documented per engineering procedures and are in sufficient detail to support the V&V effort described in Section 6.4 required for the design. Design input/output alignment, including drawings, specifications, calculations/analyses, and supporting documentation, is an integral part of the design V&V process. Product acceptance testing and inspection requirements are established in the design planning phase of development.

Computer software used in support of design analyses is identified and controlled by version; its capability to produce accurate results is verified; and its application is validated as required by NQA-1 Requirement 3/400 and described in Section 11.

When a system, assembly, or component part(s) are to be acquired as commercial grade items (CGI), Engineering determines the NQA-1-related safety function and corresponding critical characteristics for acceptance, which provide reasonable assurance that the item will perform its intended safety function.

6.3 DESIGN ANALYSES

- The FRNP NQA-1 related design analysis process is sufficiently detailed in procedures (e.g., CP3-EN-0203, *Design Change Process*, and CP3-EN-0213, *Design Analysis and Calculations*), specifications, calculations, etc., such that a person technically qualified in the subject can review and understand the analyses and verify the adequacy of the results without recourse to the originator.

- Documentation of the design analyses is retained as a record, including the objective of the analyses; design inputs and their sources; applicable background data; any previous revisions of the design analyses as available, etc.; assumptions and indication of those assumptions that are verified during the design process; details of computer calculations and computer program applications; and documented reviews and approvals. Software programs used for design calculations, adhere to additional requirements of Section 6.8, “Design Records.”

6.4 DESIGN VERIFICATION AND VALIDATION

The responsible design organization identifies and documents the particular design verification method(s) used. The results of design verification are documented with the identification of the verifier clearly indicated. Design verification is performed by any competent individual(s) or group(s) other than those who performed the original design, but who may be from the same organization. Engineering procedures

establish responsibilities and requirements for conducting verification of design documents. SQA V&V is addressed in CP3-QA-1002, *Software Quality Assurance*. Interfaces between participating design organizations are controlled as described in this procedure. Consistent with NQA-1, cursory supervisory reviews do not satisfy the intent of this program and are not allowed in FRNP procedures.

Acceptable verification methods include, but are not limited to, any one or a combination of design reviews, alternate calculations, qualification testing, and software functional testing. Design verification is performed prior to releasing the design for procurement, manufacture, construction, or use by another organization. When complete design verification cannot be performed, such as when insufficient data exists, the unverified portion of the design is identified clearly and controlled. In all cases, the design verification is completed prior to relying upon the component, system, structure, or computer program to perform its function. If the design is modified to resolve verification findings, the modified design is verified prior to release or use.

Applying a graded approach to design verification, the extent of the design verification is a function of the importance to safety, the complexity of the design, the degree of standardization, and the similarity to previously proven designs. Where the original design has been subjected to a verification process and is available, the verification process might not be duplicated for identical designs; however, the applicability of standardized or previously proven designs, with respect to meeting pertinent design inputs, is verified for each application. Known problems affecting the standard or previously proven designs and their effects on other features are considered.

Separate validation is not required for multiple use of identical or previously proven or validated designs unless the designs are intended for different applications or different performance criteria. Alternate calculations may be used to verify correctness of the original design calculations. The appropriateness of assumptions, input data used, and the computer program or other calculation methods used are reviewed for accuracy.

6.5 DESIGN CHANGE CONTROL

Written procedures and programs (e.g., CP2-EN-0201, *Configuration Management Program Description*, CP3-EN-0203, *Design Change Process*, and CP3-EN-0302, *Engineering Change Requests and Notices*) establish controls for changes to final design, field changes, modifications, and changes resulting from nonconforming items dispositioned as “Use As-Is” or “Repair.” Design change information typically is included on approved, controlled change documents. Procedures require technical justifications for design changes, including use of acceptance criteria if different from that specified in the original design. Design changes are subject to the same controls as the original design. These controls ensure that the design bases for the system, structure, or components are still valid or are revised. In addition, temporary modifications are not utilized at FRNP; instead, the design change control process is utilized.

6.6 DESIGN INTERFACE CONTROL

Design interfaces are identified and controlled using procedures and programs (e.g., CP2-EN-0201, *Configuration Management Program Description*, and CP3-EN-0203, *Design Change Process*), engineering standards, and/or formal agreements to provide effective coordination of design efforts between participating organizations. These controls describe the responsibilities of the affected organizations for initiation, development, review, V&V, approval, release, distribution, and revision of design documents, and management of the tasks.

The CP3-EN-0203 procedure for design changes, mentioned in Section 6.5, describes a process for QL-1 and QL-2 design changes that use a Modification Team to address multi-disciplinary design responsibilities and assignments. The process is led by a Modification Manager, who usually also performs the duties and responsibilities of a responsible engineer for the particular design or modification activity. Modification Team members are required to document concurrence on the Modification Team Approval Matrix with the identification and resolution of design inputs via approval of the Modification Team Approval Matrix.

6.7 CONTROL OF SOFTWARE

Development, verification, validation, configuration management, use and control of software is planned, performed, and documented according to approved procedures, including CP3-QA-1002, *Software Quality Assurance*. As required by NQA-1 Requirement 3/400, all safety-related computer programs are verified to show that they produce correct solutions for the encoded mathematical model within defined limits for each parameter employed. The encoded mathematical model is shown to produce valid solution to the physical problem associated with the particular application. In addition, the generated results of the software, as mounted on the specific hardware and operating system software will be verified and validated as required under SQA program requirements. See Section 12 for detailed requirements related to SQA.

6.8 DESIGN RECORDS

Design control procedures designate documents developed during design that are records. The Engineering File Plan provides for the collection, storage, and maintenance of design documentation and records. Design records include final design output and any revisions, such as drawings, specifications, and quality inspection plans. Also included are documents prepared during important design steps: design analysis objectives design input documents and their sources (e.g., codes, standards, laboratory reports, functional descriptions, and performance criteria); calculations/design analyses; quality assessments; design verifications; formal design reviews; computer programs; review and approval by responsible and technical design authorities; and design change documents. These design records provide evidence that the design and design verification processes were performed adequately.

6.9 CONFIGURATION MANAGEMENT

CP2-EN-0201, *Configuration Management Program Description*, describes the configuration management program for FRNP. Configuration management is a management system that establishes and maintains consistency, identification, and control among design requirements, physical configuration, and facility documentation throughout the life cycle of a facility or project, as changes occur. The configuration management program provides a system so facilities, equipment, systems, safety software and/or firmware, and associated safety basis documents are maintained consistent with the Project's safety envelope. Configuration management system requirements are applied to Nuclear Category 2 and 3 facilities with active safety systems or credited design features and hazardous material facilities classified as high risk. Temporary modifications are not utilized at FRNP; the design change control process is utilized instead. Any temporary changes to an approved configuration for a facility or safety system for testing purposes are reviewed and approved by the responsible design or technical authority and documented in drawings, specifications, or other engineering documents in accordance with applicable procedural requirements.

6.10 DISCUSSION OF SPECIFIC NQA-1 REQUIREMENTS IN CRITERION 6

Appendix B identifies the NQA-1 requirements addressed in Criterion 6. NQA-1 Requirements 3/100-900 are addressed in Sections 6.1 through 6.9. NQA-1 Requirements 6/100-300 for design documentation are addressed briefly in Section 6.8, but more thoroughly in Criterion 4. NQA-1 Part II Requirement, Subpart 2.7 for computer SQA is addressed in Section 6.7, but more thoroughly in Section 12.

6.11 CONCLUDING SUMMARY FOR SECTION 6 OF THE QAPD

Section 6 of the QAPD, in conjunction with the graded approach rationale of Section 1.4 of the QAPD, is the FRNP plan description for how the performance/design criterion of DOE O 414.1D, Chg 2 (LtdChg) is accomplished. This includes (a) design items and processes using sound engineering/scientific principles and appropriate standards; (b) incorporate applicable requirements and design basis in design work and design changes; (c) identify and control design interfaces; (d) verify or validate the adequacy of design products using individuals or groups other than those who performed the work; and (e) verify or validate work before approval and implementation of the design.

7. PROCUREMENT

7.1 PROCUREMENT PROGRAM DESCRIPTION

Detailed processes for preparing, reviewing, and approving purchase requisitions, amendments to requisitions, procurement specifications, bid packages, and other procurement documents are required. The controls established in these processes ensure that procured items and services meet established requirements and perform as specified. The procurement and procurement quality processes support the ISM core function “develop and implement controls.”

Technical, administrative, and quality requirements applicable to items or services being procured are identified and specified in procurement documents (NQA-1 Requirement 4/100). These requirements include applicable codes; regulations; industry standards; tests and inspections; traceability and special procedures or instructions; and applicable requirements from the contract. Also, applicable NQA-1 Part I and Part II requirements, or portions thereof, are flowed down to suppliers and subcontractors via procurement documents using a graded approach in accordance with CP3-QA-1007, *Procurement Quality Assurance*. Oversight of subcontractor activities assures compliance with safety, security, technical, quality, and any other requirements specified in the subcontract.

CP3-QA-1007, *Procurement Quality Assurance*, Section 6.3, controls the required content of the purchase requisition and referenced documentation for the purchased item or service in accordance with the requirements of NQA-1 Requirements 4/200-207. These requirements include scope of work; technical requirements through specific drawings, specifications, codes, standards, regulations, procedures, or instructions; vendor-provided certificates of conformance or compliance and test reports; test, inspection and acceptance criteria; quality program requirements, including QL assignments consistent with the established FRNP graded approach; access to suppliers’ facilities and records; necessary documentation for information, review or approval; verification of SQA for any computer software; supplier reports of nonconformance; requirements for spare or replacement parts; and handling and storage requirements. Procurement documents and any changes, including technical and QA requirements, are reviewed by personnel who have the pertinent information and adequate understanding of the requirements and intent of the procurement documents. Any changes made through the bid process or negotiation are incorporated

in the final procurement documents (NQA-1 Requirements 4/300-400). QA requirements for computer software to address NQA-1 Part II, Subpart 2.7 are described in Section 12 of this QAPD.

Procurement documents identify acceptable methods and criteria for acceptance or rejection of items or services. Procurement documents for items or services critical to safety or having significant operational risks are reviewed by functional area and technical personnel prior to their procurement.

Procedures provide the necessary controls and guidelines to initiate purchase requisitions, procurement specifications, and other procurement documents. These procedures define appropriate controls for the selection, suitability determination, evaluation, and receipt of items or services being procured. As stated in CP3-QA-1007, *Procurement Quality Assurance*, CP3-EN-0307, *Engineering Procurement Specification*, is used for procuring safety-related items, and procedures CP3-CP-0001, *Request for Purchase*, and CP3-SP-0005, *Preparation of Request for Proposal*, are used in the procurement of safety-related services. The procurement program includes a process for procuring off-the-shelf CGIs and dedicating these items for safety-related applications. The FRNP process for controlling the utilization, evaluation, and acceptance of CGIs and services in accordance with NQA-1 Requirement 7/700 and NQA-1 Part II, Subpart 2.14 QA requirements for CGIs and Services is described in CP3-QA-2502, *Commercial Grade Items and Services*. As part of the commercial grade dedication process, the critical characteristics of the item and associated verification requirements are defined and documented in accordance with CP3-EN-0307, *Engineering Procurement Specification*. These items are subjected to specific inspections, tests, and/or evaluations to ensure that these items will perform properly in the safety-related application in accordance with CP3-EN-0307, *Engineering Procurement Specification*, and CP3-EN-0215, *Engineering Evaluations*. Quality-related service controls (e.g., for QL-2 services) include use of suppliers that have an FRNP evaluated and accepted QAP in accordance with CP3-QA-2001, *Approved Supplier Selection Evaluation, Approved Supplier Maintenance*; use of service suppliers that work under the FRNP QAPD and implementing procedures; and/or for services only, service acceptance may be through (a) technical verification of the data submitted, (b) surveillance and/or audit of the activity, or (c) review of objective evidence for conformance to contract document requirements, in accordance with CP3-SP-0018, *Subcontractor Oversight*. Records of procurement activities, including acceptance verification results for purchased items or services and nonconformance determinations and dispositions, are maintained and controlled through the FRNP records management processes discussed in Section 4 of this QAPD.

Services provided in accordance with the requirements of an NQA-1 program and items designed and manufactured in accordance with the requirements of an NQA-1 program may be accepted through Certificate of Conformance (CoC). Additional acceptance criteria such as Source Verification, Receiving Inspection, or post installation testing may be specified as part of item acceptance. CGIs and services may be accepted through dedication using Method 1, Special Test, Inspection, and/or Analysis; Method 2, commercial grade survey of supplier; Method 3, source verification; and/or Method 4, acceptable supplier item or service record, consistent with NQA-1, Part II, Subpart 2.14 (600).

7.2 SUPPLIER SELECTION AND EVALUATION

In accordance with NQA-1 Requirements 7/100-400, controls are implemented by FRNP to ensure conformance with specified procurement requirements. Included in these controls are requirements to ensure that potential suppliers are capable of providing the items or services requested, have the technical and quality capability to satisfy the specified requirements, and can satisfy documentation requirements of the procurement. Supplier selection and evaluation applies to the procurement of items and services that are important to safety and contributes to meeting PPPO's mission at the site. Prospective suppliers are evaluated and selected through specified criteria, using a graded approach. Supplier evaluation is performed by the Quality organization in accordance with CP3-QA-2001, *Approved Supplier Selection Evaluation,*

Approved Supplier Maintenance. In addition, CP3-QA-2002, *Surveillance*, may be used to support the supplier evaluation process, e.g., instances where source surveillance is used to accept an item or service. Third party supplier assessments from the Energy Facility Contractors Group Master Supplier List or DOECAP audits of commercial waste treatment storage and disposal facilities may be used for initial placement or retention of suppliers on the FRNP Approved Supplier List (ASL) following evaluation by FRNP using procedure CP3-QA-2001 to confirm acceptability for use (e.g., assessed limitations and capabilities are within FRNP requirements, assessment meets applicable FRNP requirements). Third party accreditation through the DOECAP Accreditation Program may be used for placement or retention of analytical laboratory services providers on the ASL. Similarly, FRNP may utilize nationally/internationally recognized third-party accreditation audits [e.g., American Association for Laboratory Accreditation (A2LA), National Voluntary Laboratory Accreditation Program (NVLAP) through ISO/IEC 17025] to support a documented supplier evaluation in lieu of an on-site survey for calibration services within the accreditation scope for the proposed supplier. This flexibility may be used only when the FRNP assessment determines the supplier is acceptable according to CP3-QA-2001, and the services procured under this provision are within the accreditation scope of approval. Records of supplier evaluation and selection are maintained and controlled through the FRNP records management processes addressed in Section 4 of this QAPD.

Items or services are procured from suppliers whose qualification results satisfy the requirements of the procurement specifications. As part of the bid solicitation and evaluation processes (CP3-QA-1007, Section 6.5), reviews of the suppliers' quality system documentation and audit/assessment of the suppliers' capabilities typically are used for supplier selection based on the nature and application of items or services being procured. In addition, requalification and supplemental audits/assessments are performed on selected suppliers to verify compliance with the procurement requirements.

7.3 PRODUCT ACCEPTANCE

In accordance with NQA-1 Requirements 7/500-507, the quality of purchased items and services is verified at intervals during various phases of the procurement process, as appropriate. Prior to offering the item or service for acceptance by the purchaser, the supplier verifies that the item or service being furnished complies with the procurement requirements. Specific requirements and frequency of verification are determined by requirements of the procurement documents, applicable specification, code and standard, uniqueness, complexity, application of the item, quantity and frequency of the procurement, and previous quality-related performance of the supplier. Programs (e.g., CP3-QA-1007, *Procurement Quality Assurance,* CP3-QA-2001, *Approved Supplier Selection Evaluation, Approved Supplier Maintenance),* have been established to monitor suppliers whether providing on-site or off-site services to ensure compliance with applicable quality and technical requirements.

Purchased items or services are accepted by method(s) or criteria consistent with procedures (e.g., CP3-EN-0307, *Engineering Procurement Specifications*). Items important to nuclear safety or having significant operational or environmental risks are accepted by approved methods: (e.g., source verification; receiving inspection; special test(s), inspections or analysis). In addition, a CoC from a qualified/evaluated supplier with the appropriate receipt inspection can be used for acceptance of certain procurements. The CoC is traceable to the item and satisfies the requirements of the procurement documents. Procured services may be accepted by the review and technical verification of data/reports produced, review of objective evidence for conformance to contract document requirements, or by audit/assessment of the activity. Source verification and receiving inspection activities are performed using procurement documents as the bases. Receipt inspected items are routinely examined for potential S/CI characteristics. If identified as a potential S/CI item, they are evaluated by engineering and may be dispositioned as nonconforming items.

Processes to ensure that approved suppliers continue to provide acceptable items and services have been established and implemented in accordance with CP3-QA-1007, *Procurement Quality Assurance* and CP3-QA-2001, *Approved Supplier Selection Evaluation, and Approved Supplier Maintenance*. When required by procurement documents, audits/assessments/surveillances/inspections are conducted at supplier facilities by qualified personnel to verify compliance to requirements. These audits/assessments/surveillances/inspections may consist of inspections and tests, including witness and hold points, and document verification as specified in procurement documents. Sub-tier suppliers may also be included in the audits/assessments/surveillances/inspections when applicable. The methods by which supplier nonconformances are handled, controlled, and dispositioned are part of the supplier evaluation and selection assessment process described in CP3-QA-2001. The control of supplier nonconformances at the supplier facility is specified in one or more standard procurement clauses included as part of the solicitation and procurement package. The clause requires that records of supplier inspection and testing activities be provided to FRNP upon request. The clause also requires that the supplier submit issue and corrective action status information for identified concerns, as necessary.

Procured items are put into service only when the acceptance requirements of the procurement documents are met. If an item does not meet a specified quality or technical requirement or there is a documentation deficiency, a nonconformance is initiated to document such deficiency, and the item(s) are marked, tagged, or segregated, as appropriate, to control the item(s) and prevent inadvertent use. Identified deficiencies are dispositioned, and corrective action is taken and verified prior to the item's use. Information from these nonconformance/deficiency documents is analyzed for trends and problems.

Post-maintenance, functional, or preoperational testing is performed after installation of procured items, when specified. These tests verify actual performance against established criteria for the item and the system. Tests, in-service inspections, and maintenance programs monitor the performance of the procured item against established criteria.

7.4 DISCUSSION OF SPECIFIC NQA-1 REQUIREMENTS IN CRITERION 7

Appendix B identifies the NQA-1 requirements addressed in Criterion 7. NQA-1 Requirements 4/100-400 are described in Section 7.1. Section 7.2 describes the control and maintenance of approved suppliers in accordance with NQA-1 Requirements 7/100-400. The acceptance of items and services, as required by NQA-1 Requirements 7/500-600, is discussed in Section 7.3. The FRNP processes used to utilize, evaluate and accept CGIs and services are discussed in Section 7.1, as required by NQA-1 Requirement 7/700-705 and NQA-1 Part II, Subpart 2.14. Descriptions of the maintenance of records and documents for procurement (per NQA-1 Requirements 7/400 and 800) are addressed in Criterion 4 of this QAPD.

7.5 CONCLUDING SUMMARY FOR SECTION 7 OF THE QAPD

Section 7 of the QAPD, in conjunction with the graded approach rationale of Section 1.4 of the QAPD, is the FRNP plan description for how the performance/procurement processes criterion of DOE O 414.1D, Chg 2 (LtdChg) is accomplished. This includes (a) procure items and services that meet established requirements and perform, as specified; (b) evaluate and select prospective suppliers on the basis of specified criteria; and (c) establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.

8. INSPECTION AND ACCEPTANCE TESTING

Inspection and acceptance testing supports the requirements for design control identified in Section 3 of this QAPD and provides the ability to determine if SSCs are capable of performing their intended functions in service or to detect the presence or absence of hazards. The type, extent, and frequency of inspections and/or tests necessary to demonstrate an item's conformance with requirements and acceptance criteria may be identified in procurement documents, a subcontract, in design drawings and/or specifications, or manufacturer's recommendations and in the applicable work controlling document. The need for inspection and testing is identified as an integral part of the work planning and control process described in CP3-SM-1101, *Work Package Development*. Hold/witness points are incorporated into the work control process and performance documents to ensure that mandatory or critical inspection or acceptance steps are performed and work does not proceed beyond the hold point without specific witness of step accomplishment and consent to proceed. The supervisor responsible for the work is responsible for ensuring designated hold/witness points are not overlooked and are documented in accordance with specified requirements.

CP3-QA-2003, *Quality Inspection*, and CP3-QA-2004, *Material Receipt Inspection*, provide controls and responsibilities for ensuring the item's inspection or test status is identified so items that have not successfully passed prescribed inspections or tests are not inadvertently installed or placed in service. The inspection or test status of items will be accomplished by marking, tagging, or segregating items when practicable or by administrative means where physical identification of inspection or test status is impracticable. Methods used to identify the inspection or test status of items will not interfere with or diminish the function of the item and are durable, legible, and enable the user to verify origin and compliance with applicable requirements. In addition, controls based on a graded approach to quality are established to ensure that only correct and accepted items are installed and used. Identification is maintained on the items or documents traceable to the items such as through the use of quality acceptance tags or marking (e.g., for QL 2 and 3 items). The tags are removed upon installation and are included or referenced in the associated work packages or instructions. Provisions are included for maintaining item control when subdividing quality items from an accepted lot (e.g., create new tags to go with the subdivided item).

8.1 INSPECTION AND TEST CONTROL

Inspections are used to verify conformance of items, services, and processes to specified requirements or the continued acceptability of items in service. CP3-QA-2003, *Quality Inspection*, includes methods and responsibilities for planning and performing inspection, test control and/or acceptance testing to verify conformance of an item or service to specified requirements and criteria. This procedure primarily addresses requirements in NQA-1 Requirements 10 and 11. Section 6.2 of the procedure specifies controls for in-process inspection; Section 6.3 provides controls for in-service inspection; and Section 6.4 prescribes controls for final inspection. Inspections are planned and conducted using established acceptance and performance criteria. Inspection plans or procedures define requirements to be met and acceptance criteria identifying characteristics to be examined and inspection methods. All inspection results are documented to include the following, as a minimum: a) item inspected; b) date of inspection; c) inspector; d) type of observation; e) results or acceptability; and f) reference to information on action taken in connection with nonconformances, if any. Qualified persons other than those who performed or directly supervised the work being inspected will perform inspections. Inspection personnel are provided appropriate training in accordance with Section 2, Personnel Training and Qualification, including on-the-job training under the supervision of a qualified person. Personnel performing inspections have the authority to access appropriate information and facilities to conduct inspection, and have the freedom to report the results of inspections.

Personnel performing inspections may be a part of staff, qualified subcontractors, or from vendors specifically qualified to provide quality inspections.

CP3-QA-2003, *Quality Inspection,* includes controls for the development of test procedures and acceptance criteria where tests are required to collect data, such as for design input, to verify conformance of an item, service, or process to specified requirements, or to demonstrate satisfactory performance for service or application. Where computer program tests are required, CP3-QA-1002, *Software Quality Assurance,* is the primary implementing document for FRNP. Use of this procedure is addressed in Section 12 of this QAPD. During design and specification development, Engineering, Quality, or the requesting organization identify items, services, or processes requiring testing and the qualifications of personnel to perform the testing. Characteristics to be tested and test methods to be employed are specified in test plans, procedures, or other work control documents. Appropriate sections of standard test procedures (e.g., American Society for Testing and Materials methods, vendor manuals, maintenance instructions, approved drawings, or national standards or codes such as ASME) may be used instead of unique test procedures. Test results are documented and their conformance with test requirements and acceptance criteria are evaluated. Testing services may be procured from qualified suppliers per applicable procurement procedures.

CP3-QA-2004, *Material Receipt Inspection,* is the FRNP process for inspection of items received from suppliers. The procedure provides methods for control of quality inspected items until they are released to the requisitioner for use or installation. Items that do not pass the required inspections are processed and controlled in accordance with CP3-QA-2005, *Nonconformance Control*. The status of such items is maintained through physical location, tagging and other suitable means. Similarly, the status of systems and components in nuclear facilities is maintained in accordance with CP3-OP-0015, *Control of Equipment and System Status.*

8.2 MEASURING AND TEST EQUIPMENT

M&TE used for inspections and acceptance testing are controlled, calibrated, and maintained in accordance with implementing procedures described in Section 5.4 (e.g., CP3-SM-0017, *Measuring and Test Equipment*, CP3-HS-2038, *Industrial Hygiene Measuring and Testing Equipment Program*, CP4-QA-2133, *Metrology Measuring and Test Equipment Calibrations and Certifications*). Control of M&TE includes labeling, tagging, or otherwise controlling the M&TE to indicate calibration status. Program documents define what equipment is considered M&TE. M&TE typically includes instruments, tools, gauges, scales, torque wrenches, radiological instruments, reference and transfer standards, and nondestructive examination equipment. Calibration procedures identify or reference required accuracy and define methods and frequency of checking accuracy. Calibration and control measures are not required for commercial equipment such as rulers, tape measures, levels, etc. if the equipment provides the required accuracy.

When M&TE is requisitioned, the required measurement range(s) and accuracy (accuracy (ies) are specified and a CoC/compliance and/or a certificate of calibration or testing are required from the vendor, or the item is placed under control upon receipt and sent for calibration. Chg A

M&TE identification provides traceability to calibration and test data. Only calibration standards that are traceable to nationally recognized standards are accepted for use. Reference standards have a minimum accuracy of four times greater than the M&TE being calibrated or the basis for the selection of the standard is technically justified. If no nationally recognized standards exist, the responsible engineering organization will identify and justify use of alternative standards.

M&TE are calibrated using approved procedures that provide steps for performing the calibration and documenting the results, including standards used and their traceability. Labels or tags are used to indicate

the status of the item (e.g., in calibration, out of service). M&TE found to be past the calibration due date or out of tolerance is labeled, tagged or, if possible, segregated. The previous use of such M&TE will be investigated to determine the effect on SSCs. The basis for acceptance of the use of the M&TE since its last calibration is formally evaluated and documented. The rigor of the review is graded depending on the significance of the use since last successful calibration.

Calibration of M&TE is performed at specified intervals or prior to and after use, as established by documented requirements. Engineering is responsible for defining M&TE calibration methods and frequencies. Calibration frequencies are based on required accuracy, intended use, frequency of use, stability characteristics, and other conditions affecting M&TE performance, including environmental conditions.

Control of M&TE is discussed in Section 5.4, Control of Measuring and Test Equipment. Equipment that is used for inspections and testing is calibrated and maintained.

8.3 DISCUSSION OF SPECIFIC NQA-1 REQUIREMENTS IN CRITERION 8

Appendix B identifies the NQA-1 requirements addressed in Criterion 8. NQA-1 Requirements 3/100-900 are included, as identified in EM-QA-001, to address design control as the basis for the requirements of inspection and acceptance testing. The first sentence in Section 8 references Section 3, Design Control. NQA-1 Requirements 8/100-303 are addressed in the second paragraph of Section 8. NQA-1 Requirements 10/100-800 are reflected in Section 8.1. NQA-1 Requirements 11/100-602 are described in the discussion in Section 8.1. NQA-1 Requirements 12/100-402 are addressed in Section 8.2. NQA-1 Requirement 14 is discussed in the last paragraph of Section 8.1. NQA-1 Part II, Subparts 2.4 and 2.7 are included as supplements to NQA-1 Part I requirements discussed in Section 8.

8.4 CONCLUDING SUMMARY FOR SECTION 8 OF THE QAPD

Section 8 of the QAPD, in conjunction with the graded approach rationale of Section 1.4 of the QAPD, is the FRNP plan description for how the performance/inspection and acceptance criterion of DOE O 414.1D, Chg 2 (LtdChg) is accomplished. This includes (a) inspect and test specified items, services, and processes using established acceptance and performance criteria; and (b) calibrate and maintain equipment used for inspections and tests.

9. MANAGEMENT ASSESSMENT

In determining the type of assessment to be performed, the guidelines below are applicable to the project.

Self-assessments are used for the review of a limited area within a function, such as the implementation of the work package process or the review of a particular function or project training and qualifications. An Assessment Team Leader is not required for a self-assessment, since this can be an individually implemented process to perform self-checking.

MAs are implemented as directed by a functional manager or senior manager, as needed. These management tools are used to assist in satisfying requirements to ensure that the status, adequacy, and effectiveness of the overall quality program are assessed on an annual basis. An MA also may be driven by

industry events, including lessons learned from internal or external sources. An appropriately knowledgeable Assessment Team Leader is required for an MA.

Management and self-assessments are part of the integrated assessment program, managed under the QAPD by the CPAP organization, other aspects of the integrated assessment program are discussed under Criterion 10, Independent Assessment. Specific activities or tasks with individual QA Project Plans will integrate their assessment activities with the assessment program under this QAPD.

As part of the integrated assessment program, the assessment schedule is prepared annually and periodically updated under the supervision of the FRNP CPAP Manager. The schedule identifies the processes and/or activities that will be assessed, the assessment type, the timetable for the assessment, and the function(s) responsible for conducting and reporting the assessment.

9.1 MANAGEMENT ASSESSMENTS

MAs conducted under the QAPD are done with the objective of promoting improvement in the performance and effectiveness of the processes described in the QAPD. Senior managers and functional managers are responsible for performing assessments of their areas of responsibility. These performance-based or compliance-based "self-assessment" activities are performed by the senior managers, functional managers, or by personnel reporting to them, to ensure the effectiveness of compliance with requirements, as well as the effectiveness of their management systems from a performance efficiency perspective. These MAs may include worker assessments of their own activities. Effective MAs consider the respective mission, strategy, goals, and whether work is performed safely and in compliance with requirements.

MAs focus on areas that present the greatest risks of failure, and on identifying and resolving issues that prevent customer expectations from being met. Through this mechanism, management strives to identify higher-level concerns, such as strategic consistency with the organization's mission and objectives, effective resource management, effective communication within the unit being assessed, control of costs and schedules, and effective coordination with other organizations and systems.

CP3-QA-1003, *Management and Self-Assessment*, establishes the process and corresponding responsibilities for the performance of assessments by management personnel. Assessors are responsible for identifying evaluation criteria using applicable requirements for the assessed area (e.g., customer expectations; compliance with applicable procedures, standards, and instructions; current activities compared to the results of previous assessments; implementation of past corrective actions; recent occurrences and injuries, performance measures and indicators; and significant changes to personnel, organizations, or process/program), selecting the assessment methods, and developing an assessment plan that includes the applicable evaluation criteria.

Assessors conduct the MA using the assessment plan, gathering data using the most appropriate method, which may include direct observation of work, performance of customer satisfaction/feedback surveys, interviews, inspections, document reviews, checklists, and drills/exercises. Results and conclusions from the MAs are documented, evaluated, and issues identified are dispositioned according to Section 3, "Quality Improvement." Final MA reports are provided to the assessed organization and other appropriate personnel, including organizational managers who may be affected by or need to know the results of the MA. Records produced as a result of MAs include the schedule and the assessment report. Records produced as a result of MAs are maintained in accordance with Section 4, "Documents and Records."

9.2 SELF-ASSESSMENTS

Self-assessments support assessment requirements and commitments, and provide both individual workers and management with observation-based assessments of facility or area conditions, quality of work being performed, adequacy of procedures and compliance with requirements, material conditions, safety, and housekeeping practices. A self-assessment cannot be used in place of an MA for project readiness determination.

Self-assessments are performed based on the annual integrated assessment plan and schedule, or when deemed necessary by any level of management. The sponsoring organizational manager is responsible for defining the purpose/scope and assigning personnel to perform the assessments.

CP3-QA-1003, *Management and Self-Assessment*, establishes the process and corresponding responsibilities for the performance of self-assessments. Personnel conducting self-assessments will be familiarized with the objectives of the effort prior to conducting self-assessments and must be knowledgeable of the areas and work activities assessed. Checklists may be used for the assessment activity, with the results recorded, and issues input into the Issues Management system as directed by CP3-QA-3001, *Issues Management*.

The reports are approved by the responsible manager and results are provided to the affected management (including subcontractors). The results are retained as a record in accordance with Section 4, "Documents and Records." Issues identified during the performance of self-assessments are dispositioned in the Issues Management system in accordance with Section 3, "Quality Improvement." In addition, CP3-OP-0500, *Performance/Process Observations and Tour Process*, provides instructions for managers to perform documented real-time observations of work activities and work place conditions to interface with the workforce. The process provides a method for timely oversight and to supplement the self-assessment program. Chg A

9.3 DISCUSSION OF SPECIFIC NQA-1 REQUIREMENTS IN CRITERION 9

Appendix B identifies the NQA-1 requirements addressed in Criterion 9. NQA-1 Requirements 2/100-500 are addressed in the lead-in paragraphs of Section 9 referring to the use of self-assessments and MAs to determine the status, adequacy and effectiveness of the overall QAP. NQA-1 Requirement 16/100 describes the use of MAs in Section 9.1 to assess the implementation of past corrective actions. NQA-1 Requirements 18/100-800, with the exclusion of the independence requirement for persons performing MAs, are described by Section 9.

9.4 CONCLUDING SUMMARY FOR SECTION 9 OF THE QAPD

Section 9 of the QAPD, in conjunction with the graded approach rationale of Section 1.4 of the QAPD, is the FRNP plan description for how the assessment/management assessment criterion of DOE O 414.1D, Chg 2 (LtdChg) is accomplished. This includes (a.) ensure that managers assess their management processes and (b.) identify and correct problems that hinder the organization from achieving its objectives.

10. INDEPENDENT ASSESSMENT

Independent assessments are part of the integrated assessment program, comprised of independent assessments and surveillances, other aspects of the integrated assessment program are discussed under Criterion 9, Management Assessment. Independent assessments are performed by assessment teams comprised of personnel who are technically qualified, knowledgeable in the areas to be assessed have sufficient independence (i.e., not directly responsible for performing the activity that is audited by the individual); are led by a trained and authorized lead auditor/assessor, with sufficient authority and organizational freedom from line management to make the process meaningful and effective. Independent assessments rarely are applied to individual activities or processes, and typically focus on entire facilities or projects, programs, or management systems and processes that are used by multiple organizations and/or subcontractors. They usually are broad in scope and are performed to evaluate compliance with environmental, health, safety, quality, and regulatory requirements and to determine the effectiveness of the processes at various levels, from program, to function, to project, to task. Their purpose is to improve performance and process effectiveness through assessing item and service quality, measuring the adequacy of work performed, and promoting improvement.

Procedure CP3-QA-1004, *Independent Assessment Program*, provides the responsibilities and requirements to conduct independent assessments. Surveillances are used to support the program on a graded approach. Those used for independent assessment equivalence will meet NQA-1 assessment requirements (e.g., planned, documented, use of NQA-1 lead assessor). QA surveillances without the use of a NQA-1 lead assessor may be used to monitor or observe that project activities and items are meeting requirements, as part of routine or specific QA oversight. The inspection and test control methods described in Section 8 of this QAPD are a form of independent assessment. They are performed as independent verifications or validations by qualified persons other than those who perform or directly supervise the work, to measure item and service quality or the adequacy of work performance, both of which are requirements of Criterion 10.

10.1 ASSESSMENT PLANNING

On an annual basis, the CPAP Manager, with input from site leadership, functional areas, and the Waste Certification Official, ensures preparation and distribution of an assessment plan with schedule, which identifies activities that will be assessed, locations or facilities at which the assessment will be conducted, a general time frame the assessment will be done, and those personnel who are responsible for completing the assessment. The annual assessment schedule will include those assessments that are required to support other activities and requirements.

The assessment plan and schedule may be adjusted periodically based on project or operational needs. The assessment plan will ensure that all elements of the QAPD are assessed at least triennially.

10.2 ASSESSMENT PROCESS

The overall independent assessment process is managed in accordance with FRNP procedure CP3-QA-1004, *Independent Assessment Program,* and uses personnel who are authorized under CP3-QA-1008, *Assessor Qualification, Training, and Certification*, to perform independent assessments.

The CPAP Manager is responsible for the identification of appropriate lead assessors who are technically knowledgeable and appropriately experienced in conducting independent assessments from the identified

pool of FRNP authorized lead auditors/assessors. The selected lead auditor/assessor organizes and directs the assessment and selects the assessment team members relative to the assessment scope to assure team expertise matches scope topics. SMEs or technical specialists selected with agreement of the lead auditor/assessor will comprise the remainder of an assessment team as necessary to properly address the scope of the assessment. If SMEs or technical specialists are unavailable, assessors with similar experience and/or knowledge are substituted. FRNP auditor/assessors and lead auditor/assessors receive training on the assessment process in accordance with Section 2, "Personnel Training and Qualification."

The assessment plan is prepared by the lead auditor/assessor, and approved and distributed to the supervisor or manager responsible for the activities that will be assessed. The assessment plan identifies the scope, requirements, schedule, personnel involved in the assessment, the activities and corresponding procedures or documents that will be assessed, the assessment procedure or checklists that will be used, and how assessment results will be reported. Independent audits/assessments are accomplished through review of documentation, observation of work activities where possible, and/or personnel interviews. Entrance and exit briefings are conducted at the beginning and end of the assessment/audit, respectively. The entrance briefing is to ensure that the assessment/audit scope is communicated and support is coordinated. The exit is conducted at the close of the independent audit/assessment to inform the assessed organization (e.g., supervisor, managers, staff) responsible for the activities that have been audited/assessed of the results of the audit/assessment. Following the exit briefing, an audit/assessment report is prepared, which identifies the activities audited/assessed, personnel involved in the audit/assessment, documentation reviewed, and conclusions of the audit/assessment.

If, during the audit/assessment, an operation or process is identified that seriously jeopardizes safety, health, the environment, or has imminent life-threatening implications, then the work activity is stopped immediately. Potential occurrence, PAAA violation, nuclear safety issues, significant environmental impact, worker safety and health, or public affecting issues will immediately be communicated to the appropriate responsible manager. These issues will be handled in accordance with the processes identified in Section 1.2.2, "Stop Work Authority," and Section 3, "Quality Improvement."

10.3 REPORTING, RESPONSE, AND FOLLOW-UP

Following the exit briefing, the lead assessor coordinates development of a draft audit/assessment report that contains the scope description, team personnel, personnel contacted, summary of results, including statements of the effectiveness of elements audited/assessed, and description of each finding, observation, or noteworthy practice, including any that were identified and closed during the course of the audit/assessment. The draft report is provided to the audited/assessed project/organization. Comments are addressed, as applicable, and the final audit/assessment report is prepared, approved, and distributed in a timely manner (generally within 30 days of the exit meeting) to affected organizations, Contractor Performance Assurance, and Quality.

Audit/assessment results, including any findings or observations, are documented and tracked through completion via implementation of CP3-QA-3001, *Issues Management*, as specified in Section 3.1, and with audit/assessment records controlled, as described in Section 4.2 of this document, respectively. Internal, independent assessment findings require Contractor Performance Assurance or Quality, preferably the assigned Lead Assessor, review/approval of corrective action plans and follow-up to action item closure. Findings resulting from Independent Assessments of Safeguards and Security performed by or on behalf of DOE are tracked through the Safeguards and Security Information Management System, as applicable.

Records produced as a result of independent audits/assessments include the schedule, plans, and reports. Records produced as result of independent audits/assessments are maintained in accordance with the requirements of Section 4 of this document.

10.4 READINESS REVIEWS

Requirements for readiness reviews, as established in DOE O 425.1D, Chg 2 (MinChg), *Verification of Readiness to Start Up or Restart Nuclear Facilities*, are implemented and documented. The FRNP readiness review process is provided in CP2-OP-1119, *Readiness Review Program*. When required by the established criteria, a readiness review is performed to verify a nuclear facility's ability to start operations safely prior to initiating a new activity. The level of readiness review, either operational readiness review or RA, is established by FRNP and concurred with by PPPO, and is conducted by an independent review team. Team participants for readiness reviews must meet DOE Order requirements for independence and qualification; however, they are not subject to assessor or lead assessor NQA-1 qualification/certification requirements. Readiness reviews include, at a minimum, addressing the minimum core requirements and verification of the following characteristics:

- Work prerequisites are satisfied;
- Detailed work plans and procedures, applicable to the work scope to be performed, are reviewed for adequacy and appropriateness;
- Personnel are suitably trained and qualified; and
- Proper equipment, material, and resources are available.

10.5 DISCUSSION OF SPECIFIC NQA-1 REQUIREMENTS IN CRITERION 10

Appendix B identifies the NQA-1 requirements addressed in Criterion 10. The organizational responsibility for independent assessment is discussed in the first paragraph of Section 10 to address NQA-1 Requirements 2/100-500. NQA-1 Requirements 2/100-500 are addressed in Section 10.2 relative to the indoctrination and training requirements for independent assessors. NQA-1 Requirements 10/100-800, 11/100-600, and 15/100/400 are addressed through discussion in the lead-in paragraphs to Section 10 related to the use of inspection and test control, with the control of nonconforming items, as forms of independent assessment to measure item and service quality or the adequacy of work performance. NQA-1 Requirement 16/100 is addressed in the Section 10.3 discussion related to the use of the Issues Management process. NQA-1 Requirements 18/100-800 are described throughout Section 10 as the basis for independent assessments. Subsequent verification of corrective actions subject to Requirement 18/700 need not incur extension solely to perform the verification. Chg A

10.6 CONCLUDING SUMMARY FOR SECTION 10 OF THE QAPD

Section 10 of the QAPD, in conjunction with the graded approach rationale of Section 1.4 of the QAPD, is the FRNP plan description for how the assessment/independent assessment criterion of DOE O 414.1D, Chg 2 (LtdChg) is accomplished. This includes (a) plan and conduct independent assessments to measure item and service quality to measure the adequacy of work performance and to promote improvement; (b) establish sufficient authority and freedom from line management for independent assessment teams; and

(c) ensure persons who perform independent assessments are technically qualified and knowledgeable in the areas to be assessed.

11. SUSPECT/COUNTERFEIT ITEMS

The principal objectives of the S/CI program under CP3-QA-1006, *Suspect/Counterfeit Items*, are to document and implement effective controls and processes that will ensure items meet specified requirements; prevent entry of S/CIs into the DOE supply chain; and ensure detection, control, reporting, and disposition of S/CIs.

FRNP implements the S/CI program using a graded approach. When purchasing items, QLs are assigned based upon an analysis of the item's function relative to nuclear and radiological safety, mission criticality, and consequence of failure. This ensures that those items with the greatest consequence upon failure (SC, SS, mission critical, critical load path) undergo inspection by trained personnel ranging from QC inspectors to the workforce. Training may take the form of required reading, group briefings, classroom, or computer-based training modules.

Though the graded approach applies to safety systems, non-safety systems, mission critical facilities or activities, resources and priorities are focused on those safety systems and mission critical facilities where the introduction of S/CI would have the greatest potential for creating unsafe conditions. Once discovered, all installed S/CIs, regardless of their application, are screened for potential reporting into ORPS (e.g., Office of the Inspector General). The QA/QC Program Manager is the point of contact with the DOE Office of Health, Safety, and Security. The QA/QC Program Manager also reports to the Office of the Inspector General in accordance with DOE O 414.1D Chg 2 (LtdChg) for S/CIs prevention.

The S/CI program is defined and implemented by procedure, CP3-QA-1006, *Suspect/Counterfeit Items*, which includes the following:

- Preventing the introduction and use of S/CI through engineering analysis, design, procurement, receiving inspection, testing, field observations, maintenance, evaluation of reports, trend analysis, lessons learned, and work process controls.

- Incorporating S/CI controls that require vendors, suppliers, and subcontractors to certify that S/CIs are not contained in the items or materials that they provide, regardless of the safety classification for material requisitions (as applicable to the requisition classification) in the procurement process via Contract requirements flowdown. Training and informing the appropriate managers, supervisors, and workers on S/CI processes and controls (including prevention, detection, and disposition of S/CI) as related to their areas of responsibility (i.e., engineering; procurement; environment, safety, and health; quality; receipt inspection; warehouse and storage; maintenance; operations, and incident reporting).

- Performing walkdowns or inspections of inventory and storage areas to minimize the possibility of the introduction and use of S/CIs in equipment and facilities and to identify S/CIs that may have been inadvertently placed in service during previous work processing.

- Identifying and controlling S/CI while it is on-site, including proper disposal.

- Restricting S/CI use to only those items that have been identified, documented, and found acceptable through engineering analysis and formal disposition process.

- Collecting, maintaining, disseminating, and using the most accurate, up-to-date information on S/CIs and associated suppliers using available sources. S/CI information sources include the following:

  — DOE S/CI website (https://www.energy.gov/ehss/suspectcounterfeit-and-defective-items)

  — DOE ORPS (https://www.energy.gov/ehss/corporate-reporting-analysis/databases/occurrence-reporting-and-processing-system)

  — Operating Experience/Lessons Learned Program (https://doeopexshare.doe.gov/)

The management point of contact responsible for these activities to ensures that the DOE Office of Environment, Safety, and Health has a viable recipient for S/CI information notices is the SME for the procedure or as otherwise appointed by the QA/QC Program Manager.

11.1 CONCLUDING SUMMARY FOR SECTION 11 OF THE QAPD

Section 11 of the QAPD, in conjunction with the graded approach rationale of Section 1.4 of the QAPD, is the FRNP plan description for how S/CI item requirements criteria of DOE O 414.1D, Chg 2 (LtdChg) is accomplished. This includes meeting S/CI item requirements for Attachment 3 of the DOE Order for all items used by FRNP.

12. SOFTWARE QUALITY ASSURANCE

12.1 SOFTWARE APPLICATIONS, CATEGORIES AND GRADE LEVELS

The principal objectives of the FRNP SQA program under CP3-QA-1002, *Software Quality Assurance*, are to provide requirements for the acquisition, development, operation, maintenance, and retirement of computer programs and software in a controlled and documented process. FRNP utilizes a variety of software applications to support the Project. These range from common commercial applications used for non-safety-related purposes to safety software applications that directly support nuclear facilities and their operations or safety basis. FRNP expects that the number of safety software applications will be reduced or downgraded as the deactivation of facilities progresses. To assure that the appropriate level of rigor is devoted to the control of software applications; FRNP applies the graded approach to SQA, as reflected in CP3-QA-1002, *Software Quality Assurance*. Additional requirements for training, procurement, and recordkeeping will be applied as specified within this QAPD. In coordination with other site organizations, FRNP will interface with other on-site contractors on in-use software and applicable SQA concerns.

DOE O 414.1D, Chg 2 (LtdChg), *Quality Assurance*, definitions v., w., and x., are used to define safety software. The following are applicable definitions.

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 *CFR* § 970-5223.1.

Safety and Hazard Analysis Software and Design Software—Software that is used to classify, design, or analyze nuclear facilities. This software is not part of an SSC; however, it 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 facilities, radiological safety management programs, technical safety requirements, or other software that performs a control function that is necessary to provide adequate protection from nuclear facility or radiological hazards. This software supports elimination, limitation, or mitigation of nuclear hazards to workers, the public, or the environment as addressed in 10 *CFR* Parts 830 and 835, the DEAR Integrated Safety Management System clause, and 48 *CFR* § 970-5223.1.

Two categories of software are identified for the PGDP Deactivation and Remediation Project: non-safety and safety. Applications that are identified as safety software are assigned a grade level (shown below) considering DOE G 414.1-4, *Safety Software Guide for Use with 10 CFR Part 830, Subpart A, Quality Assurance Requirements*, and DOE O 414.1D, Chg 2 (LtdChg), *Quality Assurance*. Applications that do not meet safety software criteria according to the DOE Order definition are identified as non-safety quality affecting or non-safety non-quality affecting, depending on the assigned grade levels referenced in CP3-QA-1002, *Software Quality Assurance*.

Safety Software

- Level A—Safety software applications that meet one or more of the following criteria: (1) software failure that could compromise a limiting condition for operation; (2) software failure that could cause a reduction in the safety margin for a safety SSC that is cited in DOE-approved documented safety analysis; (3) 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, *Integrated Safety Management Policy* and the Department of Energy Acquisition Clause ISMS clause (48 *CFR* § 970.5223-1, *Integration of Environment, Safety, and Health Into Work Planning and Execution)*; and (4) software failure that could result in non-conservative safety analysis, design, or misclassification of facilities or SSCs.

- Level B—Safety software that does not meet criteria for Level A graded application software, but does meet one or more of the following criteria: (1) safety management databases used to aid in decision making whose failure could impact safety SSC operation; (2) software failure that could result in incorrect analysis, design, monitoring, alarming, or recording of hazardous exposures to workers or the public; or (3) software failure that could compromise the defense-in-depth capability for the nuclear facility.

- Level C—Software applications that do not meet Level A or Level B criteria but meet one or more of the following criteria: (1) software failure that could cause a potential violation of regulatory permitting requirements; (2) software failure that could affect environment, safety, health monitoring, or alarming systems; or (3) software failure that could affect the safe operation of an SSC. Chg A

Non-Safety Software

- Level D—Software applications that do not meet Level A, B, or C criteria, but meet one or more of the following criteria: (1) software failure would not affect safety, but could result in operating and/or recovery costs in excess of 1 million dollars or primary project activity shutdown in excess of three months; (2) failure could impact emergency communications with local, state, and federal government agencies where other means of communication do not exist; (3) failure could disrupt vital general service systems (e.g., ventilation, radiological protection systems, fire detection and suppression systems, facility security systems, etc.); (4) failure with a known probability to have adverse legal, regulatory, external milestones, or safeguards and security impact; and/or (5) failure could impact quality-related information that is required to be provided to external customers where the results are the sole source of information. Level D software is non-safety quality affecting software. Chg A

- Level E—Software applications that do not meet any of the criteria for Level A–D software. Level E software is non-safety, nonquality affecting software.

All software under CP3-QA-1002, *Software Quality Assurance*, is evaluated to determine if it is to be controlled as safety software, non-safety quality affecting software, non-safety nonquality affecting software, or exempt, based on its intended use and software failure impact. Beginning with FR2A of the QAPD, processed software classification documents that use an exemption will be used only when the software is or can be controlled as non-safety. The exemption determination process will include discussion of risks associated with software failure (e.g., safety, operation, complexity of design, similarity to previous designs), and corresponding controls for the exemptions that are used to prevent, detect, or mitigate software failure or its failure impact. Software exemptions will be tracked through the software classification process as directed by CP3-QA-1002; use controls that meet or exceed Level E software controls; and must re-enter the exemption process if the software or its controls for intended use change. Existing exemptions at FR2A of the QAPD will be processed through the new exemption process or undergo full SQA and will be tracked in Issues Management until addressed. The exemptions are consistent with provisions in NQA-1a, 2009, Part IV, Subpart 4.1, Section 101, and are used only when the software is or can be controlled as non-safety. The following are the exemptions.

- Vendor supplied software integral to and provided with a system is exempt from the detailed controls of CP3-QA-1002, *Software Quality Assurance*, provided the system is tested and/or calibrated in accordance with the applicable procedures and the software is NOT altered or adjusted otherwise by the user organization and where the functionality of the software is accepted through testing over the operational range of the system (e.g., M&TE). This exemption is documented on a software classification document and is approved consistent with CP3-QA-1002, *Software Quality Assurance*. This exemption is derived, in part, from Section 101.3 of Part IV, Subpart 4.1 of NQA-1a, 2009.

- Simple spreadsheet applications that are wholly incorporated into technical reports, calculation notes, or other documentation where the calculations, mathematical formulas, and input and output data are 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 calculations package and technical review. This exemption is documented on a software classification document and is approved consistent with CP3-QA-1002, *Software Quality Assurance*. This exemption is derived, in part, from Section 101.1 of Part IV, Subpart 4.1 of NQA-1a, 2009.

- Embedded software (firmware) that is delivered as an integral part of an item, with a software code that cannot be modified by the end user, including at runtime, and is tested as part of the item. Embedded software shall be controlled in accordance with the hardware requirements. This exemption is documented on a software classification document and is approved consistent with CP3-QA-1002, *Software Quality Assurance*. This exemption is derived, in part, from Section 101.6 of Part IV, Subpart 4.1 of NQA-1a, 2009.

Also, the general base support software maintained by the infrastructure contractor (e.g., word processors, graphing programs, presentation software, used for efficiency or productivity) does not apply, unless the software use falls within other classification criteria of this QAPD or CP3-QA-1002, *Software Quality Assurance* procedure. The infrastructure contractor controls the baselined applications to meet pertinent Order requirements. However, if the applications (e.g., Excel, Access, etc.) are used as a platform to develop an application or work-related calculation, then the intended use must be evaluated against CP3-QA-1002, *Software Quality Assurance*/QAPD requirements.

Software types include the following:

Custom Developed—Built specifically for a DOE application or to support the same function for a related government organization. It may be developed by DOE or one of its management and operating (M&O) contractors or contracted with a qualified software company through the procurement process. Examples of custom developed software includes material inventory, tracking database applications, accident consequence applications, control system applications, and embedded custom developed software that controls a hardware device.

Configurable—Commercially available software or firmware that allows the user to modify the structure and functioning of the software in a limited way that suits user needs; an example is software associated with programmable logic controllers.

Acquired—Generally supplied through basic procurements, two-party agreements, or other contractual arrangements. Acquired software includes commercial off-the-shelf (COTS) software, such as operating systems, database management systems, compilers, software development tools, commercial calculation software, and spreadsheet tools (e.g., Mathsoft's MathCad and Microsoft's Excel). Downloadable software that is available at no cost to the user (referred to as freeware) is also considered acquired software. Firmware is acquired software. Firmware is usually provided by a hardware supplier through the procurement process and cannot be modified after receipt.

Utility Calculation—Typically uses COTS spreadsheet applications as a foundation and user-developed algorithms or data structures to create simple software products. The utility calculation software within the scope of this document is used frequently to perform calculations associated with the design of an SSC. Utility software that is used with high frequency may be labeled as custom software and may justify the same safety SQA work activities as custom developed software. With utility calculation software, it is important to recognize the difference between QA of the algorithms, macros, and logic that perform the calculations versus QA of the COTS software itself. Utility calculation software includes the associated data sets, configuration information, and test cases for validation and/or calibration.

Commercial Design and Analysis—Used in conjunction with design and analysis services provided to DOE from a commercial contractor. An example would be where DOE or an M&O contractor contracts for specified design services support. The design service provider uses its independently developed or acquired software without DOE involvement or support. Afterward, DOE receives a completed design.

12.2 SOFTWARE QUALITY ASSURANCE IMPLEMENTATION

In accordance with the requirements of this QAPD and the source requirements documents referenced herein, CP3-QA-1002, *Software Quality Assurance,* provides the overall process controls, corresponding responsibilities, and criteria applicable throughout the life cycle of safety and non-safety software during the Project timeline, whether used by FRNP, teaming partners, or subcontractors. The procedure also outlines the controls, responsibilities, and criteria for SQA in terms of how acquisition, training, planning, development, design, testing, V&V, configuration management, assessment, maintenance and the retirement of software is accomplished. Responsibilities for implementation of SQA are shared and include staff from Engineering, Information Technology (IT), and the individual or organization assigned as the software owner. CP3-QA-1002 also identifies software that applies and is exempt from the formal control requirements of this QAPD; however, all applicable software regardless of exemption status will have a Software Classification Determination with sufficient justification and supporting documentation on how the specific application meets exemption. The Software Classification Determination and supporting documents will then go through the standard review and approval process. Section 12.1 of the QAPD provides details of the exemptions.

FRNP has developed the following specific responsibilities and requirements for the SQA Program, in accordance with various NQA-1 requirements (3/100, 400 and 700-900; and 11/100, 200, 400-600).

- Prepare and maintain a software inventory list with the following minimum information: 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.

- Include requirements for the procurement of software that coincide with the grade and use of the software.

- Prepare a SQA plan, as specified in the implementing program documents and procedures.

- Identify software requirements that address functionality, performance, design, analyses, constraints, attributes, and external interfaces as required by NQA-1 Requirements 400 and 700.

- Address life-cycle phases: including acquisition, maintenance, operation, development, validation, certification, retirement, and annual review.

- Prepare software design documentation in accordance with graded approach and retain the records of design for safety software as outlined in Section 4, "Documents and Records."

- Identify configuration items and establish configuration change controls relative to safety software.

- Plan, perform, and document testing, verification, and validation activities relative to safety software as required by NQA-1 Requirement 11 for computer programs.

- Supervise and otherwise ensure software is installed properly and that user training is completed.

- Retire and archive safety software when its use is no longer needed.

CP3-QA-1002, *Software Quality Assurance,* identifies additional controls used in support of SSCs or activities that are important to safety. This procedure applies the applicable guidance provided by DOE G 414.1-4, *Safety Software Guide for Use with 10 CFR Part 830, Subpart A, Quality Assurance Requirements*; DOE O 414.1D, Chg 2 (LtdChg), *Quality Assurance*; and EM-QA-001, Rev. 1, *EM Quality Assurance Program*, relevant to the following:

- Software for a nuclear facility that performs a safety function as part of a SSC and is cited in a DOE-approved documented safety analysis, TSR, or an approved hazard analysis.

- Software that is used to design, classify, or analyze nuclear facilities. This software normally is not part of an SSC, but helps evaluate or analyze accidents or hazards at a nuclear facility or an SSC that performs a safety function.

- Software that performs a hazard control function in support of a nuclear facility, radiological safety management program, TSR, or other software that performs a control function necessary to provide adequate protection from nuclear facility or radiological hazards. This type of software supports eliminating, limiting, or mitigating nuclear hazards to workers, the public, or the environment, as addressed in 10 *CFR* Part 830, 10 *CFR* Part 835, and 10 *CFR* Part 851.

The process described in the SQA procedure also addresses the life cycle of safety software in the context of the guidance provided in DOE G 414.1-4 and EM-QA-001, Rev. 1, which includes the following:

- Definition of software types and grading levels
- Software safety design methods
- Software project management and quality planning
- Risk management
- Configuration management
- Procurement and supplier management
- Requirements identification and management
- Design and implementation
- Software safety
- Testing, V&V
- Problem reporting and corrective action
- Personnel training
- Assessment and oversight

Otherwise acquired software (e.g., freeware, shareware, procured COTS, or otherwise acquired software) that has not been previously approved under NQA-1a, 2009 will meet the following for documentation and approval for use: (a) identification of the capabilities and limitations for intended use, (b) utilization of test plans and test cases as a method of acceptance to demonstrate the capabilities within the limitations, and (c) instructions for use (e.g., user manual) within the limitation of the dedicated capabilities.

The responsibilities for implementation of the SQA procedure are focused principally on the software owner or developer, with support from FRNP Engineering and IT, and can be found within the implementing procedure. In addition, the engineering design authority is involved, as applicable, in the identification of, requirements specification, acquisition, design, development, V&V (including inspection and testing), configuration management, maintenance, and retirement of safety software. Safety software inventory includes software description, software name, version identifier, safety software designation (e.g., safety system software, safety and hazard analysis software and design software, and safety management and administrative software), grade level designation, nuclear facility application, and the responsible software owner. The inventory is administered through CP3-IT-0002, *Software Configuration Management*.

For a map of software work flow activities see Appendix C of the QAPD while noting that software levels and software types are described in Section 12.1 of the QAPD. The SQA procedure (CP3-QA-1002) also may be separated into multiple procedures for ease of use without update of this QAPD, provided that requirement intent is maintained.

12.3 DISCUSSION OF SPECIFIC NQA-1 REQUIREMENTS IN CRITERION 12

Appendix B identifies the DOE O 414.1D, Chg 2 (LtdChg) and NQA-1 requirements addressed in Criterion 11. NQA-1 Requirements 3/100, 400, and 700-900 are described in bullet listings in Section 12.2. NQA-1 Requirements 11/100-602 are described in the various bullets listed in Section 12.2. NQA-1 Part II, Subpart 2.7 is listed in Appendix B to be used, as applicable, in conjunction with corresponding requirements of Part I. Appendix H of CP3-QA-1002, *Software Quality Assurance*, contains a detailed Compliance Matrix (crosswalk) of NQA-1 requirements (including Part II, Subpart 2.7 requirements) and specific sections within the procedure. Sections 5, 6, and 7 of procedure CP3-QA-1002, *Software Quality Assurance,* in conjunction with procedures and processes described in Section 7 of the QAPD, addresses

NQA-1, Part II, Subpart 2.14 for procurement of QL-2 safety software commercial grade items and services. The sections address also procurement of those QL-2 related safety software items and services under full NQA-1 controls where design and manufacture under NQA-1 is warranted or required. Similarly, Sections 5, 6, and 7 of CP3-QA-1002, *Software Quality Assurance*, addresses NQA-1a, 2009, Part II, Subpart 2.7. Section 12.1 of the QAPD discusses three software exemptions taken from NQA-1a, 2009, Part IV, Subpart 4.1 (101), which are used by FRNP, per procedure CP3-QA-1002. Appendix C of the QAPD provides a mapping document for work activities, which includes work activities for QL-2 safety software that are subject to national consensus standard NQA-1 requirements.

12.4 CONCLUDING SUMMARY FOR SECTION 12 OF THE QAPD

Section 12 of the QAPD, in conjunction with the graded approach rationale of Section 1.4 of the QAPD, is the FRNP plan description for how the software quality requirements criteria of DOE O 414.1D, Chg 2 (LtdChg) is accomplished. This includes meeting software requirements for attachment 2 of the DOE order for all software and for Attachment 4 for nuclear facilities to include safety software.

13. REFERENCES

10 *CFR* Part 830, Subpart A, *Quality Assurance Requirements*

10 *CFR* Part 835, *Occupational Radiation Protection*

10 *CFR* Part 851, *Worker Safety and Health Program*

48 *CFR* § 970.5223-1, *Integration of Environment, Safety, and Health into Work Planning and Execution*

ASME NQA-1-2008 (with Addenda through 2009), *Quality Assurance Requirements for Nuclear Facility Applications*

Deactivation and Remediation Project Contract DE-EM0004895

DOE G 414.1-4, *Safety Software Guide for Use with 10 CFR § 830, Subpart A, Quality Assurance Requirements, and DOE O 414.1C, Quality Assurance*

DOE O 226.1B, *Implementation of Department of Energy Oversight Policy*

DOE O 232.2A, Chg 1 (MinChg), *Occurrence Reporting and Processing of Operations Information*

DOE O 410.2, Admin Chg 1, *Management of Nuclear Materials*

DOE O 414.1D, Chg 2 (LtdChg), *Quality Assurance*

DOE O 422.1, Chg 3 (MinChg), *Conduct of Operations*

DOE O 425.1D, Chg 2 (MinChg), *Verification of Readiness to Start Up or Restart Nuclear Facilities*

DOE O 426.2, Admin Chg 1, *Personnel Selection, Training, Qualification, and Certification Requirements for DOE Nuclear Facilities*

DOE O 433.1B, Admin Chg 1, *Maintenance Management Program for DOE Nuclear Facilities*

DOE O 460.1D, *Hazardous Materials Packaging and Transportation Safety*

DOE O 474.2, Admin Chg 4, *Nuclear Material Control and Accountability*

DOE P 450.4A, Chg 1, *Integrated Safety Management Policy*

DOE-STD-1027-92, *Hazard Categorization and Accident Analysis Techniques for Compliance with DOE Order 5480.23, Nuclear Safety Analysis Reports*

DOE-STD-1073-2016, *Configuration Management*

EM-QA-001, Rev. 1, *Office of Environmental Management Quality Assurance Program*

14. DEFINITIONS

For a complete definition of quality-related terms used in this document refer to DOE O 414.1D, Chg 2 (LtdChg); 10 *CFR* Part 830, Subpart A; EM-QA-001, Rev. 1 and/or ASME NQA-1-2008 (with Addenda through 2009).

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APPENDIX A

APPLICABILITY MATRIX

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NQA-1-2008 (with Addenda through 2009) Part II Quality Assurance Requirements for Nuclear Facility Applications	Contract Applicability
Subpart 2.1—Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components	N/A. The controls implemented through FRNP Work Control and Subcontractor Work Control are sufficient for process completion that could occur during the scope of the Contract.
Subpart 2.2—Quality Assurance Requirements for Packaging, Shipping, Receiving, Storage, and Handling of Items for Nuclear Power Plants	Yes, as described in the safety basis for items related to uranium processing.
Subpart 2.3—Quality Assurance Requirements for Housekeeping for Nuclear Power Plants	N/A. Additional measures will not be invoked beyond those implemented through Conduct of Operations, Work Control, and Maintenance.
Subpart 2.4—Installation, Inspection, and Testing Requirements for Power, Instrumentation, and Control Equipment at Nuclear Facilities	Yes, ONLY for maintenance of uranium processing and processing facility maintenance as it relates to deactivation activities.
Subpart 2.5—Quality Assurance Requirements for Installation, Inspection, and Testing of Structural Concrete, Structural Steel, Soils, and Foundations for Nuclear Power Plants	N/A. The controls established in the Work Control program in conjunction with Subpart 2.18 are adequate for the scope of the Contract.
Subpart 2.7—Quality Assurance Requirements for Computer Software for Nuclear Facility Applications	Yes.
Subpart 2.8—Quality Assurance Requirements for Installation, Inspection, and Testing of Mechanical Equipment and Systems for Nuclear Power Plants	N/A. The controls established in the Work Control Program in conjunction with Subpart 2.18 are adequate for the scope of the Contract.
Subpart 2.14—Quality Assurance Requirements for Commercial Grade Items and Services	Yes, as applied to safety-related structures, systems, and components.
Subpart 2.15—Quality Assurance Requirements for Hoisting, Rigging, and Transporting of Items for Nuclear Power Plants	N/A. FRNP hoisting and rigging quality requirements meet those identified in DOE Standards, OSHA regulations, and American National Standards Institute (ANSI) standards.
Subpart 2.18—Quality Assurance Requirements for Maintenance of Nuclear Facilities	Yes, where maintenance of nuclear facilities is necessary to maintain operational conditions, ensure safety of workers, and protection of the environment as applied to the scope of the Contract.
Subpart 2.20—Quality Assurance Requirements for Subsurface Investigations for Nuclear Power Plants	N/A. Not anticipated under the scope of the Contract.

APPENDIX B

PERFORMANCE IMPLEMENTATION MATRIX

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APPENDIX B—PERFORMANCE IMPLEMENTATION MATRIX			
DOE Quality Assurance Requirements from DOE O 414.1D, Chg2 (LtdChg)	**ASME NQA-1-2008 (with Addenda through 2009) Requirements**	**PGDP Deactivation and Remediation Project Plans and Procedures**	**ISMS Core Functions and Guiding Principles**
Criterion 1—Management/Program *(a) Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work.* *(b) Establish management processes, including planning, scheduling, and providing resources for the work.*	**Requirement 1—Organization** 100—Basic 200–202 Structure and Responsibility 300—Interface Control **Requirement 2—Quality Assurance Program** 100—Basic 200–202 Indoctrination and Training 300–305 Qualification Requirements 400—Records of Qualification 500—Records	CP2-HS-1000, *Integrated Safety Management System* CP2-QA-3000, *Contractor Performance Assurance Program Description* CP2-ES-0100, *Four Rivers Nuclear Partnership, LLC, Sustainability Plan at the Paducah Gaseous Diffusion Plant* CP2-ES-0101, *Environmental Management System* CP3-HS-2009, *Stop/Suspend Work* CP2-OP-1101, *Conduct of Operations Applicability and Implementation Matrix* CP3-OP-1118, *Facility Management* CP2-QA-1000, *Quality Assurance Program Description* CP3-QA-1001, *Graded Approach* CP3-QA-1007, *Procurement Quality Assurance* CP3-QA-1008, *Assessor Qualification, Training, and Certification* CP3-QA-2003, *Quality Inspection* CP3-QA-1002, *Software Quality Assurance*	Core Functions: • Define Scope of Work Guiding Principles: • Line Management Responsible for Safety • Clear Roles & Responsibilities • Balanced Priorities

APPENDIX B—PERFORMANCE IMPLEMENTATION MATRIX			
DOE Quality Assurance Requirements from DOE O 414.1D, Chg 2 (LtdChg)	**ASME NQA-1-2008 (with Addenda through 2009) Requirements**	**PGDP Deactivation and Remediation Project Plans and Procedures**	**ISMS Core Functions and Guiding Principles**
		CP2-WM-0001, *FRNP Waste Management Plan* CP2-QA-2500, *FRNP Nevada National Security Site Waste Acceptance Criteria – Implementation Crosswalk (NIC)* CP3-QA-2501, *Waste Certification* CP2-SM-1000, *Activity Level Work Planning and Control Program* CP3-SM-1101, *Work Package Development* CP2-SM-0018, *Nuclear Maintenance Management Program at the Paducah Gaseous Diffusion* Plant CP2-TR-0100, *Training Program for the Paducah Gaseous Diffusion Plant Paducah, Kentucky* CP2-SS-3000, *Nuclear Materials Control and Accountability Plan* CP2-ND-1001, *Quality System for Nondestructive Assay* CP2-TS-1000, *Roles, Responsibilities, Authorities and Accountabilities for the Paducah Gaseous Diffusion Plant, Paducah, KY* CP3-TS-1000, *Administration of the Roles, Responsibilities, Authorities, and Accountabilities Process*	
	Non-Mandatory Appendices 1A-1 and 2A-1 should be considered to aid in Organizational development during QA documentation.	Non-Mandatory Appendices 1A-1 and 2A-1 will be considered during the development of the Organizational portions of the QA documentation.	

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APPENDIX B—PERFORMANCE IMPLEMENTATION MATRIX			
DOE Quality Assurance Requirements from DOE O 414.1D, Chg2 (LtdChg)	**ASME NQA-1-2008 (with Addenda through 2009) Requirements**	**PGDP Deactivation and Remediation Project Plans and Procedures**	**ISMS Core Functions and Guiding Principles**
Criterion 2—Management/Personnel Training and Qualification *(a) Train and qualify personnel to be capable of performing their assigned work.* *(b) Provide continuing training to personnel to maintain their job proficiency.*	**Requirement 2—Quality Assurance Program** 100—Basic 200–202 Indoctrination and Training 300–305 Qualification Requirements 400—Records of Qualification 500—Records	CP2-QA-1000, *Quality Assurance Program Description* CP3-QA-1008, *Assessor Qualification, Training, and Certification* CP3-QA-2003, *Quality Inspection* CP3-QA-2501, *Waste Certification* CP2-RD-0001, *Records Management Plan* CP2-TR-0100, *Training Program for the Paducah Gaseous Diffusion Plant Paducah, Kentucky* CP2-TR-0102, *Paducah Deactivation and Remediation Project Training Implementation Matrix* CP3-TR-0102, *Conduct of Training* CP3-TR-0103, *Systematic Approach to Training* CP3-QA-2006, *Inspection Personnel, Training, Qualification and Certification* CP3-QA-1039, *Written Practice for Nondestructive Testing Personnel Certification* CP3-QA-1004, *Independent Assessment Program* CP3-QA-2001, *Approved Supplier Selection, Evaluation, Approved Supplier Maintenance*	Core Functions: • None Guiding Principles: • Clear Roles and Responsibilities • Competence Commensurate with Responsibilities

APPENDIX B—PERFORMANCE IMPLEMENTATION MATRIX			
DOE Quality Assurance Requirements from DOE O 414.1D, Chg 2 (LtdChg)	**ASME NQA-1-2008 (with Addenda through 2009) Requirements**	**PGDP Deactivation and Remediation Project Plans and Procedures**	**ISMS Core Functions and Guiding Principles**
		CP3-QA-2002, *Surveillance* CP3-QA-3001, *Issues Management* CP4-RP-1602, *Radiological Control Technician and Radiological Control Supervisor Qualification and Training*	
	Non-Mandatory Appendices 2A-1 and 2A-3 should be considered to aid in the development of the QAP.	Non-Mandatory Appendices 2A-1 and 2A-3 will be considered during development of the QAP.	

APPENDIX B—PERFORMANCE IMPLEMENTATION MATRIX			
DOE Quality Assurance Requirements from DOE O 414.1D, Chg 2 (LtdChg)	**ASME NQA-1-2008 (with Addenda through 2009) Requirements**	**PGDP Deactivation and Remediation Project Plans and Procedures**	**ISMS Core Functions and Guiding Principles**
Criterion 3—Management/Quality Improvement *(a) Establish and implement processes to detect and prevent quality problems.* *(b) Identify, control, and correct items, services, and processes that do not meet established requirements.* *(c) Identify the causes of problems, and include prevention of recurrence as a part of corrective action planning.* *(d) Review item characteristics, process implementation, and other quality related information to identify items, services, and processes needing improvement.*	**Requirement 2—Quality Assurance Program** 100—Basic 200–202 Indoctrination and Training 300–305 Qualification Requirements 400—Records of Qualification 500—Records **Requirement 15—Control of Nonconforming Items** 100—Basic 200—Identification 300—Segregation 400–405 Disposition **Requirement 16—Corrective Action** 100—Basic	CP2-QA-1000, *Quality Assurance Program Description* CP2-QA-2500, *Four Rivers Nuclear Partnership, LLC, Nevada National Security Site Waste Acceptance Criteria—Implementation Crosswalk (NIC)* CP2-RD-0001, *Records Management Plan* CP3-CP-0002, *Acquisition Management* CP2-SM-1000, *Activity Level Work Planning and Control Program* CP3-SM-1101, *Work Package Development* CP3-QA-3008, *Fact Finding* CP3-HS-2009, *Stop/Suspend Work* CP2-TR-0100, *Training Program for the Paducah Gaseous Diffusion Plant Paducah, Kentucky* CP3-QA-1008, *Assessor Qualification, Training, and Certification* CP3-QA-1007, *Procurement Quality Assurance* CP3-QA-3001, *Issues Management*	Core Function: • Provide Feedback & Continuous Improvement Guiding Principles: • Line Management Responsibility for Safety • Clear Roles and Responsibilities • Identification of Safety Standards and Requirements

APPENDIX B—PERFORMANCE IMPLEMENTATION MATRIX			
DOE Quality Assurance Requirements from DOE O 414.1D, Chg 2 (LtdChg)	**ASME NQA-1-2008 (with Addenda through 2009) Requirements**	**PGDP Deactivation and Remediation Project Plans and Procedures**	**ISMS Core Functions and Guiding Principles**
		CP3-QA-2005, *Nonconformance Control* CP3-QA-3005, *Occurrence Reporting* CP3-QA-3004, *Evaluation and Reporting of Potential PAAA/WSH Noncompliances* CP2-QA-3000, *Contractor Performance Assurance Program Description* CP3-QA-3002. *Operating Experience/Lessons Learned (OE/LL)* CP3-QA-1003. *Management and Self-Assessment* CP3-QA-1004, *Independent Assessment Program* CP3-QA-2002, *Surveillance* CP3-QA-2003, *Quality Inspection* CP3-QA-2004, *Material Receipt Inspection* CP3-QA-2500, *Procurement, Inspection and Management of Items Critical for Paducah Off-Site Waste Shipments* CP3-QA-2501, *Waste Certification* CP3-QA-3007, *Issue Investigation and Causal Analysis*	

APPENDIX B—PERFORMANCE IMPLEMENTATION MATRIX			
DOE Quality Assurance Requirements from DOE O 414.1D, Chg 2 (LtdChg)	**ASME NQA-1-2008 (with Addenda through 2009) Requirements**	**PGDP Deactivation and Remediation Project Plans and Procedures**	**ISMS Core Functions and Guiding Principles**
		CP2-WM-0001, *FRNP Waste Management Plan* CP3-QA-2135, *Welder Qualification Program* CP3-OP-2024, *Initial Incident/ Event Reporting* CP3-QA-1006, *Suspect/Counterfeit Items* CP3-QA-2001, *Approved Supplier Selection, Evaluation, Approved Supplier Maintenance* CP3-HS-1000, *Integrated Safety Management System Effectiveness Review and Safety Culture Surveys* CP3-QA-3003, *Standards and Requirements Management* CP3-QA-3011, *Feedback and Continuous Improvement Program* CP3-QA-3009, *Trend Analysis*	
	Non-Mandatory Appendices 2A-4, 16A-1, and Subpart 4.5 should be considered to aid in Quality Improvement implementation	Non-Mandatory Appendices 2A-4, 16A-1, and Subpart 4.5 will be considered during Quality Improvement implementation.	

APPENDIX B—PERFORMANCE IMPLEMENTATION MATRIX			
DOE Quality Assurance Requirements from DOE O 414.1D, Chg 2 (LtdChg)	**ASME NQA-1-2008 (with Addenda through 2009) Requirements**	**PGDP Deactivation and Remediation Project Plans and Procedures**	**ISMS Core Functions and Guiding Principles**
Criterion 4—Management/Documents and Records *(a) Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design.* *(b) Specify, prepare, review, approve, and maintain records.*	**Requirement 2—Quality Assurance Program** 400—Records of Qualification 500—Records **Requirement 3—Design Control** 100—Basic 200—Design Input 900—Documentation and Records **Requirement 4—Procurement Document Control** 300—Procurement Document Review 400—Procurement Document Changes **Requirement 5—Instructions, Procedures, and Drawings** 100—Basic **Requirement 6—Document Control** 100—Basic 200—Document Control 300–302 Document Changes **Requirement 7—Control of Purchased Items and Services** 800—Records **Requirement 9—Control of Special Processes** 100—Basic 400—Records	CP3-OP-0002, *Developing and Maintaining Performance Documents* CP3-OP-0207, *Use of Procedures* CP2-RD-0001, *Records Management Plan* CP2-RD-0002, *Electronic Information System Requirements* CP3-RD-0010, *Records Management Process* CP3-OP-0025, *Document Control Process* CP3-QA-2501, *Waste Certification* CP2-EN-0201, *Configuration Management Program Description* CP3-EN-0203, *Design Change Process* CP3-EN-0307, *Engineering Procurement Specification* CP3-EN-0209, *Plant Drawings* CP3-EN-0224, *Configuration Management System (CMS) Control* CP3-EN-0215, *Engineering Evaluations*	Core Functions: • Define Scope of Work • Analyze Hazards • Define & Implement Hazard Controls • Perform Work Within Controls • Provide Feedback & Continuous Improvement Guiding Principles: • Competence Commensurate with Responsibilities • Line Management Responsible for Safety • Clear Roles & Responsibilities • Balance Priorities • Operations Authorization • Identification of Safety, Standards, and Requirements • Hazard Controls Tailored to Work Being Performed

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APPENDIX B—PERFORMANCE IMPLEMENTATION MATRIX			
DOE Quality Assurance Requirements from DOE O 414.1D, Chg 2 (LtdChg)	**ASME NQA-1-2008 (with Addenda through 2009) Requirements**	**PGDP Deactivation and Remediation Project Plans and Procedures**	**ISMS Core Functions and Guiding Principles**
	Requirement 10—Inspection 800—Records **Requirement 11—Test Control** 500—Test Results 600-602—Test Records **Requirement 12—Control of Measuring and Test Equipment** 400-402—Records **Requirement 17—Quality Assurance Records** 100—Basic 200—Generation of Records 300—Authentication of Records 400–402 Classification 500—Receipt Control of Records 600–603 Storage 700—Retention 800—Maintenance of Records	CP3-EN-0302, *Engineering Change Requests and Notices* CP2-SM-1000, *Activity Level Work Planning and Control Program*	
	Non-Mandatory Appendices 17A-1, 17A-2, and Subpart 4.4 should be considered to aid in development of document and records efforts.	Non-Mandatory Appendices 17A-1, 17A-2, and Subpart 4.4 will be considered during development of document and records efforts.	

APPENDIX B—PERFORMANCE IMPLEMENTATION MATRIX			
DOE Quality Assurance Requirements from DOE O 414.1D, Chg 2 (LtdChg)	**DOE Quality Assurance Requirements from DOE O 414.1D, Chg 2 (LtdChg)**	**DOE Quality Assurance Requirements from DOE O 414.1D, Chg 2 (LtdChg)**	**DOE Quality Assurance Requirements from DOE O 414.1D, Chg 2 (LtdChg)**
Criterion 5—Performance/Work Processes *(a) Perform work consistent with technical standards, administrative controls, and other hazard controls adopted to meet regulatory or contract requirements using approved instructions, procedures, or other appropriate means.* *(b) Identity and control items to ensure proper use.* *(c) Maintain items to prevent damage, loss, or deterioration.* *(d) Calibrate and maintain equipment used for process monitoring or data collection.*	Part I Requirements Requirement 5—Instructions, Procedures, and Drawings 100—Basic Requirement 8—Identification and Control of Items 100—Basic 200–202 Identification Methods 300–303 Specific Requirements Requirement 9—Control of Special Processes 100—Basic 200—203 Process Control 300—Responsibility 400—Records Requirement 12—Control of Measuring and Test Equipment 100—Basic 200—Selection 300–304 Calibration and Control 400–402 Records Requirement 13—Handling, Storage, and Shipping 100—Basic 200—Special Requirements 300—Procedures 400—Tools and Equipment 500—Operators 600—Marking or Labeling Requirement 14—Inspection, Test, and Operating Status 100—Basic	CP3-CP-0001, *Request for Purchase* CP3-CP-0002, *Acquisition Management* CP3-PR-3001, *Warehouse Operations and Receipt of Material* CP3-EN-0209, *Plant Drawings* CP2-EN-0201, *Configuration Management Program Description* CP3-EN-0302, *Engineering Change Requests and Notices* CP3-OP-0002, *Developing and Maintaining Performance Documents* CP3-OP-0207, *Use of Procedures* CP3-OP-1118, *Facility Management* CP2-RD-0001, *Records Management Plan* CP2-SM-0018, *Nuclear Maintenance Management Program* CP2-SM-1000, *Activity Level Work Planning and Control Program* CP3-SM-1101, *Work Package Development*	Core Functions: • Analyze Hazards • Define & Implement Hazard Controls • Perform Work Within Controls • Provide Feedback & Continuous Improvement Guiding Principles: • Clear Roles & Responsibilities • Identification of Safety, Standards, and Requirements • Hazard Controls Tailored to Work Being Performed • Operations Authorization

APPENDIX B—PERFORMANCE IMPLEMENTATION MATRIX			
DOE Quality Assurance Requirements from DOE O 414.1D, Chg 2 (LtdChg)	**ASME NQA-1-2008 (with Addenda through 2009) Requirements**	**PGDP Deactivation and Remediation Project Plans and Procedures**	**ISMS Core Functions and Guiding Principles**
	Requirement 15—Control of Nonconforming Items 100—Basic 200—Identification 300—Segregation 400–405 Disposition	CP3-SM-1102, *Activity Level Work Execution and Closeout* CP3-SM-0049, *Installed Plant Instrumentation Measuring and Test Equipment*	Chg A
	Part II Requirements **Requirement NQA-1 Part II, Subpart 2.2 Packaging, Shipping, Receiving, Storage, and Handling of Items** 100—General 200—General Requirements 300—Packaging 400—Shipping 500—Receiving 600—Storage 700—Handling 800—Records **Requirement NQA-1 Part II, Subpart 2.4 Installation, Inspection and Testing Requirements for Power, Instrumentation and Control Equipment** ANSI/Institute of Electrical and Electronics Engineers (IEEE) Std. 336-1985 IEEE Standard, Installation, Inspection and Testing Requirements for Power, Instrumentation, and Control Equipment at Nuclear Facilities **Requirement NQA-1 Part II, Subpart 2.7—Quality Assurance Requirements for Computer**	CP3-SM-0017, *Measuring and Test Equipment* CP3-HS-2038, *Industrial Hygiene Measuring and Test Equipment Program* CP4-ES-0459, *Control of Laboratory Equipment* CP4-ES-0109, *Calibration and Preventive Maintenance of Laboratory Equipment* CP2-ES-0200, *Laboratory QA Plan for the Analytical Laboratory* CP4-ER-0020, *Control and Use of Pressure-Related Measuring and Test Equipment for the Northwest and Northeast Plume Operations* CP4-QA-2133, *Metrology Measuring and Test Equipment Calibrations and Certifications* CP2-RP-0001, *Radiation Protection Program* CP4-RP-1326, *Control of Government Owned Radiological Instrumentation*	Chg A

APPENDIX B—PERFORMANCE IMPLEMENTATION MATRIX			
DOE Quality Assurance Requirements from DOE O 414.1D, Chg2 (LtdChg)	**ASME NQA-1-2008 (with Addenda through 2009) Requirements**	**PGDP Deactivation and Remediation Project Plans and Procedures**	**ISMS Core Functions and Guiding Principles**
	Software for Nuclear Facility Applications 100–102 General 200–204 General Requirements 300–302 Software Acquisition 400–407 Software Engineering Method 500—Standards, Conventions, and Other Work Practices 6006—02 Support Software 700—References **Subpart 2.18 Quality Assurance Requirements for Maintenance** 100—General 200—General Requirements 300—Preventive Maintenance 400—Corrective Maintenance 500—Records	CP4-RP-1319, *Calibration of Tennelec Series 5XLB Counting System* CP3-QA-1002, *Software Quality Assurance* CP2-QA-2500, *Four Rivers Nuclear Partnership, LLC, Nevada National Security Site Waste Acceptance Criteria—Implementation Crosswalk (NIC)* CP3-QA-1007, *Procurement Quality Assurance* CP3-QA-3001, *Issues Management* CP3-QA-2005, *Nonconformance Control* CP3-OP-0015, *Control of Equipment and System Status* CP3-SM-0051, *Hoisting and Rigging* CP3-QA-2003, *Quality Inspection* CP2-OP-1100, *Conduct of Operations Program at PGDP* CP2-SM-0001, *Surveillance and Maintenance Program* CP2-HS-2000, *Worker Safety and Health Program*	

APPENDIX B—PERFORMANCE IMPLEMENTATION MATRIX			
DOE Quality Assurance Requirements from DOE O 414.1D, Chg 2 (LtdChg)	**ASME NQA-1-2008 (with Addenda through 2009) Requirements**	**PGDP Deactivation and Remediation Project Plans and Procedures**	**ISMS Core Functions and Guiding Principles**
		CP2-WM-0001, *FRNP Waste Management Plan* CP2-WM-0704, *Qualifying Waste Streams for Disposal at the Nevada National Security Site* CP3-WM-1017, *Safe Handling and Opening of Sealed Containers* CP3-WM-1037, *Generation and Temporary Storage of Waste Materials* CP3-WM-3015, *Waste Packaging* CP3-WM-0707, *NNSS Specific Waste Characterization, Profiling, Packaging, and Shipping* CP3-WM-3028, *Off-Site Shipping* CP3-WM-9503, *Off-Site Shipments by Air Transport* CP3-QA-2501, *Waste Certification* CP3-QA-2500, *Procurement, Inspection and Management of Items Critical for Paducah Off-Site Waste Shipments* CP3-QA-2004, *Material Receipt Inspection*	

APPENDIX B—PERFORMANCE IMPLEMENTATION MATRIX			
DOE Quality Assurance Requirements from DOE O 414.1D, Chg2 (LtdChg)	**ASME NQA-1-2008 (with Addenda through 2009) Requirements**	**PGDP Deactivation and Remediation Project Plans and Procedures**	**ISMS Core Functions and Guiding Principles**
		CP2-SM-0011, *Welding Program General Requirements and Processes* CP3-QA-2135, *Welder Qualification Program* CP2-ES-0100, *Sustainability Plan at the Paducah Gaseous Diffusion Plant* CP2-ES-0101, *Environmental Management System* CP2-ND-1001, *Quality System for Nondestructive Assay Plan* CP3-HS-2004, *Job Hazard Analysis* CP3-OP-0316, *Pre-Job Briefings and Post Job Reviews* CP3-QA-1006, *Suspect Counterfeit Items* CP3-SP-0018, *Subcontractor Oversight*	
	Non-Mandatory Appendices 2A-1, 2A-3, 2A-4, 10A-1, 11A-1, 16A-1, and 18A-1 should be considered to aid in the development of independent assessment processes.	Non-Mandatory Appendices 2A-1, 2A-3, 2A-4, 10A-1, 11A-1, 16A-1, and 18A-1 will be considered during the development of the independent assessment processes.	

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APPENDIX B—PERFORMANCE IMPLEMENTATION MATRIX			
DOE Quality Assurance Requirements from DOE O 414.1D, Chg2 (LtdChg)	**ASME NQA-1-2008 (with Addenda through 2009) Requirements**	**PGDP Deactivation and Remediation Project Plans and Procedures**	**ISMS Core Functions and Guiding Principles**
Criterion 6—Performance/Design *(a) Design items and processes using sound engineering/scientific principles and appropriate standards.* *(b)Incorporate applicable requirements and design bases in design work and design changes.* *(c) Identify and control design interfaces.* *(d) Verify or validate the adequacy of design products using individuals or groups other than those who performed the work.* *(e) Verify or validate work before approval and implementation of the design.*	**Requirement 3—Design Control** 100—Basic 200—Design Input 300—Design Process 400–402 Design Analyses 500–501.3 Design Verification 600–601.9 Change Control 700—Interface Control 800–802.3 Software Design Control 900—Documentation and Records **Requirement 6—Document Control** 100—Basic 200—Document Control 300—Document Changes **Requirement NQA-1 Part II, Subpart 2.7—Quality Assurance Requirements for Computer Software for Nuclear Facility Applications** 100–102 General 200–204 General Requirements 300–302 Software Acquisition 400–407 Software Engineering Method 500—Standards, Conventions, and Other Work Practices 600–602 Support Software 700—References	CP2-RD-0001, *Records Management Plan* CP2-EN-0201, *Configuration Management Program Description* CP3-EN-0203, *Design Change Process* CP3-EN-0213, *Design Analysis and Calculations* CP3-EN-0215, *Engineering Evaluations* CP3-EN-0209, *Plant Drawings* CP3-EN-0224, *Configuration Management System (CMS) Control* CP3-EN-0307, *Engineering Procurement Specification* CP4-EN-0301, *Equivalency/Substitution Evaluation Process* ES-0.9-22, *System Notebooks, System Health Reports and System Health Walkdowns* CP3-OP-0025, *Document Control Process* CP3-EN-0302, *Engineering Change Requests and Notices*	Core Functions: • None Guiding Principles: • Identification of Safety, Standards, and Requirements • Hazard Controls Tailored to Work Being Performed

APPENDIX B—PERFORMANCE IMPLEMENTATION MATRIX			
DOE Quality Assurance Requirements from DOE O 414.1D, Chg 2 (LtdChg)	**DOE Quality Assurance Requirements from DOE O 414.1D, Chg 2 (LtdChg)**	**DOE Quality Assurance Requirements from DOE O 414.1D, Chg 2 (LtdChg)**	**DOE Quality Assurance Requirements from DOE O 414.1D, Chg 2 (LtdChg)**
		CP3-QA-1002, *Software Quality Assurance* CP3-EN-0207, *Facility Change Process*	
	Non-Mandatory Appendix 3A-1, and Subpart 4.1, should be considered to aid in the development of Design Control.	Non-Mandatory Appendix 3A-1, and Subpart 4.1, will be considered during development of Design Control	

CP2-QA-1000/FR4

APPENDIX B—PERFORMANCE IMPLEMENTATION MATRIX			
DOE Quality Assurance Requirements from DOE O 414.1D, Chg 2 (LtdChg)	**ASME NQA-1-2008 (with Addenda through 2009) Requirements**	**PGDP Deactivation and Remediation Project Plans and Procedures**	**ISMS Core Functions and Guiding Principles**
Criterion 7—Performance/Procurement *(a) Procure items and services that meet established requirements and perform as specified.* *(b) Evaluate and select prospective suppliers on the basis of specified criteria.* *(c) Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.*	**Requirement 4—Procurement Document Control** 100—Basic 200–207 Content of Procurement Documents 300—Procurement Document Review 400—Procurement Document Changes **Requirement 7—Control of Purchased Items and Service** 100—Basic 200—Supplier Evaluation and Selection 300—Bid Evaluation 400—Control of Supplier-Generated Documents 500–507 Acceptance of Item or Service 600—Control of Supplier Nonconformances 700–705 Commercial Grade Items and Services 800—Records **Requirement NQA-1 Part II, Subpart 2.7—Quality Assurance Requirements for Computer Software for Nuclear Facility Applications** 100–102 General 200–204 General Requirements 300–302 Software Acquisition 400–407 Software Engineering Method 500—Standards, Conventions, and Other Work Practices 600–602 Support Software 700—References	CP3-CP-0001, *Request for Purchase* CP2-RD-0001, *Records Management Plan* CP3-CP-0002, *Acquisition Management* CP3-EN-0215, *Engineering Evaluations* CP3-EN-0307, *Engineering Procurement Specification* CP3-QA-2003, *Quality Inspection* CP3-QA-1007, *Procurement Quality Assurance* CP3-QA-2001, *Approved Supplier Selection Evaluation, Approved Supplier Maintenance* CP3-QA-1002, *Software Quality Assurance* CP3-SP-0018, *Subcontractor Oversight* CP3-QA-2004, *Material Receipt Inspection* CP3-QA-2500, *Procurement, Inspection and Management of Items Critical for Paducah Off-Site Waste Shipments*	Core Functions: • None Guiding Principles: • Balanced Priorities • Identification of Safety, Standards, and Requirements

APPENDIX B—PERFORMANCE IMPLEMENTATION MATRIX			
DOE Quality Assurance Requirements from DOE O 414.1D, Chg 2 (LtdChg)	**ASME NQA-1-2008 (with Addenda through 2009) Requirements**	**PGDP Deactivation and Remediation Project Plans and Procedures**	**ISMS Core Functions and Guiding Principles**
	Part II, Subpart 2.14—Quality Assurance Requirements for Commercial Grade Items and Services 100–101—General 200—Commercial Grade Items Definition Applications 300—Utilization 400–403—Technical Evaluation 500—Critical Characteristics 600–606—Methods of Accepting Commercial Grade Items and Services 700—Commercial Grade Services 800—Documentation 900—References	CP3-QA-2502, *Commercial Grade Items and Services* CP3-PR-3001, Warehouse Operations and Receipt of Material NOTE: For S/CI Items information see information after Criterion 10.	
	Non-Mandatory Appendix 4A-1, 7A-1 should be considered to aid in the development of Procurement processes.	Non-Mandatory Appendix 4A-1, 7A-1 will be considered during development of the Procurement processes.	

APPENDIX B—PERFORMANCE IMPLEMENTATION MATRIX			
DOE Quality Assurance Requirements from DOE O 414.1D, Chg 2 (LtdChg)	**ASME NQA-1-2008 (with Addenda through 2009) Requirements**	**PGDP Deactivation and Remediation Project Plans and Procedures**	**ISMS Core Functions and Guiding Principles**
Criterion 8—Performance/Inspection and Acceptance Testing *(a) Inspect and test specified items, services, and processes using established acceptance and performance criteria.* *(b) Calibrate and maintain equipment used for inspections and tests.*	**Requirement 3—Design Control** 100—Basic 200—Design Input 300—Design Process 400–402 Design Analysis 500–501.3 Design Verification 600–601.9 Change Control 700—Interface Control 800–802.3 Software Design Control 900—Documentation and Records **Requirement 8—Identification and Control of Items** 100—Basic 200–202 Identification Methods 300–303 Specific Requirements Text Deleted **Requirement 10—Inspection** 100—Basic 200—Inspection Requirements 300—Inspection Hold Points 400–402 Inspection Planning 500—In-Process Inspection 600–604 Final Inspections	CP2-RD-0001, *Records Management Plan* CP2-SM-1000, *Activity Level Work Planning and Control Program* CP3-SM-1101, *Work Package Development* CP3-QA-2003, *Quality Inspection* CP3-QA-2004, *Material Receipt Inspection* CP3-SM-0017, *Measuring and Test Equipment* (also see Criterion 5 for additional examples of M&TE-related procedures) CP3-QA-2005, *Nonconformance Control* CP3-QA-3001, *Issues Management* CP3-QA-1002, *Software Quality Assurance* CP3-QA-2500, *Procurement, Inspection and Management of Items Critical for Paducah Off-Site Waste Shipments* CP3-QA-2003, *Quality Inspection* CP3-OP-0015, *Control of Equipment and System Status*	Core Functions: • Perform Work within Controls Guiding Principles: None

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APPENDIX B—PERFORMANCE IMPLEMENTATION MATRIX			
DOE Quality Assurance Requirements from DOE O 414.1D, Chg 2 (LtdChg)	**ASME NQA-1-2008 (with Addenda through 2009) Requirements**	**PGDP Deactivation and Remediation Project Plans and Procedures**	**ISMS Core Functions and Guiding Principles**
	700—Inspections During Operations 800—Records **Requirement 11—Test Control** 100—Basic 200—Test Requirements 300—Test Procedures (Other Than for Computer Programs) 400—Computer Program Test Procedures 500—Test Results 600–602 Test Records **Requirement 12—Control of Measuring and Test Equipment** 100—Basic 200—Selection 300–304 Calibration and Control 400–402 Records **Requirement 14—Inspection, Test, and Operating Status** 100—Basic **Part II Requirements** **Subpart 2.4 Installation, Inspection and Testing Requirements for Power, Instrumentation and Control Equipment** ANSI/IEEE Std. 336-1985 IEEE Standard, Installation, Inspection and Testing Requirements for Power, Instrumentation, and Control Equipment at Nuclear Facilities	CP3-SM-0017, *Measuring and Test Equipment* (also see Criterion 5 for additional examples of M&TE-related procedures) CP4-QA-2118, *Visual Examination of Welds and Cascade Equipment* CP4-ND-1013, *Control of Nondestructive Assay Equipment* CP4-ND-1010, *Administration of Nondestructive Assay Sources* CP4-RP-1326, *Control of Government Owned Radiological Instrumentation*	

APPENDIX B—PERFORMANCE IMPLEMENTATION MATRIX			
DOE Quality Assurance Requirements from DOE O 414.1D, Chg2 (LtdChg)	**ASME NQA-1-2008 (with Addenda through 2009) Requirements**	**PGDP Deactivation and Remediation Project Plans and Procedures**	**ISMS Core Functions and Guiding Principles**
	Subpart 2.7—Quality Assurance Requirements for Computer Software for Nuclear Facility Applications 100–102 General 200–204 General Requirements 300–302 Software Acquisition 400–407 Software Engineering Method 500—Standards, Conventions, and Other Work Practices 600–602 Support Software 700—References		
	Non-Mandatory Appendices 10A-1 and 11A-1 should be considered to aid in development of inspection and testing processes	Non-Mandatory Appendices 10A-1 and 11A-1 will be considered during development of inspection and testing processes.	

APPENDIX B—PERFORMANCE IMPLEMENTATION MATRIX			
DOE Quality Assurance Requirements from DOE O 414.1D, Chg2 (LtdChg)	**ASME NQA-1-2008 (with Addenda through 2009) Requirements**	**PGDP Deactivation and Remediation Project Plans and Procedures**	**ISMS Core Functions and Guiding Principles**
Criterion 9—Assessment/Management Assessment *Ensure that managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.*	**Requirement 2—Quality Assurance Program** 100—Basic 200–202 Indoctrination and Training 300–305 Qualification Requirements; 400—Records of Qualification 500—Records **Requirement 16—Corrective Action** 100—Basic **Requirement 18—Audits** 100—Basic 200—Scheduling 300–303 Preparation 400—Performance 500—Reporting 600—Response 700—Follow-up Action 800—Records	CP2-QA-1000, *Quality Assurance Program Description* CP2-TR-0100, *Training Program for the Paducah Gaseous Diffusion Plant, Paducah, Kentucky* CP2-RD-0001, *Records Management Plan* CP3-QA-3005, *Occurrence Reporting* CP2-QA-3000, *Contractor Performance Assurance Program* CP3-QA-3002, *Operating Experience/Lessons Learned (OE/LL)* CP3-QA-3001, *Issues Management* CP3-QA-1003, *Management and Self-Assessment* CP3-QA-1008, *Assessor Qualification, Training, and Certification* CP3-OP-0500, *Performance/Process Observations and Tour Process* CP2-OP-1119, *Readiness Review Program*	Core Functions: • Define the Scope of Work • Provide Feedback and Continuous Improvement Guiding Principles: • Identification of Safety Standards and Requirements
	Non-Mandatory Appendices 2A-1, 2A-3, 2A-4, 18A-1, and Subpart 4.5 should be considered to aid in organizational development of assessment processes.	Non-Mandatory Appendices 2A-1, 2A-3, 2A-4, 18A-1, and Subpart 4.5 will be considered during development of the assessment processes.	

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APPENDIX B—PERFORMANCE IMPLEMENTATION MATRIX			
DOE Quality Assurance Requirements from DOE O 414.1D, Chg 2 (LtdChg)	**ASME NQA-1-2008 (with Addenda through 2009) Requirements**	**PGDP Deactivation and Remediation Project Plans and Procedures**	**ISMS Core Functions and Guiding Principles**
Criterion 10—Assessment/Independent Assessment *(a) Plan and conduct independent assessments to measure item and service quality, to measure the adequacy of work performance, and to promote improvement.* *(b) Establish sufficient authority and freedom from line management for independent assessment teams.* *(c) Ensure persons who perform independent assessments are technically qualified and knowledgeable in the areas to be assessed.*	**Requirement 1—Organization** 100—Basic 200–202 Structure and Responsibility 300—Interface Control **Requirement 2—Quality Assurance Program** 100—Basic 200–202 Indoctrination and Training 300–305 Qualification Requirements 400—Records of Qualification 500—Records **Requirement 10—Inspection** 100—Basic 200—Inspection Requirements 300—Inspection Hold Points 400–402 Inspection Planning 500—In-Process Inspection 600—604 Final Inspections 700—Inspections During Operations 800—Records **Requirement 11—Test Control** 100—Basic 200—Test Requirements 300—Test Procedures (Other Than for Computer Programs) 400—Computer Program Test Procedures 500—Test Results 600—602 Test Records **Requirement 15—Control of Nonconforming Items** 100—Basic 200—Identification 300—Segregation 400–405 Disposition	CP2-QA-1000, *Quality Assurance Program Description* CP2-RD-0001, *Records Management Plan* CP3-QA-3005, *Occurrence Reporting* CP2-QA-3000, *Contractor Performance Assurance Program* CP3-QA-3002, *Operating Experience/Lessons Learned (OE/LL)* CP3-QA-3001, *Issues Management* CP3-QA-1004, *Independent Assessment Program* CP3-QA-1008, *Assessor Qualification, Training, and Certification* CP3-QA-2002, *Surveillance* CP3-QA-2003, *Quality Inspection* CP3-QA-2004, *Material Receipt Inspection* CP3-QA-2500, *Procurement, Inspection and Management of Items Critical for Paducah Off-Site Waste Shipments* CP3-QA-2005, *Nonconformance Control*	Core Functions: • Define the Scope of Work • Provide Feedback and Continuous Improvement Guiding Principles • None

APPENDIX B—PERFORMANCE IMPLEMENTATION MATRIX			
DOE Quality Assurance Requirements from DOE O 414.1D, Chg 2 (LtdChg)	**ASME NQA-1-2008 (with Addenda through 2009) Requirements**	**PGDP Deactivation and Remediation Project Plans and Procedures**	**ISMS Core Functions and Guiding Principles**
	Requirement 16—Corrective Action 100—Basic **Requirement 18—Audits** 100—Basic 200—Scheduling 300–303 Preparation 400—Performance 500—Reporting 600—Response 700—Follow-up Action 800—Records	CP2-OP-1119, *Readiness Review Program* All procedures listed for these requirements under Management/Criterion 3, Quality Improvement, are applicable.	
	Non-Mandatory Appendices 2A-3, 2A-4, 16A-1, and 18A-1 should be considered to aid in the development of independent assessment processes.	Non-Mandatory Appendices 2A-3, 2A-4, 16A-1, and 18A-1 will be considered during the development of the independent assessment processes.	

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APPENDIX B—PERFORMANCE IMPLEMENTATION MATRIX			
DOE Quality Assurance Requirements from DOE O 414.1D, Chg 2 (LtdChg)	**ASME NQA-1-2008 (with Addenda through 2009) Requirements**	**PGDP Deactivation and Remediation Project Plans and Procedures**	**ISMS Core Functions and Guiding Principles**
DOE O 414.1D, Chg 2 (LtdChg), Attachment 3, Suspect/Counterfeit Items Prevention, Paragraph 2	**Part I Requirements** **Requirement 2—Quality Assurance Program** 100—Basic 200—Indoctrination and Training 300—Qualification Requirements 400—Certification of Qualification 500—Records **Requirement 15—Control of Nonconforming Items** 100—Basic 200—Identification 300—Segregation **400—Disposition**	CP3-QA-1006, *Suspect/Counterfeit Items* CP3-QA-2005, *Nonconformance Control* CP3-QA-2003, *Quality Inspection* CP3-PR-3001, *Warehouse Operations and Receipt of Material*	Core Functions: • Define & Implement Hazard Controls • Provide Feedback & Continuous Improvement Guiding Principles • Line Management Responsible for Safety
DOE O 414.1D, Chg 2 (LtdChg), Attachment 4, Safety Software Quality Assurance Requirements for Nuclear Facilities	**Part I Requirements** **Requirement 3—Design Control** 100—Basic 400—Design Analysis 700—Interface Control 800—Software Design Control 900—Documentation and Records **Requirement 11—Test Control** 100—Basic 200—Test Requirements	CP3-QA-1002, *Software Quality Assurance* CP3-IT-0002, *Software Configuration Management* CP2-RD-0002, *Electronic Information System Requirements* CP3-QA-1001, *Graded Approach* See also Criterion 5, 7, and 8 for implementation information.	Core Functions: • Analyze Hazards • Define & Implement Hazard Controls • Perform Work within Controls • Provide Feedback & Continuous Improvement Guiding Principles: • Line Management Responsible for Safety • Balanced Priorities • Identification of Safety, Standards, and Requirements

Chg A

APPENDIX B—PERFORMANCE IMPLEMENTATION MATRIX			
DOE Quality Assurance Requirements from DOE O 414.1D, Chg 2 (LtdChg)	**ASME NQA-1-2008 (with Addenda through 2009) Requirements**	**PGDP Deactivation and Remediation Project Plans and Procedures**	**ISMS Core Functions and Guiding Principles**
	400—Computer Program Test Procedures 500—Test Results 600 (602)—Test Records **Part II Requirements** **Subpart 2.7—Quality Assurance Requirements for Computer Software for Nuclear Facility Applications** 100—General 200—General Requirements 300—Software Acquisition 400—Software Engineering Method 500—Standards, Conventions, and Other Work Practices 600—Support Software 700—References See Criterion 6 as Non-Mandatory; Subpart 4.1 applies to software quality assurance considerations as well		• Hazard Controls Tailored to Work Being Performed

APPENDIX C

REQUIRED SOFTWARE QUALITY ASSURANCE WORK ACTIVITY MAP

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	Level A					Level B					Level C Quality Affecting					Level D Quality Affecting					Level E Non-Quality Affecting				
Software Type / SQA Work Activity *Note 1	Custom Developed	Configurable	Acquired	Utility Calc	Commercial D&A	Custom Developed	Configurable	Acquired	Utility Calc	Commercial D&A	Custom Developed	Configurable	Acquired	Utility Calc	Commercial D&A	Custom Developed	Configurable	Acquired	Utility Calc	Commercial D&A	Custom Developed	Configurable	Acquired	Utility Calc	Commercial D&A
Software Project Management and Quality Planning	F	F	G	G	NA	F	F	G	G	NA	G	G	G	G	NA	G	G	G	G	NA	NR	NR	NR	NR	NA
Software Risk Management	F	F	F	F	NA	G	G	G	G	NA	G	G	G	G	NA	NR	NR	NR	NR	NA	NR	NR	NR	NR	NA
Software Configuration Management	F	G	G	G	G	F	G	G	G	G	G	G	G	G	G	G	G	G	G	G	G	G	G	G	G
Procurement and Supplier Management	F	F	F	F	F	F	F	F	F	F	F	F	F	F	F	G	G	G	G	G	NR	NR	NR	NR	NR
Software Requirements Identification and Management	F	F	F	F	F	F	F	F	F	F	F	F	F	F	F	F	G	G	G	G	NR	NR	NR	NR	NR
Software Design and Implementation	F	G	NA	G	NA	F	G	NA	G	NA	F	G	NA	G	NA	G	G	NA	G	NA	NR	NR	NA	NR	NA
Software Safety	F	F	F	NA	NA	G	G	G	NA	NA	G	G	G	NA	NA	NR	NR	NR	NA	NA	NR	NR	NR	NA	NA
Verification and Validation	F	F	F	G	NA	G	G	G	G	NA	G	G	G	G	NA	G	G	G	G	NA	NR	NR	NR	NR	NA
Problem Reporting and Corrective Action	F	F	F	G	F	F	F	F	G	F	F	G	G	G	G	G	G	G	G	G	NR	NR	NR	NR	NR
Personnel Training	F	F	F	F	NA	G	G	G	G	NA	G	G	G	G	NA	NR	NR	NR	NR	NA	NR	NR	NR	NR	NA

F = Full Compliance NR = Not Required

G = Graded Compliance NA = Not Applicable (Feasible) for the software type

*Note 1: Section 12.3 of the QAPD provides discussion on consensus standard NQA-1 requirements that correlate and apply to the QL-2 safety software activities (see QAPD 1.4).

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