QUALITY ASSURANCE GUIDE
FOR PROJECT MANAGEMENT

[This Guide describes suggested non-mandatory approaches for meeting requirements. Guides are not requirements documents and are not to be construed as requirements in any audit or appraisal for compliance with the parent Policy, Order, Notice, or Manual.]

U.S. Department of Energy
Washington, D.C.

PREFACE

This Department of Energy (DOE) Guide is for use by DOE elements. This Guide provides acceptable approaches for implementing the Quality Assurance requirements and criteria required by DOE O 413.3A, *Program and Project Management for the Acquisition of Capital Assets*, related to the development and implementation of a Quality Assurance program for the project. This Guide describes suggested non-mandatory approaches for meeting requirements. DOE Guides are part of the DOE Directives System and are issued to provide supplemental information regarding the Department's expectations of its requirements as contained in rules, Orders, Notices, and regulatory standards. Guides may also provide acceptable methods for implementing these requirements. Guides are not substitutes for requirements nor do they replace technical standards that are used to describe established practices and procedures for implementing requirements.

TABLE OF CONTENTS

LIST OF APPENDICES

LIST OF FIGURES

LIST OF TABLES

1.0   PURPOSE

This Guide provides information to assist U.S. Department of Energy (DOE) Federal Project Directors (FPD) and their Integrated Project Teams (IPT) in carrying out their Quality Assurance (QA)-related roles and responsibilities. The Guide supplements DOE O 413.3A, *Program and Project Management for the Acquisition of Capital Assets*. It is consistent with DOE O 414.1C (*Quality Assurance*), i.e., DOE QA Order; 10 CFR 830 Subpart A ("Quality Assurance Requirements"), i.e., QA Rule; and 10 CFR 63.142 ("Quality Assurance Criteria").

The Guide identifies key areas in which the FPD's involvement is crucial to QA-related mission success. The Guide helps FPDs plan, develop, and implement a project-specific QA program that satisfies QA requirements throughout the Critical Decision process.

Appendix A of this QA Guide identifies the DOE Directives and Guides related to quality assurance. This QA Guide references applicable guidance and information from these Directives and Guides related to an FPD's QA duties and responsibilities as defined by DOE O 413.3A.

2.0   SCOPE

This Guide is for use by DOE elements where DOE O 413.3A applies. FPDs can use it to identify and implement their QA-related roles and responsibilities in accordance with DOE O 413.3A. This Guide applies to Critical Decisions and projects, including design, design – build, design – bid – build, operations, maintenance, decontamination, decommissioning, and environmental restoration.

The role of the FPD is to develop the overall project strategy; establish requirements and performance expectations; manage the contract; monitor and assess performance; and proactively anticipate and resolve issues that impact project success. While the overall project is executed under the direction of the Federal staff, the contractor typically manages daily execution. Accordingly, this Guide provides contractors insight into the FPD's expectations of them in terms of the FPD's roles and responsibilities.

The methods and references described in this Guide do not add, modify, or delete any requirements identified in the DOE QA Order or QA Rule. Use of this Guide in conjunction with appropriate standards will facilitate development of a QA program compliant with the DOE QA Order and QA Rule. As with any guide, alternative methods can be used as long as the requirements of the DOE QA Order and QA Rule are satisfied.

> Note: A QA program is a management system to help an organization "do work correctly." The QA Plan is the document describing the QA program the project will implement. Per DOE O 413.3A, the project's application of QA is documented in either the organization- or project-specific QA Plan. Existing site-wide QA programs may be used, but should be referenced in the project's project execution plan (PEP).

3.0   GUIDE CONTENT

Figure 1 shows how this Guide is organized. The Guide provides information organized by each Critical Decision.

4.1	4.2
QA Sources	Developing a QA Strategy & Policy

4.3	4.4
Essential Steps in Developing a QA Program	QA Program Development & Implementation by Critical Decision
Organizational Structure (4.3.1)	CD-0 (4.4.1)
	CD-1 (4.4.2)
Selecting a Consensus Standard (4.3.2)	CD-2 (4.4.3)
Graded Approach (4.3.3)	CD-3 (4.4.4)
	CD-4 (4.4.5)
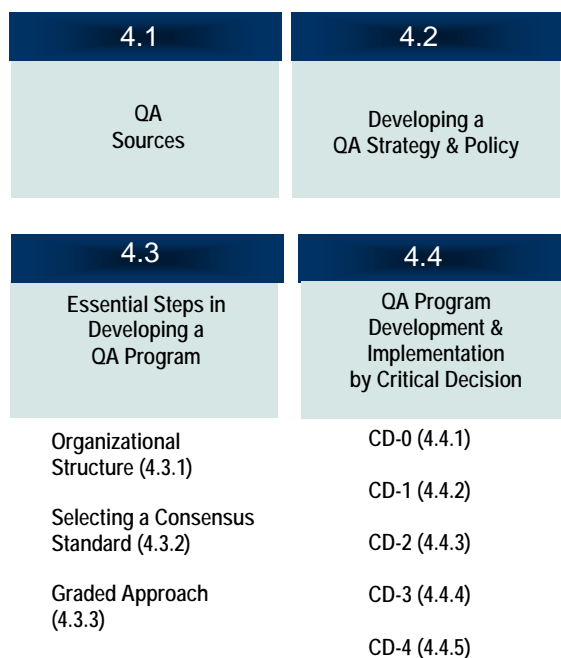
Figure 1. How this Guide is Organized

This Guide also contains five appendices to assist the FPD in establishing their project-specific QA program:

- Appendix A.   DOE Directives and Guides Related to Quality Assurance

- Appendix B.   Voluntary Consensus Standards

- Appendix C.   Quality Assurance Attributes/Characteristics, and Identification of Value Added Matrix

- Appendix D.   Suggested QA Activities to Support Critical Decision Requirements

- Appendix E.   Lessons Learned

4.0   GUIDE METHODOLOGY

4.1   Quality Assurance Sources

DOE QA requirements are contained in the DOE QA Order and the QA Rule. For nuclear projects, the FPD should ensure implementation of a QA program compliant with 10 CFR 830

Subpart A (i.e., QA Rule), and the DOE QA Order. For other non-nuclear projects, the FPD should ensure application of a QA program compliant with the DOE QA Order covering the activities of the project. For a Work for Others project, any client-specific QA requirements should also be identified.

> Note: DOE O 414.1C, (3.a) states: "Where a work activity, process or item is specifically identified as within the scope of a QA regulation (e.g., 10 CFR 830 or 10 CFR 63), that regulation prevails. In the event of a conflict [such that compliance with both sets of requirements cannot be met because of contradictory requirements] between this Order (414.1C) and any regulation, the regulation prevails."

The DOE Directives System contains the QA Order and its accompanying Guides, which specify requirements and provide guidance respectively and information on principles and practices to establish and implement effective QA programs. These directives and guides are identified and summarized in Appendix A. Voluntary consensus standards also provide "how to" information. Quality Assurance related voluntary consensus standards are summarized in Appendix B.

> Note: In the past many contractor QA programs were solely based on the ten (10) DOE QA criteria without the benefit of the "how to" information made available through voluntary consensus standards. This approach can result in QA programs with insufficient details and controls.

> Note: When using voluntary consensus standards, the project-specific QA program may vary from the 10 DOE QA-criteria format. While this variation is acceptable, the FPD should understand the relationship between the project-specific QA program and the 10 DOE QA criteria. For example, quality improvement and management assessment are not addressed in American Society of Mechanical Engineers (ASME) Nuclear Quality Assurance (NQA)-1.

4.2   Developing a Quality Assurance Strategy and Policy

As early in the acquisition process as practicable, the FPD should:

- Decide whether to use an existing site-wide QA program, use the contractor's corporate QA program, or develop a project-specific QA program.

> Note: Wherever practicable, it is desirable to use existing QA programs to meet the needs of new projects. This approach maximizes the use of Federal resources while minimizing overlapping QA programs that are complex and expensive to implement and maintain. Using an existing QA program may not be viable for exceptionally large, complex, or unique projects. In these cases, the contractor should be encouraged to develop a standalone, project-specific QA program.

> Note: FPD experience shows performing a gap analysis between existing QA programs (i.e., site-wide and/or contractor) and project QA requirements is essential.

- Ensure QA requirements are documented in vendor or subcontractor contracts.

- Address when and where the QA oversight and reporting chain will exist in the project and contractor organizations (i.e., who reports to whom).

> Note: For Federal site offices, the QA organization typically has an independent reporting relationship; that is, a relationship that allows the reporting of issues independent of cost and schedule considerations and which normally reports to the most senior person in the organization. The line organization has responsibility for meeting the project's quality requirements within its area of responsibility, and individuals are responsible for the quality of their work. The line organization and the QA organization share the responsibility for the verification of quality.

- Identify the applicable DOE QA requirements from DOE O 414.1C, 10 CFR 830 Subpart A, or 10 CFR 63.142 and applicable voluntary consensus standard or standards, such as NQA-1, International Organization for Standardization (ISO) 9000, etc.

- Ensure implementing procedures are developed and implemented before the requisite work is performed.

> Note: Implementing procedures provide direction to personnel doing the work. Without procedures, consistent reliable high quality work is unlikely. For example, on a recent DOE project, unacceptable equipment and services were procured because procedures were not in place.

- Evaluate the adequacy of the project-specific QA program or the corresponding contractor's project-specific QA program.

- Ensure the availability of appropriate personnel resources to support project-specific QA program implementation, including QA oversight.

> Note: Many FPDs may not have direct/full-time access to appropriate QA subject matter expertise (e.g., weld inspectors). If this is the case, the FPD may need to ensure that adequate funds are available for these services.

- Identify key QA leaders in the DOE and contractor organizations.

- Identify document control and records management systems, consistent with applicable codes, regulations, and directives.

> Note: It is vitally important that required and expected documentation is clearly identified early in the project, that resources (funding and system owners) are identified early and loaded throughout project closeout, and that activities to collect, review, and control these documents are also started early in the project life.

Having a QA policy statement for the project is not a DOE QA Order or QA Rule requirement but may be required by the adopted consensus standard and should be considered as a good practice. A project QA policy statement should address:

- Senior management commitment and acknowledgement of ownership for project quality
- Commitment to the QA program as the mechanism to ensure requirements are met
- Commitment to define quality requirements before work starts
- Commitment to comply with project quality requirements
- Commitment to stop work if unable to comply with quality requirements
- Commitment to monitor processes continuously

Appropriate management should endorse the QA Policy in writing.

4.3   Developing a Quality Assurance Program

The QA program is an organization's quality-related management system to "do work correctly." When developing the QA program, the FPD should, where consistent with contract or regulatory requirements:

- Implement the QA criteria identified in the DOE QA Order using a graded approach (and describe how the criteria and graded approach are applied)

- Use national or international consensus standards and identify the standards used

- Apply additional standards as necessary to address unique/specific work activities (e.g., development and use of safety software or establishing the competence of a testing and calibration laboratory)

- Integrate QA criteria as defined in the DOE QA Order (e.g., the suspect/counterfeit item (S/CI) prevention process and safety software quality requirements) with other QA criteria or management system requirements in DOE directives and external requirements

The criteria of the DOE QA Rule and QA Order are broadly written. This allows the FPD to determine how to best apply these documents to a wide range of projects. How the FPD chooses to implement the criteria depends on a number of factors associated with the project. For example, in nuclear and environmentally significant (regulatory driven) projects, the FPD may impose quality requirements that provide objective evidence (i.e., written documentation) that regulatory requirements are met.

The following sections provide guidance on important aspects of the QA program. They are not intended to provide detailed guidance on how to develop a project-specific QA plan. Additional guidance on developing QA plans can be found in the DOE Directives System and voluntary consensus standards (see Appendices A and B).

4.3.1 Organizational Structure and Responsibilities

Every project needs to clearly define responsibilities, interfaces, and organizational accountability. The FPD should define how to work with management, the IPT, and other participants, including the contractor(s), to ensure safety and quality.

In most cases, except when Federal staff is responsible for direct execution of work, the contractor will develop and implement a project-specific QA program. The FPD should ensure the contractor has assigned QA roles and responsibilities, which include:

- Identifying key participants in charge of major project activities

- Identifying work assigned to each project participant

- Defining a detailed project organizational structure including interfaces with internal and external organizations

- Defining individuals' responsibilities and authorities, including authority to stop unsafe or unsatisfactory work, and for communicating quality or safety concerns, without fear of reprisal, to a level of management with appropriate authority to resolve concerns

- Defining specific QA oversight responsibilities for each project organizational element

4.3.1.1   Federal Organization

In most cases, the FPD's role in QA focuses on assessing or otherwise verifying that the contractor has executed its QA-related contractual obligations. Typically, these obligations include everything from QA program development and implementation to working-level procedure execution. It is essential that the grading process (see Section 4.3.3) for the project is understood when performing this oversight function. Knowing why a particular item or activity has a higher or lower quality level is essential during the performance of oversight activities.

The FPD should ensure that the staff has the relevant experience, qualifications, certifications, and specialized training to fulfill their responsibilities, including identifying a qualified QA subject matter expert, as required. The following are recommended QA responsibilities and composition of the Federal organization:

Federal Project Director:

- Ensures that design, construction, environmental, safety, security, health, and quality efforts comply with the contract (including List A or B requirements), public law, and regulations

- Ensures that safety, security, environmental, and quality considerations are fully integrated into appropriate phases of the project

- Applies the DOE QA program and recommends approval, modification, or rejection of the contractor's project-specific QA programs to the designated approval authority

Integrated Project Team:

The IPT is an essential element of DOE's acquisition process. It is used during the phases of a project life cycle. The IPT represents diverse disciplines with the specific knowledge, skills, and abilities necessary to support the successful execution of projects. IPT roles and responsibilities encompass quality and performance improvement, including:

- Performing monthly reviews and assessments of project performance and status against established performance parameters, baselines, milestones, and deliverables

- Planning and participating in project reviews, audits, and appraisals

- Reviewing and commenting on project deliverables (e.g., drawings, specifications, procurement, and construction packages)

- Reviewing change requests and supporting change control boards

> Note: Some FPDs may choose to include the contractor on their IPT. For more information on Integrated Project Teams, refer to additional DOE Directives.

4.3.1.2   Contractor Organization

The FPD through the contracting officer imposes requirements on the contractors, including QA, as defined in the contractor requirements document (CRD). Regardless of who performs the work for the contractor (e.g., subcontractor, vendor, etc.), the contractor is ultimately responsible for complying with the requirements of the CRD as included in the contract. The contractor is responsible for flowing down CRD requirements to subcontractors at any tier, to the extent necessary to ensure compliance. The project contractor lead and the FPD should have well-established communication protocol including understanding expectations, interfaces, chain of command, etc.

The FPD should also consider whether the project requires having and defining the roles (generally in the contractor's organization) of:

- Quality Assurance Function—Assists with the interpretation of the project-specific QA program requirements, verifies program implementation, and evaluates effectiveness by surveillances and assessments

- Quality Control Function—Responsible for quality verification, inspection, documentation, and surveillance of hardware, including structures, systems, and components (SSC) and services

- Quality Engineering Function—Responsible for verification of the design, procurement, installation, test, inclusion of appropriate inspection acceptance criteria, and turnover control system

4.3.2   Identification of Quality Consensus Standards

The QA Order requires that each DOE organization "uses national or international consensus standards where practicable and consistent with contractual or regulatory requirements." Appropriate standards are discussed in Appendix B.

A project's application of QA is documented in either the organization- or project-specific QA program. If the decision is made not to use the existing organizational QA program, the FPD, based on input from the contractor where appropriate, may select a nationally or internationally recognized quality-related consensus standard to be incorporated into project contracts. The selection should occur as early as possible, but no later than the beginning of conceptual design. Consensus standards reflect practices that have "withstood the test of time," often decades of successful application, yet are revised on a three- to five-year cycle to ensure incorporation of emerging technology and practices.

> Note: DOE O 414.1C, Attachment 2, paragraph 2a (3) states: "These standards are sometimes referred to as 'voluntary standards.' However, once the practicable standard(s) is adopted through regulation, code, contract, QA plan, or procedure, compliance with the standard is required and is not voluntary."

The FPD should ensure the contractor selects a consensus standard that meets project-specific quality requirements and closely reflects the anticipated work. In some cases, the selected consensus standard may differ from existing site practice and contractual agreements. The FPD should request that the selection be formally documented and have an appropriate quality professional and higher level of management endorse the selection.

If the FPD is not using the existing organizational QA program, the FPD and IPT should develop and document in a QA plan a project-specific QA program that addresses the criteria of the DOE QA Order and/or QA Rule, as applicable.

Some sites may be involved in both nuclear and non-nuclear project activities. In such instances, an organization may have an established QA program based on one or more of the consensus standards (e.g., ISO 9001 for nonnuclear activities or NQA-1 for nuclear-related activities) and need to modify it for an additional nuclear or non-nuclear need. While some requirements are unique to each standard, there are many common requirements (see Appendix B). This enables an existing QA program based on one standard to be applied with little or no modification to satisfy specific requirements of an additional standard.

> Note: For construction of facilities that include nuclear-related activities, it is acceptable and appropriate to apply NQA-1 on a graded basis to the entire facility.

Appendix C shows the value added by elements of a QA Program. It also illustrates the similarities and differences between DOE's QA requirements contained in 10 CFR 830 Subpart A (QA Rule) and DOE Order 414.1C (DOE QA Order), and two voluntary consensus standards.

4.3.3 Graded Approach

The FPD should use a graded approach for developing the project's QA program. The level of QA required varies with the project's complexity and risks. It is therefore essential that the FPD realize the grading process may raise the required QA level depending on the risk. The challenge for the FPD is to ensure the level of detail and resources are sufficient to meet the project's objectives.

At the point when SSCs are known, the FPD should develop a list of items and activities and determine the significance of the item or activity to the success of the project. Things to consider in assigning significance include, but are not limited to:

- Relative importance to safety, safeguards, and security
- Magnitude of any hazard involved
- Life-cycle stage of a facility or item
- Programmatic mission of a facility
- Potential radiological or industrial safety impact to the public and worker
- Potential to impact the environment
- Potential to impact the acceptability to the customer
- Regulatory significance

Grading is accomplished by determining the relative importance of an item or activity to the success of the project considering the list of characteristics defined above. Although many different approaches are used, a typical approach is to establish a Quality Level (e.g., 1, 2, 3, and 4), with Quality Level 1 being the most risk sensitive classification, requiring the most rigorous application of QA requirements.

The graded approach process should not be used to "grade to zero" (i.e., eliminate requirements). Even in the least stringent application of the graded approach process, compliance with the applicable requirements is mandatory.

4.4 Quality Assurance Program Development and Implementation by DOE O 413.3A Critical Decisions

The following sections summarize important QA-related considerations for the FPD at each Critical Decision (CD) as identified in DOE O 413.3A. Appendix D contains tables for each CD that can be used by FPDs as checklists against which to conduct independent assessments of work. The FPD should apply their judgment regarding the actual applicability of each to their project.

4.4.1 QA Guidance for CD-0, Approval of Mission Need

DOE O 413.3A, Table 2, CD-0 Requirement—No project-specific QA program is needed. (At CD-0, an FPD has not been selected; however, the following QA activities should be considered.)

Quality of Mission Need products should be controlled by the site or program office QA
Program. See additional DOE Guides for developing mission need products.

Appendix D – Table D-1 presents a crosswalk of key products and activities supporting CD-0
requirements (DOE O 413.3A – Table 2) and suggested QA activities and QA criteria (from
DOE O 414.1C, 10 CFR 830 Subpart A, and 10 CFR 63.142).

4.4.2   QA Guidance for CD-1, Approval of Alternative Selection and Cost Range

> **DOE O 413.3A, Table 2, CD-1 Requirement - Determine that the QA program is
> acceptable and continues to apply**. The QA program must fully address all applicable
> QA criteria as defined in 10 CFR 830 Subpart A (QA Rule) and the DOE QA Order.

With regard to QA program development, there are instances where the FPD develops the QA
program. However, it is more typical for the FPD to oversee the contractor's development of the
QA program prior to CD-1 submittal. In either event, the following should be performed:

- Develop a project-specific QA program that includes portions of the existing site QA
  program, as appropriate, with emphasis on:

  – Building quality into design prior to starting work (in preparation for CD-2)

  – Defining roles and responsibilities, including interfaces, of project, contractor, and
    subcontractor personnel, in detail

  – Ensuring that records management and document control processes are consistent
    with applicable codes, regulations, and directives

  > Note: It is important that required documents and records are identified/defined early in the
  > project and activities to identify, collect, review, maintain, and control these records, as well
  > as a processes to determine if any records are to be dispositioned as permanent or life-time
  > QA records, are developed early in the project's life.

  – Design activities, including: constructability, vendor capability, component and
    system attainability, testability/acceptability, maintainability, and sustainability

  – Designing QA/Quality Control (QC) processes and procedures (and management
    systems) to control the design and changes (see Section 6.0, "Definitions")

  – Software control, especially safety software

  – S/CI control

  – Personnel training and qualification

- Ensure independence of the QA organization (QA organization is independent from the
  line organization and has the ability to raise issues independent of cost and schedule)

- Determine how and where to address QA in the PEP

- Investigate the project acquisition strategy and quality levels (grading process) and ensure consistency between the acquisition strategy and QA Program

- Confirm there are adequate numbers of trained and qualified QA organization staff

Appendix D – Table D-2 presents a crosswalk of key products and activities supporting CD-1 requirements (DOE O 413.3A – Table 2) and suggested QA activities and QA criteria (from DOE O 414.1C, 10 CFR 830 Subpart A, and 10 CFR 63.142).

4.4.3   QA Guidance for CD-2, Approval of Performance Baseline

DOE O 413.3A, Table 2, CD-2 Requirement - Determine that the QA program is acceptable and continues to apply. The QA program must fully address all applicable QA criteria as defined in 10 CFR 830 Subpart A (QA Rule) and the DOE QA Order.

Either the cognizant FPD and their IPT or the contractor performs the following to refine the QA program prior to CD-2 submittal:

- Further refine the existing comprehensive project-specific assessment program that includes the levels of Federal and contractor activities

- Ensure that work processes covered by the QA Program are established and documented in procedures

> Note: It is possible for the project to lose configuration control of their procedures and/or design documents (i.e., procedures or design documents can be changed based upon internal or external commitments). Over time, the reasons for the changes are lost and the change is "undone" in a subsequent revision. An experienced QA individual can assist by providing simple tools such as an implementation matrix for maintaining and referencing a revision history to help the project avoid these problems.

- Review and revise the QA program based on improved knowledge of the project

- Ensure the Federal and contractor organizations have the correct balance of quality-related expertise (i.e., individuals with requisite training and qualifications)

- Ensure there is appropriate QA organization representation during the development of and subsequent revisions to the PEP

- Ensure there is appropriate QA organization representation during safety reviews

Either the cognizant FPD or contractor should understand:

- Flowdown of requirements and expected implementation (including oversight activities)

- SSCs and associated quality levels

- National standard design and construction tolerance relationships

> Example: During design, one project placed unrealistically close tolerances on building construction. This caused significant constructability issues and resulted in many change notices and nonconformance reports. FPDs need to consider constructability carefully during all phases of the design and resist attempts to rush project designs to meet unrealistic time/cost. expectations.

- Design philosophy (identification and flowdown of requirements into the design/performance specifications) to ensure it is coordinated with the acquisition strategy and QA strategy

The FPD may need to assign funding from the contractor baseline to ensure independent assessment is conducted as required (possibly by applying directly to a support contractor). If an FPD does not have the necessary in-house QA support, they may need to request funds to conduct assessments.

> Note: Often the requirements for external/internal oversight, assessments, and surveillances are not adequately covered in the baselines (both in terms of cost and schedule) of contractors (including Maintenance and Operations contractors), subcontractors, vendors, etc. It is essential that the FPD ensures these requirements are clearly defined and flowed down in contractual language of all types; especially when fixed-price subcontracting is used. In addition to the flowdown of requirements, it is essential that contractors/vendors clearly understand the requirements. This is especially true for such things as nuclear grade construction and design where the contractor pool may not truly understand the costs for implementing an effective QA program (which includes an oversight function). The FPD should ensure that during procurement evaluation these requirements are included in contractor technical approach, cost, and schedule. Weighted procurements should be strongly considered when high or unusual quality levels are required for a project.

For projects with a significant construction component, the FPD should understand and consider the following during CD-2 preparation:

- Ensure the IPT and the contractor have a common understanding of the QA requirements established in the latest versions of applicable DOE Orders, 10 CFR 830 Subpart A, and the contract and have qualified personnel in place to manage, perform, and assess work activities

- Ensure the IPT and the contractor have a common understanding of the acquisition strategy/plan and how the QA requirements are going to be identified, allocated, and implemented

- Ensure the IPT, the contractor, and the contractor procurement manager have a common understanding of the technical and programmatic risks associated with implementing the stated QA requirements within the acquisition strategy/plan and initiate the necessary mitigating activities to ensure the industry/market that will be solicited or performing the work clearly understands the expectations/requirements

- Ensure proper organizational QA processes and implementing procedures are developed, and assigned personnel are properly trained and qualified

- Ensure QA resources are defined, communicated to management, and incorporated into project budget requests

Appendix D – Table D-3 presents a crosswalk of key products and activities supporting CD-2 requirements (DOE O 413.3A – Table 2) and suggested QA activities and QA criteria (from DOE O 414.1C, 10 CFR 830 Subpart A, and 10 CFR 63.142).

4.4.4   QA Guidance for CD-3, Approve Start of Construction

DOE O 413.3A, Table 2, CD-3 Requirement - Update the Quality Assurance program for construction, field design changes, and procurement activities.

Either the cognizant FPD and their IPT or the contractor performs the following prior to CD-3 submittal:

- Ensure the QA program is updated prior to the submittal of CD-3

- Ensure acquisition documents (e.g., construction Request for Proposal, etc.) include appropriate QA requirements

- Ensure the technical evaluation is supported by experienced QA individuals

- Ensure design interfaces are reviewed and approved

- Ensure the use of qualified vendors

- Ensure in-depth oversight of the QA program(s) of the prime contractor and key subcontractors (if applicable) is conducted

- Ensure SSCs are properly graded

- Ensure adequate systems, processes, implementing procedures are in place and mature, and supported by experienced personnel

- Ensure integrated oversight/assessment/surveillance/inspection plans and schedules are developed, implemented, and maintained

- Ensure proper contractor performance metrics are established

- Ensure IPT and project meetings include a QA representative and a review of QA activities

- Ensure there is appropriate QA organization representation during revisions to the PEP

- Ensure there is appropriate QA organization representation during external independent reviews for construction or execution readiness

- Ensure there is a process in place to integrate the results of project oversight programs

- Ensure the distribution of oversight is adjusted based on the level of maturity of the contractor's oversight programs

- Ensure the quality-related activities (e.g., hold points, assessments, oversight, etc.) are reflected in the integrated project schedule and work breakdown structure (WBS)

- Ensure documents and records (objective evidence) for in-process and completed quality-related items and activities are maintained and readily retrievable, consistent with applicable codes, regulations, and directives

- Ensure, through independent assessments, that quality is being incorporated into the work processes (e.g., design, construction, etc.) – not inspected in (i.e., not relying on oversight to find and fix issues)

- Evaluate/accommodate changes in skills mix and specific disciplines (e.g., electrical, civil, mechanical) as the project progresses through the construction phase.

Appendix D – Table D-4 presents a crosswalk of key products and activities supporting CD-3 requirements (DOE O 413.3A – Table 2) and suggested QA activities and QA criteria (from DOE O 414.1C, 10 CFR 830 Subpart A, and 10 CFR 63.142).

4.4.5   QA Guidance for CD-4, Approve Start of Operations or Project Completion

DOE O 413.3A, Table 2, CD-4 Requirement: Issue an updated QA Plan to address testing, identified deficiencies, startup, transition, and operation activities.

Either the cognizant FPD and their IPT or the contractor performs the following prior to CD-4 submittal:

- Ensure continuous improvement; execution, oversight, feedback from oversight, and modification

- Ensure, through observation, oversight, the use of QA representatives, and independent assessments, that quality is being incorporated into the work processes and activities (e.g., design, construction, etc.) – not inspected in

- Evaluate/accommodate changes in skills mix and specific disciplines (e.g., electrical, civil, mechanical) as the project progresses through the construction phase

- Routinely evaluate QA organization performance and make staffing adjustments as necessary

- Ensure project lessons learned (positive and negative) are produced

- Ensure complex wide lessons learned are analyzed and project changes are implemented, as necessary

- Ensure as-builts are developed, including maintaining plant configuration

  Note: Like oversight, the FPD may have to "set aside" funding to ensure this important activity occurs.

- Ensure the project is implementing an effective issues management system

- Provide an updated QA program plan and lessons learned to operations as a source for updating existing operational QA program plans and other operational-related documentation

- Ensure records validation/authentication and turnover, consistent with applicable codes, regulations, and directives

Appendix D – Table D-5 presents a crosswalk of key products and activities supporting CD-4 requirements (DOE O 413.3A – Table 2) and suggested QA activities and QA criteria (from DOE O 414.1C, 10 CFR 830 Subpart A, and 10 CFR 63.142).

Some FPD responsibilities at CD-4 will vary depending on project type. For example, new construction will require preparations for readiness reviews, systems checks, etc. Cleanup projects may require communications with the DOE Office of Legacy Management.

Appendix D – Table D-6 presents a crosswalk of key products and activities supporting post CD-4 requirements (DOE O 413.3A – Table 2) and suggested QA activities and QA criteria (from DOE O 414.1C, 10 CFR 830 Subpart A, and 10 CFR 63.142).

5.0   ACRONYMS

ANSI	American National Standards Institute
ASME	American Society of Mechanical Engineers
ASQ	American Society for Quality
CD	Critical Decision
CFR	Code of Federal Regulations
CRD	contractor requirements document
DOE	U.S. Department of Energy
ES&H	environmental safety and health
FPD	Federal Project Director
IAEA	International Atomic Energy Agency

IPT	Integrated Project Team
ISMS	Integrated Safety Management System
ISO	International Organization for Standardization
M&TE	measuring and test equipment
NDE	Non-Destructive Examination
NEPA	*National Environmental Policy Act of 1969*
NQA	Nuclear Quality Assurance
OECM	Office of Engineering and Construction Management
OMB	Office of Management and Budget
PEP	project execution plan
PMI	Project Management Institute
PMBOK	Project Management Body of Knowledge
QA	quality assurance
QAP	quality assurance plan
QC	quality control
RIDS	records inventory and disposal schedule
S/CI	suspect/counterfeit item
SMS	Safety Management System
SQA	software quality assurance
SSC	structures, systems, and components
WBS	work breakdown structure

6.0 DEFINITIONS

> Note: Sources for many of the definitions in this section are the DOE Orders. Refer to the DOE Directives Management System for additional definitions of items, terms, and concepts.

<u>Federal Project Director (FPD)</u>. The individual responsible and accountable to the Acquisition Executive/Program Secretarial Officer for project execution; one who is responsible for the management of services provided to DOE on a specific project, beginning at the start of design and continuing through the completion of construction, for planning, organizing, directing, controlling, and reporting on the status of the project. Responsibilities include developing and maintaining the project management plans; managing project resources; establishing and implementing management systems, including performance measurement systems; and approving and implementing changes to project baselines. (DOE O 361.1A)

Integrated Project Team. A cross-functional group organized for the specific purpose of delivering a project to an external or internal customer. (DOE O 413.3A)

Project. A unique effort that supports a program mission having defined points for starting and ending, undertaken to create a product, facility, or system and containing interdependent activities planned to meet a common objective or mission. A project is a basic building block (in relation to a program) that is individually planned, approved, and managed. A project is not constrained to any specific element of the budget structure (e.g., operating expense, plant, or capital equipment). Projects include planning and execution of construction, assembly, renovation, modification, environmental restoration, decontamination and decommissioning, large capital equipment, and technology development activities. Work that does not include the above elements–e.g., basic research, grants, ordinary repairs, maintenance, and operation of facilities–are not considered projects. However, these activities can be managed as projects. (DOE O 413.3A)

Quality Control. The organization or group typically responsible for quality verification, inspection, documentation, and surveillance of hardware, including SSCs and services.

QA Plan. The document describing the QA program (requirements) the project will implement. The QA plan typically includes a matrix of the QA requirements and the associated implementing procedures used by the project.

QA Program. The overall program or management system established to assign responsibilities and authorities, define policies and requirements, and provide for the performance and assessment of work. (10 CFR 830.3)

7.0   REFERENCES

- 10 CFR 63, "Disposal of High-Level Radioactive Wastes in a Geologic Repository at Yucca Mountain, Nevada," Code of Federal Regulations, as amended.

- 10 CFR 830, Subpart A, "Quality Assurance Requirements," Code of Federal Regulations, as amended.

- ASME-NQA-1-2000, *Quality Assurance Requirements for Nuclear Facility Applications*, American Society of Mechanical Engineers, International, New York, New York.

- ASME-NQA-1-2004, *Quality Assurance Requirements for Nuclear Facility Applications*, American Society of Mechanical Engineers, International, New York, New York.

- DOE O 413.3A, 2006, *Program and Project Management for the Acquisition of Capital Assets*, Change No. 1, U.S. Department of Energy, Office of Management, Budget and Evaluation, Washington, D.C.

- DOE O 414.1C, 2005, *Quality Assurance*, U.S. Department of Energy, Office of Health, Safety and Security, Washington, D.C.

- ISO 9001:2000, *Quality Management Systems, International Organization for Standardizatio*n, Geneva, Switzerland.

- *National Environmental Policy Act of 1969*, 42 U.S.C. 4321-4347, as amended.

APPENDIX A. DOE Directives and Guides Related to Quality Assurance

Directive Number	Directive Title	Purpose
DOE O 413.3A	*Program and Project Management for the Acquisition of Capital Assets*	To provide project management direction for the acquisition of capital assets with the goal of delivering projects on schedule, within budget, and fully capable of meeting mission performance, safeguards and security, and environmental, safety, and health standards.
DOE G 414.1-1B	*Management Assessment and Independent Assessment Guide*	To provide information on establishing processes and performing effective assessments when required to perform management and independent assessments per DOE Policies, regulations, and Orders.
DOE G 414.1-2A	*Quality Assurance Management System Guide for Use with 10 CFR 830 Subpart A, Quality Assurance Requirements, and DOE O 414.1C, Quality Assurance*	To provide information on principles and practices used to establish and implement an effective quality assurance program or quality management system in accordance with the requirements of 10 CFR 830 Subpart A and DOE O 414.1C.
DOE G 414.1-3	*Suspect/Counterfeit Items Guide for Use with 10 CFR 830 Subpart A, Quality Assurance Requirements, and DOE O 414.1B, Quality Assurance*	To assist in mitigating the safety threat of suspect/counterfeit items (S/CI).
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*	To provide acceptable methods for implementing the safety software quality assurance requirements of DOE O 414.1C.
DOE G 414.1-5	*Corrective Action Program Guide*	To assist in the development, implementation, and followup of corrective action programs utilizing the feedback and improvement core safety function within DOE's Integrated Safety Management System (ISMS).
DOE O 414.1C	*Quality Assurance*	To ensure that the quality of products and services meets or exceeds the customers' expectations.

APPENDIX B. Voluntary Consensus Standards

Office of Management and Budget (OMB) Circular A-119 directs Federal agencies, like the U.S. Department of Energy (DOE), to use voluntary consensus standards. Voluntary consensus standards are considered voluntary, in that users select the one standard or combination of standards that best serves their purposes. Once selected and incorporated into licensing documents or contracts, the standard or standards become mandatory for the work the user designates. Voluntary consensus standards are consensus because "standards bodies" (e.g., American National Standards Institute [ANSI]/American Society of Mechanical Engineers [ASME] and the International Organization for Standardization [ISO]) consisting of private sector and federal representatives plan, develop, establish, and coordinate them.

Voluntary consensus standards provide detailed information and guidance on "how to" meet requirements. There are many voluntary consensus standards from which to select, each with a different focus and constituency. The most widely accepted and used are (1) ANSI/ASME NQA-1; (2) ISO 9000 series; (3) International Atomic Energy Agency (IAEA) 50-SG-Q Safety Guide Series; and (4) the Project Management Institute's (PMI) Project Management Body of Knowledge (PMBOK).

ANSI/ASME NQA-1

NQA-1 is a *management system* organized into 18 criteria (like 10 CFR 50, Appendix B and 10 CFR 63.142). As stated in ASME, "The Standard reflects industry experience and current understanding of the quality assurance requirements necessary to achieve safe, reliable, and efficient utilization of nuclear energy, and management and processing of radioactive materials. The Standard focuses on the achievement of results, emphasizes the role of the individual and line management in the achievement of quality, and fosters the application of these requirements in a manner consistent with the relative importance of the item or activity." NQA-1 is primarily a nuclear-related standard, but can be used in non-nuclear applications as well.

ISO 9001

ISO 9001 is a *management system* consisting of eight quality management principles. According to ISO, "ISO 9001 specifies requirements for a quality management system for any organization that needs to demonstrate its ability to consistently provide a product that meets customer and applicable regulatory requirements and aims to enhance customer satisfaction. The standard is used for certification/registration and contractual purposes by organizations seeking recognition of their quality management system." ISO 9001 is a manufacturing/industrial-oriented standard with nuclear and non-nuclear application.

IAEA Safety Guide Series 50-SG-Q

IAEA Safety Guide Series 50-SG-Q is a *management system* organized into 10 criteria (like IAEA QA Code 50-C-Q, DOE Order 414.1C, and 10 CFR 830 Subpart A). In the IAEA's words, "The Safety Guides are issued to describe to Member States acceptable methods of

implementing particular parts of the relevant Codes." IAEA standards 50-SG-Q are primarily nuclear-related, but can be used in non-nuclear applications as well.

PMI Project Management Body of Knowledge

The PMBOK represents an extensive collection of project management standards, including QA. The PMI standards focus exclusively on project management and have broad industrial, manufacturing, nuclear, and non-nuclear application.

Several voluntary consensus standards contain matrices that provide guidance to users who elect to use another standard to meet the project-specific QA program requirements. A listing of where these matrices can be found is provided below.

- ASME NQA-1-2004, Part IV, Subpart 4.5, "Application Guide on the Use of NQA-1-2000 for Compliance With Department of Energy Quality Assurance Requirements 10 CFR 830 Subpart A and the DOE O 414.1C"

- ASME NQA-1-2004, Part IV, Subpart 4.3, "Guide to Modification of an ISO 9001-2000 Quality Program to Meet NQA-1-2000 Requirements"

- ANSI/ISO/ASQ Q9001-2000, "Annex A, Correspondence Between ISO 9001:2000 and ISO 14001:1996"

- ANSI/ISO/ASQ Q9001-2000, "Annex B, Correspondence Between ISO 9001:2000 and ISO 9001:1994"

- ANSI/ASQ E4-2000, "Annex C, Crosswalk Between ANSI/ASQ E4 and ISO 9001"

Note: When using these matrices as guidance, it is important to note the version number of the source document (e.g., DOE O 414.1A versus DOE O 414.1C) to ensure that all applicable requirements are considered.

APPENDIX C. Quality Assurance Attributes/Characteristics, and Identification of Value Added Matrix

This appendix shows the value added by elements of a QA Program. It also illustrates the similarities and differences between DOE's QA requirements contained in 10 CFR 830 Subpart A and DOE O 414.1C, and two voluntary consensus standards, ISO 9001:2000 and NQA-1-2000.

DOE O 414.1C and 10 CFR 830 Subpart A QA Criterion	Attributes/Characteristics	Value Added	ISO 9001:2000	NQA-1-2000
PROGRAM Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing work Establish management processes, including planning, scheduling, and providing resources for work	Organizational structure • Organizational Chart • Defining Document Functional Responsibilities & Levels of Authority & Interfaces • Defined roles, responsibilities, authorities, and accountabilities, for workers • Interfaces are defined • Identification of senior management position responsible for the development, implementation, assessment, maintenance and improvement of the Quality Assurance Plan (QAP) • Endorsement of QAP by senior management • Autonomy of Quality personnel from line management and access to senior management • Identify lines of communication Management Process • Requirements are captured in – QA Order/QA Rule and other applicable contractual requirements – Requirements built into Management System (First order policy & procedures applicable to the staff) • QA policy and objectives support management and customer mission areas – Allows for the application of a graded	Confidence that there is a structure to implement work Increased assurance of compliance/legal requirements Senior management accountability/Line management responsibility • Clear roles and responsibilities • Balanced priorities Provides increased assurance product/service integrity Only appropriate levels of controls are applied (graded approach) Communication and resolution of issues is clearly defined Effective and economical use of manpower, equipment, facilities, and money Future opportunities, problems, and obstacles are anticipated Current decisions made to support future goals and objectives Clearly defined objectives help motivate people Sound procedures ensure consistency in performing repetitive work	4.0 Quality Management System 4.1 Quality Management System- General Requirements 4.2 Documentation Requirements -General 4.2.2 Quality Manual 5.0 Management Responsibility 5.1 Management Commitment 5.3 Quality Policy 5.4.1 Quality Objectives 5.4.2 Quality Management System Planning 5.5.1 Responsibility and Authority 5.5.2 Management Representative 5.5.3 Internal Communication 5.6.1 Management Review - General 5.6.2 Review of Input 5.6.3 Review Output 6.1 Provision of Resources 6.2.1 Human Resources-General	1. Organization 2. Quality Assurance Program

DOE O 414.1C and 10 CFR 830 Subpart A QA Criterion	Attributes/Characteristics	Value Added	ISO 9001:2000	NQA-1-2000
	approach – Rigor of implementation based on risk, consequence and cost • Integration of ISM principles into QAP implementing processes • Annual planning and budgeting processes – Links to highest level of mission, goals and objectives of organization – Provided necessary resource allocation for Quality program implementation	Meet or exceed customer expectations	6.3 Infrastructure 6.4 Work Environment 7.1 Planning of Product Realization 7.2.1 Determination of Requirements Related to the Product 7.2.2 Review of Requirements Related to the Product 7.2.3 Customer Communication 8.2.1 Monitoring and Measurement of Customer Satisfaction 8.2.3 Monitoring and Measurement of Processes 8.4 Analysis of data 8.5.1 Continual Improvement	
PERSONNEL TRAINING AND QUALIFICATIONS Train and qualify personnel to be capable of performing assigned work Provide continuing training to personnel to maintain job proficiency	Training requirements clearly defined • Regulatory drivers and • Job requirements analyzed Functional training, Certification and Qualification program Responsibility for training and development processes, tools, and documentation is identified • Training program includes minimum training, continuing training and acceptable mode of delivery • Training and Qualification—requirements for each employee are derived from procedures and documented Competence commensurate with responsibilities Documented training and qualification procedures and guidelines	Management and customer have confidence that personnel are trained and qualified to work effectively and safely Provides systematic processes and tools for training Integrated hiring practices and training processes Improved knowledge, attitudes, and skills of workforce • Regulatory requirements are met Documented procedures simplify training	6.2.2 Competence, Awareness and Training	2. Quality Assurance Program

DOE O 414.1C and 10 CFR 830 Subpart A QA Criterion	Attributes/Characteristics	Value Added	ISO 9001:2000	NQA-1-2000
	Line managers responsible for ensuring staff are trained & qualified Periodic reviews of training assignments conducted by line management Training measures and metrics developed			
QUALITY IMPROVEMENT Establish and implement processes to detect and prevent quality problems Identify, control, and correct items, services, and processes that do not meet established requirements Identify the causes of problems and include prevention of recurrence as a part of corrective action planning Review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement	Data from assessment processes • Monitoring process performance/efficiency • Metrics to monitor continuous improvement • Input from Lessons Learned/Best Practices • DOE/HQ, S/CI, defective items, safety alert dissemination Corrective Action Management Program for process issues contains processes for identification, control, correction prevention of recurrence, extent and significance determination, and defines reporting requirements Documented processes and system which allow for tracking and trending and provides input to the lessons learned program Process for identification of nonconforming items, administrative, physical segregation, tagging, etc. Effective disposition (use-as-is, repair, rework, scrap, etc.) Personnel performing disposition have discipline specific competence Defined responsibility and authority for evaluation and disposition of nonconformance • Addresses causal analysis requirements including methods, types, rigor, and binning issues into categories Follow-up performed to verify completion of	Feedback and continuous improvement Standardized processes Improved communication Problems prevented initially and/or from recurring Data driven management decisions Improved process performance Intensifies focus and resources on issue identification and prevention vs. issue resolution Prompt, decisive steps to correct matters that are out of control Defective items managed and prevented from getting into processes	8.3 Control of Nonconforming Product 8.5.2 Corrective Action 8.5.3 Preventive Action	2. Quality Assurance Program 15 Control of Nonconforming Items 16 Corrective Action

DOE O 414.1C and 10 CFR 830 Subpart A QA Criterion	Attributes/Characteristics	Value Added	ISO 9001:2000	NQA-1-2000
	corrective action Customer feedback loop established			
DOCUMENTS AND RECORDS Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design Specify, prepare, review, approve, and maintain records	**Document Control** Provides document control system Provides for preparing, distributing and closeout of documents • Provides revision control and receipt verification processes • Documents reviewed and approved for release by authorized personnel • Latest documents to control work are available at the work location • Establishes a document hierarchy **Records** A formal records management program is implemented that: • Defines and specifies records that provide objective evidence of product or service quality • Provides for authentication of records • Establishes Records Inventory and Disposal Schedule requirements • Provides for storage and retrieval • Supports project needs • Provides objective evidence that work controls and processes have been implemented	Integrity of documentation is established Current and effective documents are used to perform work Documentation supports the decrease of re-work and the elimination of performing the wrong work because of the verification and validation of pre-work documentation Records documenting work performed are readily available and retrievable Assurance that records are available when needed Provides complete and accurate records to protect the interests of the enterprise and it's customers Formal and consistent method for structuring documents	4.2.3 Control of Documents 4.2.4 Control of Records	5. Instructions, Procedures and Drawings 6 Document Control 17 Quality Assurance Records
WORK PROCESSES Perform work consistent with technical standards, administrative controls, and hazard controls adopted to meet regulatory or contract requirements using approved instructions,	Identify method for work to be controlled Work documents are developed for work activities: • Based on integrated safety and security principles which identify risks, hazards, and required controls • Are validated and verified to ensure identified hazards are addressed with appropriate controls	Work force is included in walk down of processes and working conditions Hazards are identified, analyzed, and mitigated; work instructions are generated to ensure work can be performed safely and securely Work processes defined in the three major operating levels (enterprise/facility/activity) within the	7.5.1 Control of Production and Service Provision 7.5.2 Validation of Processes for Production and Service Provision 7.5.3 Identification and Traceability 7.5.4 Customer Property	5. Instructions, Procedures and Drawings 8. Identification and Control of Items 12. Control of Measuring and Test Equipment 13. Handling, Storage

DOE O 414.1C and 10 CFR 830 Subpart A QA Criterion	Attributes/Characteristics	Value Added	ISO 9001:2000	NQA-1-2000
procedures, etc. Identify and control items to ensure their proper use Maintain items to prevent their damage, loss, or deterioration Calibrate and maintain equipment used for process monitoring or data collection	Work process control provides: • Identification and traceability control when required • Control of special processes where qualified personnel and qualified procedures are required • Control for handling, storing, cleaning, packaging, shipping, and preserving of items to prevent damage or loss and minimize deterioration • Equipment used to collect data or take measurements for quality purposes is identified, controlled, calibrated when necessary, adjusted, and maintained to required accuracy limits	enterprise Present infrastructure enables effective planning, safe work execution and continuous improvement Ensures work is performed with calibrated M&TE Ensures items are proper and in good condition Ensures that only correct and accepted items are used or installed Specified quality is achieved where quality of the product cannot be readily determined by inspection or test (special process control) Cost avoidance to replace lost, damaged, or deteriorated items Accurate and reliable data used for product acceptance or process monitoring Work performed safely and in compliance with orders/laws Work is accomplished in accordance with requirements	7.5.5 Preservation of Product 7.6 Control of Monitoring and Measuring Devices 8.1 Measurement, Analysis and Improvement—General 8.2.4 Monitoring and Measurement of Product	and Shipping 14. Inspection, Test and Operating Status Part 1 Introduction
DESIGN Design items and processes using sound engineering/ scientific principles and appropriate standards Incorporate applicable requirements and design bases in design work and design changes	Define the design process Design control applied to manufacturing or production systems (process design) as well as hardware items Identify the design authority Quality Engineering function defined and implemented throughout the design process Definition of the function of the structure, system, process, component, hardware and software • Performance requirements	The SSC will perform its intended function and support the mission Modifications and changes for procurements during construction will be kept to a minimum Overall cost will be lower Schedule will be maintainable Failures can be quickly analyzed and addressed Future changes will be able to be made more efficiently	7.3.1 Design and Development Planning 7.3.2 Design and Development Inputs 7.3.3 Design and Development Outputs 7.3.4 Design and Development Review 7.3.5 Design and Development Verifications 7.3.6 Design and Development	3. Design Control

DOE O 414.1C and 10 CFR 830 Subpart A QA Criterion	Attributes/Characteristics	Value Added	ISO 9001:2000	NQA-1-2000
Identify and control design interfaces Verify/validate the adequacy of design products using individuals or groups other than those who performed the work Verify/validate work before approval and implementation of the design	• Applicable codes, standards, and design criteria • Design conditions • Interfaces defined • S/CI considerations Selection of design inputs documented, reviewed, and approved Design analysis sufficiently detailed to allow independent verification Computer programs used for design analysis are pre-verified and documented for acceptability Safety design subject to DOE O 414.1C software QA Design adequacy independently verified Define design verification methods Design changes justified and controlled commensurate with controls applied to the original design Configuration management program established commensurate with the beginning of final design Interface control established for design information transmitted between/within organizations Design process documented, approved, and controlled (see SQA section below) Design documentation and records allow retracing important steps in the design process As-built and modification documents accurately reflect facility configuration	Provides objective evidence for future reviews/assessments Demonstrates the ability of the Design process to meet customer expectations S/CI program integration into the engineering process Final design meets design input criteria Design basis is maintained to support evaluation of future changes to operating facility configuration Configuration is maintained consistent with design requirements	Validation 7.3.7 Control of Design and Development Changes	
PROCUREMENT Procure items and services that meet established requirements and	Definition of desired product/work • Technical specs/critical attributes • Quality requirements • Vendor access • Delivery needs • Cost	Item performs satisfactorily when placed in service and incorrect or defective items are prevented from entering the process Minimal rework	7.4.1 Purchasing Process 7.4.2 Purchasing Information 7.4.3 Verification of Purchased Product	4. Procurement Document Control 7 Control of Purchased Items and Services

DOE O 414.1C and 10 CFR 830 Subpart A QA Criterion	Attributes/Characteristics	Value Added	ISO 9001:2000	NQA-1-2000
perform as specified Evaluate and select prospective suppliers on the basis of specified criteria Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services	• S/CI clause Qualified vendors (audits/history) • Selection process/criteria • Supplier (QAP) evaluation process • Oversight during manufacture of critical items • On time delivery Receipt inspection for items • Critical attributes • Supplier submittals Evaluation for services Certification program for lead auditors who evaluate suppliers Commercial grade item dedication process S/CI program prevention tools (S/CI clause, inspection attributes, etc.) Procurement requirements are commensurate with the risk of the purchased items or services to the project or activity Regulatory requirements are contractually flowed down to contractors and lowest levels of suppliers (e.g., 10 CFR Parts 851; 830)	Reliability Low overall cost Elimination of bad suppliers from business Project schedules and costs maintained S/CI program integration into the procurement process Customer/supplier partnerships Clear communication of expectations between customer and supplier Engineering involvement in procurement process		
INSPECTION AND ACCEPTANCE TEST Inspect and test specified items, services, and processes using established acceptance and performance criteria Calibrate and maintain equipment used for inspections and tests	Development of a program that critically evaluates items manufactured or purchased to assure they meet the criteria of requirements for their intended use including: • Incorporation of S/CI criteria into inspection processes • Evaluation and documentation of the rational for required inspection/acceptance and the type of results required • Inspection and acceptance techniques that are traceable to acceptable standards • Minimization of measurement uncertainty • Documentation of individual item requirements and status of	Consistency in the Inspection and Acceptance Program Documentation of inspection and test results Equipment that is in calibration or certification Certifications are traceable to standards used S/CI program integration into the inspection process The correct item performs satisfactorily when placed in service	7.5.3 Identification and Traceability 7.6 Control of Monitoring and Measuring Devices	10. Inspection 11. Test Control 12. Control of Measuring and Test Equipment

DOE O 414.1C and 10 CFR 830 Subpart A QA Criterion	Attributes/Characteristics	Value Added	ISO 9001:2000	NQA-1-2000
	inspection/acceptance • Procurement of goods • Process to verify integrity of work products – QC/Non-Destructive Examination (NDE)/Peer Review for products Calibration Program • Use of M&TE in accordance with Sec. 5 (Work Processes)			
MANAGEMENT ASSESSMENT Ensure that Managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives	Managers assess their processes to ensure results contribute to improved performance of the programs, systems, and work processes Managers receive timely, objective feedback from assessments Assessment feedback is a tool used to addresses the effectiveness of applicable policies, requirements, standards, processes, and procedures, and their implementation Assessment process is planned, coordinated and integrated to promote efficiency and effectiveness of assessments Organizational culture is one of seeking quality improvement, and assessments are accepted as contributors to the improvement culture Assessment processes and results support management's goal to protect people and the environment from harm Quality problems (including Environmental Safety and Health [ES&H] issues) are identified for resolution by management Management takes timely and appropriate actions to resolve quality problems	Results oriented management system Introspective self-analysis to determine whether the management infrastructure is properly focused on achieving desired results Mechanism to ensure that the organizations products and services are meeting the customer's requirements/expectations Promotes continuous improvement objectives Provides objective evidence of those areas needing improvement Managers more knowledgeable of organization's performance and pressing problems Enhanced line management ownership in quality of work processes and products	5.6.1 Management Review—General 5.6.2 Review Input 5.6.3 Review Output 7.2.3 Customer Communication 8.2.1 Monitoring and Measurement Customer Satisfaction 8.2.3 Monitoring and Measurement Processes 8.4 Analysis of Data 8.5.1 Continual Improvement	2. Quality Assurance Program

DOE O 414.1C and 10 CFR 830 Subpart A QA Criterion	Attributes/Characteristics	Value Added	ISO 9001:2000	NQA-1-2000
INDEPENDENT ASSESSMENT Plan and conduct independent assessments to measure item and service quality and the adequacy of work performance and to promote improvement Establish sufficient authority and freedom from line management for independent assessment teams Ensure that persons conducting independent assessments are technically qualified and knowledgeable in the areas to be assessed	Evaluates the performance of work processes with regard to requirements, compliance and expectations for performing the work and achieving the goals of the organization Establishes compliance as a minimum requirement and incorporates effectiveness and performance based assessment methods Assessors • Have no direct responsibility for the work or organization being audited • Verify effectiveness of corrective actions	Improved product/service performance and process effectiveness Provides senior executive management information on operational activities and programs Continuous improvement is facilitated by identifying ways programs, systems and processes can be improved Builds confidence that management can meet customer expectations Measures QAP implementation and effectiveness Results may identify areas for improvement and status of compliance Unbiased assessments May provide justification for reduction in the number of total assessments needed May provide information to develop effective corrective actions	5.0 Management Responsibility 5.5.1 Responsibility and Authority 5.5.2 Management Representative 5.6.1 Management Review—General 8.2.2 Internal Audits 8.3 Control of Nonconforming Product 8.4 Analysis of Data 8.5.1 Continual Improvement 8.5.2 Corrective Action 8.5.3 Preventive Action	18. Audits

APPENDIX D. Suggested QA Activities to Support Critical Decision Requirements

Table D-1. CD-0 - QA Activities

CD-0 Requirements	QA Criterion	QA Activities
Perform Pre-conceptual Planning Activities	1	Determine whether adequate resources have been identified to describe management processes, including planning, scheduling, and providing funding for the work.
Prepare Mission Need Statement	N/A	(See additional DOE Guides)
Prepare Tailoring Strategy, if required	4	Ensure that processes for preparation, review, approval, issuance, use, and revision of documents that prescribe processes, requirements, and design are implemented.
	6	Ensure that a design process that provides appropriate control of design inputs, outputs, verification, configuration and design changes, and technical and administrative interfaces is implemented.
Perform Mission Validation Independent Project Review on all Major System Projects	10	Ensure that lines of inquiry for the review are developed and that QA expertise is utilized. Note: Ensure that the review team has the right skill mix, including a review team member assigned to review QA-related lines of inquiry. For larger, more complex projects, one or more of the team members should have QA expertise and focus on QA-related lines of inquiry. (See additional DOE Guides)
Prepare Program Requirements Document (for National Nuclear Security Administration only)	4	Ensure that processes for preparation, review, approval, issuance, use, and revision of documents that prescribe processes, requirements, and design are implemented.
Evaluate Projects for Information Technology Elements within Departmental Enterprise Architecture Framework	N/A	None

Table D-2. CD-1 - QA Activities

CD-1 Requirements	QA Criterion	QA Activities
Prepare Conceptual Design Report	4	Ensure that processes for preparation, review, approval, issuance, use, and revision of documents that prescribe processes, requirements, and design are implemented.
	4	Ensure that processes for specification, preparation, review, approval, and maintenance of records are implemented.
	6	Ensure that a design process is in place that provides appropriate control of design inputs, outputs, verification, configuration and design changes, and technical and administrative interfaces.
	6	Ensure that verification of design activities is covered by a documented process.

Table D-2. CD-1 - QA Activities

CD-1 Requirements	QA Criterion	QA Activities
Prepare Acquisition Strategy	4	Ensure that processes for preparation, review, approval, issuance, use, and revision of documents that prescribe processes, requirements, and design are implemented.
	7	Ensure that QA expertise is utilized to assist with procurement (acquisition) planning.
	7	Ensure that a procurement (acquisition) process to ensure items and/or services provided by suppliers meets the requirements and expectations of the end user is implemented. Note: Quality level determination should be factored into the acquisition strategy, especially when procuring services to perform work. (See additional DOE Guides)
Comply with One-for-One Replacement Legislation	N/A	None
Prepare a Preliminary Project Execution Plan	4	Ensure that processes for preparation, review, approval, issuance use, and revision of documents that prescribe processes, requirements, and design are implemented Notes: (1) Significant QA participation is emphasized in the development and review of this document. Most projects with a PEP have a robust preliminary QA program. (2) Need to ensure that sufficient quality resources are planned and included in the project baseline to support quality systems, processes, and procedures required for design work after CD-1 approval. (See additional DOE Guides)
Approve Appointment of Federal Project Director	2	Ensure that policies and procedures that describe personnel selection, training, and qualification requirements are implemented.
Establish and Charter Integrated Project Team	2	Ensure that policies and procedures that describe personnel selection, training, and qualification requirements are implemented.
	2	Ensure that a QA representative (with specific QA expertise) is a member of the IPT. In instances where it is impractical to include Federal QA expertise, ensure QA functional support on the IPT. (See additional DOE Guides)
Conduct Design Review of Conceptual Design	2	Ensure that personnel achieve initial proficiency; maintain proficiency; and adapt to changes in technology, methods, or job responsibilities.

Table D-2. CD-1 - QA Activities

CD-1 Requirements	QA Criterion	QA Activities
	6	Ensure that processes for conducting design reviews are implemented to ensure that the design inputs were correctly selected and incorporated; assumptions necessary to perform the design were adequately described, reasonable, and where applicable, identified as requiring confirmation as the design proceeds; appropriate design methods, and computer programs when applicable, were used; design outputs are reasonable compared to design inputs; and the necessary design inputs from interfacing organizations were specified in the design documents.
	4	Ensure that processes for preparation, review, approval, issuance, use, and revision of documents that prescribe processes, requirements, and design are implemented.
	10	Ensure that persons conducting reviews are technically qualified and knowledgeable in the areas to be reviewed.
	10	Ensure that persons conducting independent reviews have sufficient authority and freedom from line management. Note: In addition to participating as a formal reviewer, focusing specifically on QA-related lines of inquiry, utilize QA expertise to help determine appropriate skill mix for review team, and to assist FPD with conducting the design review.
Prepare Project Data Sheet for Line Item Projects	4	Ensure that processes for preparation, review, approval, issuance, use, and revision of documents that prescribe processes, requirements, and design are implemented.
	4	Ensure that processes for specification, preparation, review, approval, and maintenance of records are implemented.
Approve Long-Lead Procurements, if necessary	4	Ensure that processes for specification, preparation, review, approval, and maintenance of records are implemented.
	5	Ensure that work processes consist of a series of actions planned and carried out by qualified personnel using approved procedures, instructions, and equipment under administrative, technical, and environmental controls.
	7	Ensure that the selection of procurement requirements is commensurate with the importance of the end use of the purchased item or service and that management controls exist for DOE procurement and subcontracts. Note: QA expertise should be utilized to ensure that required QA requirements are adequately incorporated into contracts, subcontracts, and other vendor procurement documents. This should be done early in the procurement process and checked prior to contract award.

Table D-2. CD-1 - QA Activities

CD-1 Requirements	QA Criterion	QA Activities
Implement Integrated Safety Management	1	Ensure that the QA program complements and is integrated with the Safety Management System (SMS).
	1	Ensure that the QA program provides processes and tools for ensuring that Integrated Safety Management System (ISMS) objectives are achieved.
	5	Ensure that procedures, work instructions, or other appropriate means used to define work processes are documented and controlled.
	5	Ensure that the control of processes, skills, hazards, and equipment are clearly specified, understood, and fully documented.
Prepare Environmental Documents including National Environmental Policy Act (NEPA) Strategy and Analyses, and Permit Applications	4	Ensure that processes for specification, preparation, review, approval, and maintenance of records are implemented.
	4	Ensure that processes for preparation, review, approval, issuance, use, and revision of documents that prescribe processes, requirements, and design are implemented.
	5	Ensure that procedures, work instructions, or other appropriate means used to define work processes are documented and controlled.
Document High Performance Sustainable Building Considerations, as appropriate	6	Ensure that applicable design inputs (such as design bases, conceptual design reports, performance requirements, regulatory requirements, codes, and standards) are controlled (i.e., identified and documented and that changes from approved design inputs and reasons for the changes are identified, approved, documented, and controlled). (See additional DOE Guides)
Prepare Preliminary Security Vulnerability Assessment Report	4	Ensure that processes for specification, preparation, review, approval, and maintenance of records are implemented.
	4	Ensure that processes for preparation, review, approval, issuance, use, and revision of documents that prescribe processes, requirements, and design are implemented.
Prepare Initial Cyber Security Plan for Information Technology Projects	5	Ensure that procedures, work instructions, or other appropriate means used to define work processes are documented and controlled.
	5	Ensure that work processes consist of series of actions planned and carried out by qualified personnel using approved procedures, instructions, and equipment under administrative, technical, and environmental controls. (See additional DOE Guides)
Prepare Conceptual Safety Design Report for Hazard Category 1, 2, and 3 Nuclear Facilities	4	Ensure that processes for preparation, review, approval, issuance, use, and revision of documents that prescribe processes, requirements, and design are implemented.
	4	Ensure that processes for specification, preparation, review, approval, and maintenance of records are implemented.

Table D-2. CD-1 - QA Activities

CD-1 Requirements	QA Criterion	QA Activities
	6	Ensure that design processes that provide appropriate control of design inputs, outputs, verification, configuration and design changes, and technical and administrative interfaces are implemented.
	6	Ensure that processes for verification of design activities are implemented
Prepare Preliminary Hazard Analysis Report	1	Ensure that processes (which adequately addresses hazards) for grading the application of requirements are implemented.
	4	Ensure that processes for preparation, review, approval, issuance, use, and revision of documents that prescribe processes, requirements, and design are implemented.
Prepare Preliminary Safety Validation Report	4	Ensure that processes for preparation, review, approval, issuance, use, and revision of documents that prescribe processes, requirements, and design are implemented.
	6	Ensure that work is verified/validated before approval and implementation of the design.
Determine Quality Assurance Program is Acceptable and Continues to Apply	1	Ensure that the QA program describes the established organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work.
	1	Ensure that adequate resources have been identified for quality program activities, such as planning, auditing, supplier qualification, technical document review, inspection, calibration, etc.
	9	Ensure that managers at every level periodically assess their organizations and functions to determine how well they meet customer and performance expectations and mission objectives, identify strengths or improvement opportunities, and correct problems. Notes: (1) In-process quality standards for design for constructability, maintainability, sustainability, etc should be established/defined to allow in-process assessments and surveillances prior to starting design activities. (2) Quality-level determinations and flow down of QA requirements should be evaluated. (3) The FPD/IPT should evaluate if a project-specific QA program is required.

Table D-3. CD-2 - QA Activities

CD-2 Requirements	QA Criterion	QA Activities
Establish Performance Baseline	4	Ensure that processes for document preparation, review, approval, and change control are implemented. (See additional DOE Guides)
Update Project Execution Plan	4	Ensure that processes for preparation, review, approval, issuance, use, and revision of documents that prescribe processes, requirements, and design are implemented. (See additional DOE Guides)
Employ Earned Value Management System	4	Ensure that processes for document preparation, review, approval, and change control are implemented. (See additional DOE Guides)
Perform Performance Baseline Validation External Independent Review or Performance Baseline Validation Independent Project Review	4	Ensure that processes for document preparation, review, approval, and change control are implemented.
	10	Ensure that processes to plan and conduct independent reviews to measure item and service quality and the adequacy of work performance and to promote improvement are implemented.
	10	Ensure that persons conducting reviews are technically qualified and knowledgeable in the areas to be reviewed.
	10	Ensure that persons conducting independent reviews have sufficient authority and freedom from line management. Note: Ensure that the review team has the right skill mix, including a review team member assigned to review QA-related lines of inquiry. For larger, more complex projects, one or more of the team members should have QA expertise and focus on QA-related lines of inquiry. (See additional DOE Guides)
Develop Independent Cost Estimate or Perform Independent Cost Review for Major System Projects	4	Ensure that processes for document preparation, review, approval, and change control are implemented.
	10	Ensure that processes to plan and conduct independent reviews to measure item and service quality and the adequacy of work performance and to promote improvement are implemented.
	10	Ensure that persons conducting reviews are technically qualified and knowledgeable in the areas to be reviewed.
	10	Ensure that persons conducting independent reviews have sufficient authority and freedom from line management. Note: Ensure that the review team has the right skill mix, including a review team member assigned to review QA-related lines of inquiry. For larger, more complex projects, one or more of the team members should have QA expertise and focus on QA-related lines of inquiry. (See additional DOE Guides)
Determine Quality Assurance Program is Acceptable and Continues to Apply	1	Ensure that the QA program describes the established organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work.

Table D-3. CD-2 - QA Activities

CD-2 Requirements	QA Criterion	QA Activities
	1	Ensure that adequate resources have been identified for QA program activities, such as planning, auditing, supplier qualification, technical document review, inspection, calibration, etc.
	9	Ensure that managers at every level are periodically assessing their organizations and functions to determine how well they meet customer and performance expectations and mission objectives, identify strengths or improvement opportunities, and correct problems. Notes: (1) In-process quality standards for design for constructability, maintainability, sustainability, etc should be established/defined to allow in-process assessments and surveillances prior to starting design activities. (2) Quality-level determinations and flow down of QA requirements should be evaluated. (3) The FPD/IPT should evaluate if a project-specific QA program is required.
Prepare Preliminary Design	2	Ensure that processes are implemented for personnel to achieve initial proficiency; maintain proficiency; and adapt to changes in technology, methods, or job responsibilities.
	4	Ensure that processes for preparation, review, approval, issuance, use, and revision of documents that prescribe processes, requirements, and design are implemented.
	4	Ensure that processes for specification, preparation, review, approval, and maintenance of records are implemented.
	6	Ensure that applicable design inputs (such as design bases, conceptual design reports, performance requirements, regulatory requirements, codes, and standards) are controlled (i.e., identified and documented and changes from approved design inputs and reasons for the changes are identified, approved, documented, and controlled).
	6	Ensure that design processes use sound engineering/scientific principles and appropriate standards; incorporate applicable requirements and design bases in design work and design changes; identify and control design interfaces; verify/validate the adequacy of design products using individuals or groups other than those who performed the work; verify/validate work before approval and implementation of the design.
	6	Ensure that processes for verification of design activities are implemented
Update Project Data Sheet, if applicable	4	Ensure that processes for preparation, review, approval, issuance, use, and revision of documents that prescribe processes, requirements, and design are implemented.
	4	Ensure that processes for specification, preparation, review, approval, and maintenance of records are implemented.

Table D-3. CD-2 - QA Activities

CD-2 Requirements	QA Criterion	QA Activities
Conduct Design Review of Preliminary Design	2	Ensure that processes are implemented for personnel to achieve initial proficiency; maintain proficiency; and adapt to changes in technology, methods, or job responsibilities.
	6	Ensure that processes for conducting design reviews are implemented to ensure that the design inputs were correctly selected and incorporated; assumptions necessary to perform the design were adequately described, reasonable, and where applicable, identified as requiring confirmation as the design proceeds; appropriate design methods, and computer programs when applicable, were used; design outputs are reasonable compared to design inputs; and the necessary design inputs from interfacing organizations were specified in the design documents.
	4	Ensure that processes for preparation, review, approval, issuance, use, and revision of documents that prescribe processes, requirements, and design are implemented.
	10	Ensure that persons conducting reviews are technically qualified and knowledgeable in the areas to be reviewed.
	10	Ensure that persons conducting independent reviews have sufficient authority and freedom from line management. Note: In addition to participating as a formal reviewer, focusing specifically on QA-related lines of inquiry, utilize QA expertise to help determine appropriate skill mix for review teams and to assist the FPD with conducting the design review.
Prepare Preliminary Safety Design Report	1	Ensure that processes (which adequately addresses hazards) for grading the application of requirements are implemented.
	4	Ensure that processes for preparation, review, approval, issuance, use, and revision of documents that prescribe processes, requirements, and design are implemented.
	4	Ensure that processes for specification, preparation, review, approval, and maintenance of records are implemented.
	6	Ensure that design processes that provide appropriate control of design inputs, outputs, verification, configuration and design changes, and technical and administrative interfaces are implemented.
Prepare Hazard Analysis Report	1	Ensure that processes (which adequately addresses hazards) for grading the application of requirements are implemented.
	4	Ensure that processes for preparation, review, approval, issuance, use, and revision of documents that prescribe processes, requirements, and design are implemented.
	6	Ensure that processes for appropriate control of design inputs, outputs, verification, configuration and design changes, and technical and administrative interfaces are implemented.

Table D-3. CD-2 - QA Activities

CD-2 Requirements	QA Criterion	QA Activities
Update Preliminary Security Vulnerability Assessment Report	4	Ensure that processes for preparation, review, approval, issuance, use, and revision of documents that prescribe processes, requirements, and design are implemented.
Update Initial Cyber Security Plan for Information Technology Projects	4	Ensure that processes for preparation, review, approval, issuance, use, and revision of documents that prescribe processes, requirements, and design are implemented.
Prepare Preliminary Safety Validation Report	1	Ensure that processes (which adequately addresses hazards) for grading the application of requirements are implemented.
	4	Ensure that processes for preparation, review, approval, issuance, use, and revision of documents that prescribe processes, requirements, and design are implemented.
Incorporate Preliminary Sustainable Environmental Stewardship-High Performance Sustainable Building provisions into Preliminary Design and Design Review	6	Ensure that applicable design inputs (such as design bases, conceptual design reports, performance requirements, regulatory requirements, codes, and standards) are controlled (i.e., identified and documented and changes from approved design inputs and reasons for the changes are identified, approved, documented, and controlled). (See additional DOE Guides)
Complete (or obtain approval of) Final National Environmental Policy Act (NEPA) Documentation	4	Ensure that processes for preparation, review, approval, issuance, use, and revision of documents that prescribe processes, requirements, and design are implemented.

Table D-4. CD-3 - QA Activities

CD-3 Requirements	QA Criterion	QA Activities
Complete and Review Final Design or Determine Design is Sufficiently Mature to Start Procurement or Construction	2	Ensure that processes are implemented for personnel to achieve initial proficiency; maintain proficiency; and adapt to changes in technology, methods, or job responsibilities.
	6	Ensure that applicable design inputs (such as design bases, conceptual design reports, performance requirements, regulatory requirements, codes, and standards) are controlled (i.e., identified and documented and changes from approved design inputs and reasons for the changes are identified, approved, documented, and controlled).

Table D-4. CD-3 - QA Activities

CD-3 Requirements	QA Criterion	QA Activities
	6	Ensure that processes for conducting design reviews are implemented to ensure that the design inputs were correctly selected and incorporated; assumptions necessary to perform the design were adequately described, reasonable, and where applicable, identified as requiring confirmation as the design proceeds; appropriate design methods, and computer programs when applicable, were used; design outputs are reasonable compared to design inputs; and the necessary design inputs from interfacing organizations were specified in the design documents.
	6	Ensure that design processes use sound engineering/scientific principles and appropriate standards; incorporate applicable requirements and design bases in design work and design changes; identify and control design interfaces; verify/validate the adequacy of design products using individuals or groups other than those who performed the work; verify/validate work before approval and implementation of the design.
	6	Ensure that processes for verification of design activities are implemented.
Update CD-2 Project Documentation and Required Approvals to Reflect Any Changes Resulting from Final Design, including the PEP, Performance Baseline, Project Data Sheet, etc.	4	Ensure that processes for preparation, review, approval, issuance, use, and revision of documents that prescribe processes, requirements, and design are implemented.
	4	Ensure that processes for document preparation, review, approval, and change control are implemented.
Perform External Independent Review for Construction or Execution Readiness	10	Ensure that processes to plan and conduct independent reviews to measure item and service quality and the adequacy of work performance and to promote improvement are implemented.
	10	Ensure that persons conducting reviews are technically qualified and knowledgeable in the areas to be reviewed.
	10	Ensure that persons conducting independent reviews have sufficient authority and freedom from line management. Note: Ensure that the review team has the right skill mix, including a review team member assigned to review QA-related lines of inquiry. For larger, more complex projects, one or more of the team members should have QA expertise and focus on QA-related lines of inquiry. (See additional DOE Guides)
Prepare Preliminary Documented Safety Analysis Report	1	Ensure that processes (which adequately addresses hazards) for grading the application of requirements are implemented.
	4	Ensure that processes for preparation, review, approval, issuance, use, and revision of documents that prescribe processes, requirements, and design are implemented.

Table D-4. CD-3 - QA Activities

CD-3 Requirements	QA Criterion	QA Activities
	4	Ensure that processes for specification, preparation, review, approval, and maintenance of records are implemented.
	6	Ensure that design processes that provide appropriate control of design inputs, outputs, verification, configuration and design changes, and technical and administrative interfaces are implemented.
Update Hazard Analysis Report and Obtain DOE Approval	1	Ensure that processes (which adequately addresses hazards) for grading the application of requirements are implemented.
	4	Ensure that processes for preparation, review, approval, issuance, use, and revision of documents that prescribe processes, requirements, and design are implemented.
	6	Ensure that design processes that provide appropriate control of design inputs, outputs, verification, configuration and design changes, and technical and administrative interfaces are implemented.
Update Preliminary Security Vulnerability Assessment Report	4	Ensure that processes for preparation, review, approval, issuance, use, and revision of documents that prescribe processes, requirements, and design are implemented.
Update Cyber Security Plan for Information Technology Projects	4	Ensure that processes for preparation, review, approval, issuance, use, and revision of documents that prescribe processes, requirements, and design are implemented.
	4	Ensure that processes for specification, preparation, review, approval, and maintenance of records are implemented.
Prepare Safety Evaluation Report	1	Ensure that processes (which adequately addresses hazards) for grading the application of requirements are implemented.
	4	Ensure that processes for preparation, review, approval, issuance, use, and revision of documents that prescribe processes, requirements, and design are implemented.
	4	Ensure that processes for specification, preparation, review, approval, and maintenance of records are implemented.
	6	Ensure that design processes that provide appropriate control of design inputs, outputs, verification, configuration and design changes, and technical and administrative interfaces are implemented.
Prepare Construction Project Safety and Health Plan	4	Ensure that processes for preparation, review, approval, issuance, use, and revision of documents that prescribe processes, requirements, and design are implemented.

Table D-4. CD-3 - QA Activities

CD-3 Requirements	QA Criterion	QA Activities
Incorporate Final Sustainable Environmental Stewardship-High Performance Sustainable Building Provisions into Final Design and External Independent Review	6	Ensure that applicable design inputs (such as design bases, conceptual design reports, performance requirements, regulatory requirements, codes, and standards) are controlled (i.e., identified and documented and changes from approved design inputs and reasons for the changes are identified, approved, documented, and controlled). (See additional DOE Guides)
Update Quality Assurance Program for Construction, Field Design Changes, and Procurement Activities	1	Ensure that the QA program describes the established organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work.
	9	Ensure that managers at every level are periodically assessing their organizations and functions to determine how well they meet customer and performance expectations and mission objectives, identify strengths or improvement opportunities, and correct problems. Note: This revision/update to the QA program should represent the final acquisition strategy and flow down of QA-related requirements.

Table D-5. CD-4 - QA Activities

CD-4 Requirements	QA Criterion	QA Activities
Verify Key Performance Parameters or Project Completion Criteria Have Been Met and Mission Requirements Achieved	3	Ensure that processes to identify, control, and correct items, services, and processes that do not meet established requirements are implemented.
	5	Ensure that work is performed consistent with technical standards, administrative controls, and hazard controls adopted to meet regulatory or contract requirements using approved instructions, procedures, etc.
Complete Readiness Assessment or Operational Readiness Review	3	Ensure that processes to identify, control, and correct items, services, and processes that do not meet established requirements are implemented.
	5	Ensure that the planned scope of work demonstrates that work prerequisites have been satisfied, personnel have been suitably trained and qualified, detailed implementing documents and management controls are available and approved.
	10	Ensure that persons conducting reviews are technically qualified and knowledgeable in the areas to be reviewed. Note: Ensure that the review team has the right skill mix, including a review team member assigned to review QA-related lines of inquiry. For larger, more complex projects, one or more of the team members should have QA expertise and focus on QA-related lines of inquiry.

Table D-5. CD-4 - QA Activities

CD-4 Requirements	QA Criterion	QA Activities
Issue Checkout, Testing, and Commissioning Plan	4	Ensure that processes for preparation, review, approval, issuance, use, and revision of documents that prescribe processes, requirements, and design are implemented.
	8	Ensure that performance expectations, acceptance criteria, inspections and tests, and hold points are identified/considered early in the design process and/or specified in the design output and procurement documents. Address the calibration of measuring and testing equipment (M&TE).
Issue Project Transition to Operations Plan	1	Ensure that processes to implement a quality management approach are established and implemented.
	4	Ensure that processes for preparation, review, approval, issuance, use, and revision of documents that prescribe processes, requirements, and design are implemented.
Issue Updated Quality Assurance Plan	1	Ensure that the QA program describes the established organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work.
	4	Ensure that processes for preparation, review, approval, issuance, use, and revision of documents that prescribe processes, requirements, and design are implemented.
Revise Environmental Management System	4	Ensure that processes for preparation, review, approval, issuance, use, and revision of documents that prescribe processes, requirements, and design are implemented.
	5	Ensure that actions are planned and carried out by qualified personnel using approved procedures, instructions, and equipment under administrative, technical, and environmental controls.
Prepare Documented Safety Analysis Report with Technical Safety Requirements for Hazard Category 1, 2, and 3 Nuclear Facilities	4	Ensure that processes for preparation, review, approval, issuance, use, and revision of documents that prescribe processes, requirements, and design are implemented.
	6	Ensure that applicable design inputs (such as design bases, conceptual design reports, performance requirements, regulatory requirements, codes, and standards) are controlled (i.e., identified and documented and that changes from approved design inputs and reasons for the changes are identified, approved, documented, and controlled).
Update Construction Project Safety and Health Plan	4	Ensure that processes for preparation, review, approval, issuance, use, and revision of documents that prescribe processes, requirements, and design are implemented.
	5	Ensure that actions are planned and carried out by qualified personnel using approved procedures, instructions, and equipment under administrative, technical, and environmental controls.
Finalize Hazard Analysis Report	1	Ensure that processes (which adequately addresses hazards) for grading the application of requirements are implemented.

Table D-5. CD-4 - QA Activities

CD-4 Requirements	QA Criterion	QA Activities
	4	Ensure that processes for preparation, review, approval, issuance, use, and revision of documents that prescribe processes, requirements, and design are implemented.
	6	Ensure that design processes that provide appropriate control of design inputs, outputs, verification, configuration and design changes, and technical and administrative interfaces are implemented.
Finalize Security Vulnerability Assessment Report	4	Ensure that processes for preparation, review, approval, issuance, use, and revision of documents that prescribe processes, requirements, and design are implemented.
Finalize Cyber Security Plan for Information Technology Projects and Complete Certification and Accreditation, as required	4	Ensure that processes for preparation, review, approval, issuance, use, and revision of documents that prescribe processes, requirements, and design are implemented.
	4	Ensure that processes for specification, preparation, review, approval, and maintenance of records are implemented.
Prepare Safety Evaluation Report Based on Review of Preliminary Documented Safety Analysis for Category 1, 2, and 3 Nuclear Facilities	4	Ensure that processes for preparation, review, approval, issuance, use, and revision of documents that prescribe processes, requirements, and design are implemented.
	5	Ensure that actions are planned and carried out by qualified personnel using approved procedures, instructions, and equipment under administrative, technical, and environmental controls.

Table D-6. Post CD-4 - QA Activities

Post CD-4 Requirements	QA Criterion	QA Activities
Perform Final Administrative and Financial Closeout and Prepare Final Project Closeout Report	3	Ensure that the organization established, implemented, and documented processes to detect and prevent quality problems and that problems have been corrected.
	4	Ensure that processes for preparation, review, approval, issuance, use, and revision of documents that prescribe processes, requirements, and design are implemented.
Prepare Lessons Learned Report and Submit to Office of Engineering and Construction Management (OECM)	3	Ensure that processes to detect and prevent quality problems are implemented.
	4	Ensure that processes for preparation, review, approval, issuance, use, and revision of documents that prescribe processes, requirements, and design are implemented.

Table D-7. Post CD-4 - QA Activities		
Post CD-4 Requirements	**QA Criterion**	**QA Activities**
Complete Project Required Operational Documentation	4	Ensure that processes for preparation, review, approval, issuance, use, and revision of documents that prescribe processes, requirements, and design are implemented.
	4	Ensure that processes for specification, preparation, review, approval, and maintenance of records are implemented.
Conduct Post Implementation Review for Information Technology Projects	9	Ensure that processes to plan and conduct reviews to measure item and service quality and the adequacy of work performance and to promote improvement are implemented.

APPENDIX E. Lessons Learned

By definition, a lessons learned is:

> *A "good work practice" or innovative approach that is captured and shared to promote repeat applications or an adverse work practice or experience that is captured and shared to avoid a recurrence.*

One of the primary goals of the U.S. Department of Energy (DOE) lessons learned process is to connect DOE Sites through shared information so DOE employees can benefit from each other's innovations and prevent repeating unfortunate events. DOE encourages its employees to utilize this valuable tool. Federal project directors (FPD) are encouraged to contact their site Lessons Learned program office for more information.

An essential lessons learned source is the Office of Health, Safety and Security Corporate Operating Experience webpage at http://hss.energy.gov/CSA/Analysis/ll/. This site is continually updated to improve content and usefulness.

FPDs may also want to refer to the Energy Facility Contractors Group (EFCOG) Best Practices website at http://www.efcog.org/bp/index.htm.