



DOE - EM - SRP - 2010

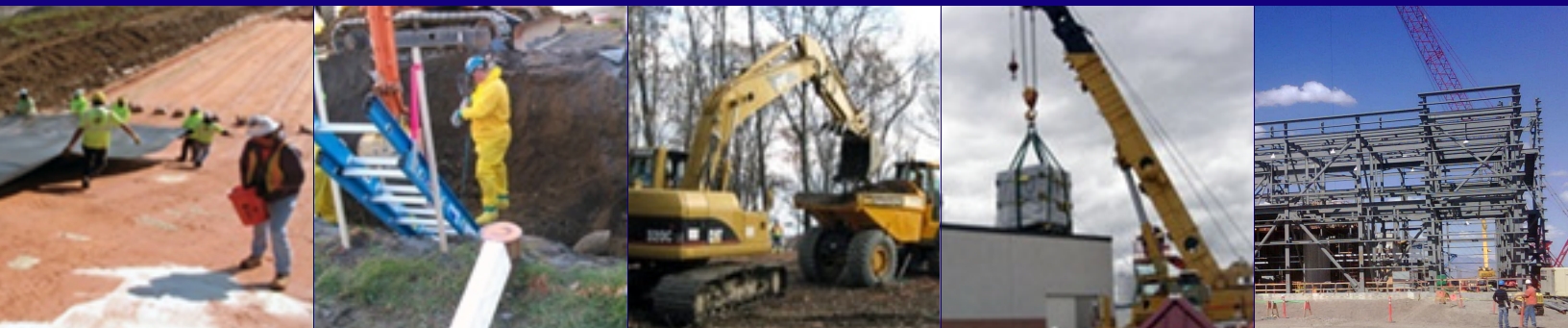
2nd Edition

Environmental Management

Safety ▪ Performance ▪ Cleanup ▪ Closure

STANDARD REVIEW PLAN (SRP)

**QUALITY ASSURANCE FOR
CRITICAL DECISION REVIEWS MODULE**



**CORPORATE CRITICAL DECISION (CD) REVIEW AND
APPROVAL FRAMEWORK ASSOCIATED WITH NUCLEAR FACILITY CAPITAL AND
MAJOR CONSTRUCTION PROJECTS**

MARCH 2010

OFFICE OF ENVIRONMENTAL MANAGEMENT
U.S. DEPARTMENT OF ENERGY
WASHINGTON D. C. 20585

OFFICE OF ENVIRONMENTAL MANAGEMENT

Standard Review Plan (SRP)

Quality Assurance (QA)

Review Module

Critical Decision (CD) Applicability					
CD-0	CD-1	CD-2	CD-3	CD-4	Post Operation
	✓	✓	✓	✓	



March 2010

FOREWORD

The Standard Review Plan (SRP)¹ provides a consistent, predictable corporate review framework to ensure that issues and risks that could challenge the success of Office of Environmental Management (EM) projects are identified early and addressed proactively. The internal EM project review process encompasses key milestones established by DOE O 413.3A, Change 1, *Program and Project Management for the Acquisition of Capital Assets*, DOE-STD-1189-2008, *Integration of Safety into the Design Process*, and EM's internal business management practices.

The SRP follows the Critical Decision (CD) process and consists of a series of Review Modules that address key functional areas of project management, engineering and design, safety, environment, security, and quality assurance, grouped by each specific CD phase.

This Review Module provides the starting point for a set of corporate Performance Expectations and Criteria. Review teams are expected to build on these and develop additional project-specific Lines of Inquiry, as needed. The criteria and the review process are intended to be used on an ongoing basis during the appropriate CD phase to ensure that issues are identified and resolved.

¹ *The entire EM SRP and individual Review Modules can be accessed on EM website at <http://www.em.doe.gov/Pages/Safety.aspx>, or on EM's internet Portal at <https://edoe.doe.gov/portal/server.pt> Please see under /Programmatic Folder/Project Management Subfolder.*

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ACRONYMS

ASME	American Society of Mechanical Engineers
CD	Critical Decision
CDR	Conceptual Design Report
CSDR	Conceptual Safety Design Report
DOE	Department of Energy
DSA	Documented Safety Analysis
EIR	External Independent Review
EM	Environmental Management
EMS	Environmental Management System
EVMS	Earned Value Management
FPD	Federal Project Director
IPR	Independent Project Review
IPT	Integrated Project Team
LOI	Line of Inquiry
NEPA	National Environmental Policy Act
NQA-1	Nuclear Quality Assurance-1
PEP	Preliminary Project Execution Plan
PDS	Project Data Sheet
PDSA	Preliminary Documented Safety Analysis
PSVR	Preliminary Safety Validation Report
QAP	Quality Assurance Plan
QA	Quality Assurance

QIP	Quality Assurance Implementation Plan
SDS	Safety Design Strategy
SER	Safety Evaluation Report
TSR	Technical Safety Requirements

I. INTRODUCTION

As required by Department of Energy (DOE) O 413.3A, Change 1, *Program and Project Management for the Acquisition of Capital Assets*, Quality Assurance (QA) begins at project inception and continues through the project's life cycle. Each Environmental Management (EM) capital project is responsible for planning and implementing a Quality Assurance Program (QAP) for the project. Quality affects cost, availability, reliability, safety, and performance. Appropriate aspects of QA need to be considered during the planning and preparation of project documents and execution of project activities. The project's application of QA is documented in either the organizational or project-specific QAP or the approved Quality Assurance Implementation Plan (QIP) that addresses the 10 DOE QA Criteria. These are Program, Personnel Training and Qualification, Quality Improvement, Documents and Records, Work Processes, Design, Procurement, Inspection and Acceptance, Management Access, and Independent Assessment.

The 10 DOE QA Criteria are specified and described in EM-QA-001, *Office of Environmental Management Quality Assurance Plan*, October 2008 (EM Corporate QAP). The EM Corporate QAP captures the QA requirements of 10 CFR 830 Part A, *Quality Assurance Requirements*, DOE O 414.1C, *Quality Assurance*, and ASME NQA-1 2004, *Part I: Requirements for Quality Assurance Programs for Nuclear Facilities*, and addenda through 2007, and a series of management expectations. Collectively they provide the technical basis for assessing the QA activities for preparing Critical Decision documents and conducting project activities, as required by DOE O 413.3.A.

II. PURPOSE

The purpose of this Quality Assurance for Capital Project Critical Decision Review Module (QA RM) is to identify, integrate, and clarify the QA performance objectives, criteria, and guidance needed to review project documents and activities. The use of the QA RM by the review teams (Headquarters, site, and project) would help facilitate the review of QA activities at each Critical Decision (CD) phase, from CD-0 through CD-4. For each capital project, the QA RM should be used as a starting point for both desktop and field reviews. It is expected that project-specific Lines of Inquiry (LOIs) are developed to supplement those of this RM.

III. ROLES AND RESPONSIBILITIES

A successful QA review, at each of the Critical Decision phase, depends on an experienced and qualified team. As identified in DOE G 414.1-2A, as a minimum personnel assigned to lead review teams should have completed the *Department of Energy (DOE) Quality Assurance Functional Area Qualification Standard*, DOE-STD-1150-2002. Team members may also be qualified, but as a minimum should have specific types of expertise dependent on the type of facility being reviewed, as well as other factors such as complexity, hazards, and risks. The QA review can be conducted along with other planned reviews, including design, safety, construction readiness, and readiness reviews.

The roles and responsibilities for all involved in the QA review must be clear and consistent. The table below provides a compilation of QA review roles and responsibilities.

Position	Responsibility
Field Element Manager	Provides support and resources to the Federal Project Director and Review Team Leader in carrying out the Quality Assurance (QA) review.
	Facilitates the conduct of the QA review. Assigns office space, computer equipment, and support personnel to the team as necessary to accomplish the review in the scheduled time frame
Federal Project Director	Identifies the need for a FPD and determines the scope of the review effort.
	In conjunction with the Contractor Project Manager, develops the briefing materials and schedule for the review activities.
	Coordinates the review team pre-visit activities and follows up review team requests for personnel to interview or material to review.
	Coordinates the necessary training and orientation activities to enable the review team members to access the facility and perform the review.
	Unless other personnel are assigned, acts as the site liaison with the review team. Tracks the status of requests for additional information.
	Coordinates the Federal site staff factual accuracy review of the draft report.
	Leads the development of the corrective action plan if required. Tracks the completion of corrective actions resulting from the review.
Review Team Leader	In coordination with the Federal Project Director, selects the areas to be reviewed.
	Based on the areas selected for review, project complexity and hazards involved, selects the members of the review team.
	Verifies the qualifications: technical knowledge; process knowledge; facility specific information; and independence of the Team Members.
	Leads the QA review pre-visit.
	Leads the review team in completing the Review Criteria for the various areas to be reviewed.
	Coordinates the development of the data call and forwards to the Federal Project Director, a list of documents, briefings, interviews, and presentations needed to support the review.
	Forwards the final review plan to the FPD and EM management for approval.
	Leads the on-site review.
	Ensures the review team members complete and document their portions of the review and characterizes the findings.
	Coordinates incorporation of factual accuracy comments by Federal and Contractor personnel on the draft report.
	Forwards the final review report to the FPD and EM management for consideration in making the decision to authorize start of construction.
	Participates, as necessary in the closure verification of the findings from the review report.
	Review Team Member
Develops and provides the data call of documents, briefings, interviews, and presentations needed for his or her area of the review.	
Completes training and orientation activities necessary for the review. Conducts any necessary pre visit document review.	

Position	Responsibility
	Participates in the on-site review activities, conducts interviews, document reviews, walk downs, and observations as necessary.
	Based on the criteria and review approaches in the Review Plan, assesses whether his or her assigned criteria have been met.
	Documents the results of the review for his/her areas. Prepares input to the review report.
	Makes recommendations to the Review Team Leader for characterization of findings in his or her area of review.
	Resolves applicable Federal and Contractor factual accuracy comments on the draft review report.
	Prepares the final review report for his or her area of review.

IV. REVIEW SCOPE AND CRITERIA

This QA RM provides a roadmap for conducting QA review for the Critical Decision (CD) activities and documents. Appendix A identifies the DOE O 413.3A required activities and documents for the CD phases. For each CD activity and document, Appendix A identifies the appropriate EM QAP Criteria and the Lines of Inquiry (LOIs).

The QA review as defined by Appendix A relies on the more detailed set of LOIs as defined for each of the 10 QA Criteria of the EM Corporate QAP. The QA review teams should refer to the LOIs contained in Table 2 and Table 4 of the *Protocol for EM Review/ Field Self-Assessment of Site-Specific Quality Assurance Programs (QAPs)/Quality Implementation Plans (QIPs)*, dated, February 2010. Table 1 contains the LOIs for each of the 10 EM QAP QA Criteria. The italicized text reflects *Assessment Expectations for Federal Project Directors (FPDs) and Integrated Project Teams (IPTs) Review Attributes/Characteristics* developed by the Office of Environmental Management and Energy Contractors Group Quality Assurance Improvement Project Plan, Task #5.8.

Table 2 supports the implementation of the LOIs specified in Table 1. It defines the 18 ASME NQA-1 Part 1 Requirements and the Subpart 2.7 Requirement on Computer Software. LOIs are defined for each of these ASME NQA-1 areas.

The combination of this review module, the *Protocol for EM Review/ Field Self-Assessment of Site-Specific Quality Assurance Programs (QAPs)/Quality Implementation Plans (QIPs)*, dated February 2010, and the NQA-1 review protocol, provides a complete technical basis for use by appropriate EM personnel to evaluate all aspects of a project with regard to the QA program.

The Critical Decision review topics, as defined in Appendix A are listed below.

Project Approval of Mission Need

The review area focuses on the QA adequacy of the project documents and activities needed for CD-0 approval of Mission Need. The review areas include: Pre-Conceptual Planning; Tailoring Strategy; and Mission Validation Independent Project Review.

Approval of Alternative Selection and Cost Range

The review area focuses on the QA adequacy of the project documents and activities needed for CD-1 approval of Alternative Selection and Cost Range. The review areas include: Conceptual Design Report preparation; Acquisition Strategy preparation; Preliminary Project Execution Plan preparation; selection of the FPD; establishment of the IPT; and preparation of safety documents.

Approval of Performance Baseline

The review area focuses on the QA adequacy of the project documents and activities needed for CD-2 approval of Performance Baseline. The review areas include: Earned Value Management System preparation; design documents preparation, QAP preparation; safety documents preparations; and NEPA documents preparation.

Approval of Start of Construction

The review area focuses on the QA adequacy of the project documents and activities needed for CD-3 approval of prior to Start of Construction. The review areas include: final design documents preparation; safety documents preparation; and updating of project management documents.

Approval of Start of Operations and Project Completion

The review area focuses on the QA adequacy of the project documents and activities needed for CD-4 approval of Start of Operations and Project Completion. The review areas include: conduct of Readiness Assessment or Operational Readiness Review; Commissioning Planning preparation; final safety documents preparation; Lessons Learned preparation; and conduct of Post Implementation Review.

V. REVIEW PLANS AND DOCUMENTATION

The quality assurance review is essential to the overall DOE process for the implementation of the comprehensive management system for DOE work. The focus of the quality management system is to properly and safely accomplish the mission or objective.

The following activities should be conducted as part of the QA review plan development and documentation/closure of the review:

- Subsequent to the selection, formation and chartering of the review team and receipt and review of the prerequisite documents; assignment of responsibilities for the development of specific lines of inquiry should be made.
- The review team members should develop specific lines of inquiry utilizing the topics and areas listed in the respective appendices of this guide.

- The individual lines of inquiry should be compiled and submitted to the manager authorizing the review for concurrence prior to starting the review. Once approved by the manager they should be provided to the organization being reviewed along with a schedule for the planned assessment.
- The project-specific review plan should be compiled with a consistent and uniform numbering scheme that provided for a unique identifier for each line of inquiry, arranged by subject area such that the results of each line of inquiry can be documented and tracked to closure.
- The lines of inquiry should be satisfied via document review and personnel interviews and any combination of these methods. For the field assessment these techniques are augmented by the direct observation of work to verify procedure execution as appropriate. The method used the basis for closure, comment, and finding the result of the inquiry should all be documented and tracked.

VI. REFERENCE MATERIAL

- 10 CFR 830.120, *Quality Assurance Requirements*
- DOE Order O 414.1C, *Quality Assurance*
- DOE O 413.3A, Change 1, *Program and Project Management for the Acquisition of Capital Asset*
- ASME NQA-1 2004, *Part I: Requirements for Quality Assurance Programs for Nuclear Facilities*, and addenda through 2007
- *Quality Assurance Program Plan*, Office of Environmental Management Headquarters, May 2008
- *Protocol for EM-HQ Review of EM Field/Site-Specific Quality Assurance Program (QAP)/Implementation Plans (QIP)*, draft, July 2009
- DOE G 413.3-2, *Quality Assurance Guide for Project Management*, June 2008
- ANSI/ASQ Q 9001-2000, *Quality Management System Requirements*;
- ANSI/ASQ Z 1.13, *Quality Guidelines for Research*;
- DOE P 450.4, *Safety Management System Policy*;
- DOE P 450.5, *Line Environment, Safety and Health Oversight*;
- Quality Assurance Improvement Initiative, EM Centralized Training Platform Project Plan, April 2009
- DOE-STD-1150-2002, *Quality Assurance Functional Area Qualification Standard*
- DOE 5480.20A, *Personnel Selection, Qualification and Training Requirements for DOE Nuclear Facilities*
- DOE G 414.1-1B, *Management Assessment and Independent Assessment Guide*
- DOE G 414.1-2A, *Quality Assurance Management System Guide*
- DOE G 414.1-3, *Suspect/Counterfeit Items Guide*
- DOE G 414.1-4, *Safety Software Guide*
- DOE G 414.1-5, *Corrective Action Program Guide*
- Office of Environmental Management and Energy Contractors Group Quality Assurance Improvement Project Plan, Task #5.8, CD Tables w/Requirements and Performance Objectives, Measures & Commitments

- Office of Environmental Management and Energy Contractors Group Quality Assurance Improvement Project Plan, Task #5.8, Assessment Expectations for Federal Project Directors (FPDs) and Integrated Project Teams (IPTs) Review Attributes/Characteristics.
- *Protocol for EM Review/ Field Self-Assessment of Site-Specific Quality Assurance Programs (QAPs)/Quality Implementation Plans (QIPs)*, February 2010.

APPENDIX A- PERFORMANCE OBJECTIVES AND CRITERIA

Legend of Quality Assurance Review Topics

Review Topical Area	Identifier
Project Approval of Mission Need	CD-0
Approval of Alternative Selection and Cost Range	CD-1
Approval of Performance Baseline	CD-2
Approval of Start of Construction	CD-3
Approval of Start of Operations and Project Completion	CD-4

ID #	Performance Objectives and Criteria ^{2 3}	Met?
Project Approval of Mission Need		
CD-0	Are the QA expectations of the EM Corporate QAP integrated into the project activities prior to CD-0 approval?	
	For performing Pre-Conceptual Planning activities, is Criterion 1 (Program) being implemented to <i>determine whether adequate resources have been identified to describe management processes, including planning, scheduling, and providing funding for the work?</i> (CD-0.1)	
	Is Criterion 4 (Documents and Records) being implemented to ensure that <i>processes for preparation, review, approval, issuing, using, and revising documents that prescribe processes, requirements and design are implemented?</i> (CD-0.2)	
	For performing Mission Validation Independent Project Review , is Criterion 10 (Independent Assessment) being implemented to ensure that the lines of inquiry for the review are developed and that QA expertise is utilized? (CD-0.3)	
	<i>Determine that a Mission Need Statement has been developed and approved.</i>	
	<i>Criterion 6 - Verify that a design process is implemented.</i>	
	<i>Determine if the project's approach for adapting CD requirements based on the project's risk and complexity is appropriate for the project based on the best available information.</i>	
Approval of Alternative Selection and Cost Range		
CD-1	Are the QA expectations of the EM Corporate QAP integrated into the project activities prior to CD-1 approval?	

² The italicized text reflects Assessment Expectations for Federal Project Directors (FPDs) and Integrated Project Teams (IPTs) Review Attributes/Characteristics developed by the Office of Environmental Management and Energy Contractors Group Quality Assurance Improvement Project Plan, Task #5.8.

³ The site should provide the technical bases and assumptions that support the answers provided to each Line of Inquiry. If possible, the review teams should independently verify the technical bases and assumptions.

ID #	Performance Objectives and Criteria ^{2 3}	Met?
	<p>For preparing the Conceptual Design Report (CDR), are the following expectations being implemented? (CD-1.1)</p> <ul style="list-style-type: none"> • Criterion 4 (Document and Records) <i>to ensure that processes for preparation, review, approval, issuance, use, and revision of the CDR are implemented.</i> • Criterion 4 <i>to ensure that processes for specification, preparation, review, approval, and maintenance of records are implemented.</i> • Criterion 6 (Design) <i>to ensure that a design process is in place that provides appropriate control of design inputs, outputs, verification, configuration a design changes, and technical and administrative interfaces</i> • Criterion 6 <i>to ensure that design activities are verified and documented</i> 	
	<p>For preparing the Acquisition Strategy, is Criterion 4 (Document and Records) being implemented to ensure that processes for preparation, review, approval, issuance, use, and revision of the Acquisition Strategy document are implemented? (CD-1.2)</p>	
	<p><i>Criterion 7 - Determine that a procurement (acquisition) process to ensure items and/or services provided by suppliers meets the requirements and expectations of the end user is developed and implemented and that quality level determination are factored into the acquisition strategy, especially when procuring services to perform work.</i></p>	
	<p><i>Criterion 7 - Verify that QA expertise is utilized to assist with procurement (acquisition) planning.</i></p>	
	<p>For preparing a Preliminary Project Execution Plan (PEP), is Criterion 4 (Documents and Records) <i>being implemented to ensure that processes for preparation, review, approval, issuance use, and revision of the PEP are implemented?</i> (CD-1.3)</p>	
	<p><i>Determine that significant QA participation is emphasized in the development and review of the PEP</i></p>	
	<p>For the selection and approval of the Federal Project Director, is Criterion 2 (Personnel Training and Qualification) being implemented to <i>ensure that policies and procedures that describe personnel selection, training, and qualification requirements are developed and implemented?</i> (CD-1.4)</p>	
	<p>For establishing and chartering the Integrated Project Team (IPT), is Criterion 2 (Personnel Training and Qualification) being implemented to ensure that:</p> <ul style="list-style-type: none"> • <i>policies and procedures that describe personnel selection, training, and qualification requirements are developed and implemented</i> • <i>a QA representative is a member of the IPT</i> (CD-1.5) 	

ID #	Performance Objectives and Criteria ^{2 3}	Met?
	<p>For conducting design review of the Conceptual Design, are the following expectations being implemented? (CD-1.6)</p> <ul style="list-style-type: none"> • Criterion 2 (Personnel Training and Qualification) to ensure that personnel achieve initial proficiency; maintain proficiency; and adapt to changes in technology, methods, or job responsibilities. • Criterion 4 (Document and Records) <i>to ensure that processes for preparation, review, approval, issuance, use, and revision of design review documents are described and implemented.</i> • Criterion 6 (Design) to ensure that: <ul style="list-style-type: none"> ○ 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 • Criterion 10 (Independent Assessment) to ensure that persons conducting reviews are technically qualified and knowledgeable in the review areas • Criterion 10 to ensure that persons conducting independent reviews have sufficient authority and freedom from line management. 	
	<p>For preparing the Project Data Sheet (PDS), is Criterion 4 (Document and Records) being implemented to ensure that:</p> <ul style="list-style-type: none"> • Processes for preparation, review, approval, issuance, use, and revision of PDS are implemented? and • Processes for specification, preparation, review, approval, and maintenance of records are implemented? (CD-1.7) 	
	<p>For Long-Lead Procurement approval, are the following expectations being implemented? (CD-1.8)</p> <ul style="list-style-type: none"> • Criterion 4 (Document and Records) to ensure that processes for specification, preparation, review, approval, and maintenance of records are implemented. • Criterion 5 (Work Processes) <i>to 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.</i> • Criterion 7 (Procurement) to 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. 	

ID #	Performance Objectives and Criteria ^{2 3}	Met?
	<p>For implementing an Integrated Safety Management System (ISMS), are the following expectations being implemented? (CD-1.9)</p> <ul style="list-style-type: none"> • Criterion 1 (Program) to ensure that the QA program complements and is integrated with ISMS. • Criterion 1 to ensure that the QA program provides processes and tools for ensuring that ISMS objectives are achieved. • Criterion 5 (Work Processes) <i>to 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.</i> • Criterion 5 to ensure that the control of processes, skills, hazards, and equipment are clearly specified, understood, and fully documented. 	
	<p>For preparing Environmental Documents including National Environmental Policy Act (NEPA) Strategy and Analyses, and Permit Applications, is Criterion 4 (Document and Records) being implemented to ensure that:</p> <ul style="list-style-type: none"> • Processes for specification, preparation, review, approval, and maintenance of records are implemented? • Procedures, work instructions, or other appropriate means used to define work processes are documented and controlled? • Processes for preparation, review, approval, issuance, use, and revision of documents are implemented? (CD-1.10) 	
	<p>For addressing and documenting High Performance Sustainable Building design considerations, is Criterion 6 (Design) being implemented to ensure that applicable design inputs are controlled? (CD-1-11)</p>	
	<p>For preparing the Preliminary Security Vulnerability Assessment Report, is Criterion 4 (Documents and Records) being implemented to ensure that:</p> <ul style="list-style-type: none"> • Processes for <i>specification, preparation, review, approval, and maintenance of records are implemented?</i> • Processes for preparation, review, approval, issuance, use, and revision of documents are implemented? (CD-1-12) 	
	<p>For preparing the Initial Cyber Security Plan, is Criterion 5 (Work Processes) being implemented to ensure that:</p> <ul style="list-style-type: none"> • <i>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?</i> • Procedures, work instructions, or other appropriate means used to define work processes are documented and controlled? (CD-1-13) 	

ID #	Performance Objectives and Criteria ^{2 3}	Met?
	<p>For preparing the Conceptual Safety Design Report (CSDR), are the following expectations being implemented? (CD-1.14)</p> <ul style="list-style-type: none"> • Criterion 4 (Document and Records) to ensure that processes for preparation, review, approval, issuance, use, and revision of the CSDR are implemented • Criterion 4 to <i>ensure that processes for specification, preparation, review, approval, and maintenance of records are implemented</i> • Criterion 6 (Design) to ensure that design processes that provide appropriate control of design inputs, outputs, verification, configuration and design changes, and technical and administrative interfaces are implemented • Criterion 6 to <i>ensure that processes for verification of design activities are implemented</i> 	
	<p>For preparing the Preliminary Hazard Analysis Report, are the following expectations being implemented? (CD-1.15)</p> <ul style="list-style-type: none"> • Criterion 4 (Document and Records) <i>to ensure that processes for specification, preparation, review, approval, and maintenance of records are implemented</i> • Criterion 1 (Program) to ensure that processes (which adequately addresses hazards) for grading the application of requirements are implemented 	
	<p>For preparing the Conceptual Safety Validation Report, are the following expectations being implemented? (CD-1.16)</p> <ul style="list-style-type: none"> • Criterion 4 (Document and Records) <i>to ensure that processes for specification, preparation, review, approval, and maintenance of records are implemented and followed DOE-STD-1104</i> • Criterion 6 (Design) <i>to ensure processes for verification of design activities are implemented and followed DOE-STD-1104</i> 	
	<p>For determining if the Quality Assurance Program is acceptable, are the following expectations being implemented? (CD-1.17)</p> <ul style="list-style-type: none"> • Criterion 1 (Program) <i>to 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</i> • Criterion 1 <i>to ensure that adequate resources have been identified for quality program activities, such as planning, auditing, supplier qualification, technical document review, inspection, and calibration</i> • <i>Ensure that sufficient quality resources are planned and included in project baseline to support quality systems, processes, and procedures required for design work after CD-1 approval.</i> • Criterion 9 (Management Assessment) <i>to 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</i> 	

ID #	Performance Objectives and Criteria ^{2 3}	Met?
	<p>For developing the Safety Design Strategy (SDS), are the following expectations being implemented (CD-1.18)</p> <ul style="list-style-type: none"> • Criterion 4 (Document and Records) to ensure that processes for preparation, review, approval, issuance, use, and revision of the SDS are implemented. • Criterion 4 <i>to ensure that processes for specification, preparation, review, approval, and maintenance of records are implemented.</i> • Criterion 5 (Work Processes) <i>to 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?</i> 	
Approval of Performance Baseline		
CD-2	Are the QA activities integrated into the project activities prior to CD-2 approval?	
	<i>GENERAL: Verify that processes (which adequately addresses hazards) for grading the application of requirements are implemented.</i>	
	<i>Criterion 5 - Verify 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.</i>	
	<i>Verify that software quality assurance process implementation is performed in accordance with the Corporate DOE Office of Environmental Management Quality Assurance Program.</i>	
	For establishing the Performance Baseline , is Criterion 4 (Document and Records) being implemented to ensure that the processes for document preparation, review, approval, and change control are implemented? (CD-2.1)	
	For updating the Project Execution Plan , is Criterion 4 (Document and Records) being implemented to ensure that processes for preparation, review, approval, issuance, use, and revision of documents are implemented? (CD-2.2)	
	For establishing the Earned Value Management System (EVMS) , is Criterion 4 (Document and Records) being implemented to ensure that the processes for document preparation, review, approval, and change control are implemented? (CD-2.3)	

ID #	Performance Objectives and Criteria ^{2 3}	Met?
	<p>For conducting Performance Baseline Validation External Independent Review (EIR) or Performance Baseline Validation Independent Project Review (IPR), are the following expectations being implemented? (CD-2.4)</p> <ul style="list-style-type: none"> • Criterion 4 (Document and Records) to ensure that the processes for document preparation, review, approval, and change control are implemented • Criterion 10 (Independent Assessment) to ensure that the 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 • Criterion 10 to ensure that the persons conducting reviews are technically qualified and knowledgeable in the areas to be reviewed • Criterion 10 to ensure that the persons conducting independent reviews have sufficient authority and freedom from line management 	
	<p>For developing Independent Cost Estimate or Performing Independent Cost Review, are the following expectations being implemented? (CD-2.5)</p> <ul style="list-style-type: none"> • Criterion 4 (Document and Records) to ensure that the processes for document preparation, review, approval, and change control are implemented • Criterion 10 (Independent Assessment) <i>to ensure that the 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</i> • Criterion 10 <i>to ensure that the persons conducting reviews are technically qualified and knowledgeable in the areas to be reviewed</i> • Criterion 10 <i>to ensure that the persons conducting independent reviews have sufficient authority and freedom from line management</i> 	
	<p>For determining if the Quality Assurance Program is acceptable and continued to apply, are the following expectations being implemented? (CD-2.6)</p> <ul style="list-style-type: none"> • Criterion 1 (Program) <i>to 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</i> • Criterion 1 <i>to ensure that adequate resources have been identified for quality program activities, such as planning, auditing, supplier qualification, technical document review, inspection, calibration, etc.</i> • Criterion 9 (Management Assessment) to 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 	

ID #	Performance Objectives and Criteria ^{2 3}	Met?
	<p>For preparing the Preliminary Design, are the following expectations being implemented? (CD-2.7)</p> <ul style="list-style-type: none"> • Criterion 2 (Personnel Training and Qualification) <i>to ensure that processes are implemented for personnel to achieve initial proficiency; maintain proficiency; and adapt to changes in technology, methods, or job responsibilities</i> • Criterion 4 (Document and Records) <i>to ensure that processes for preparation, review, approval, issuance, use, and revision of documents are implemented</i> • Criterion 4 <i>to ensure that processes for specification, preparation, review, approval, and maintenance of records are implemented</i> • Criterion 4 <i>to ensure that processes for appropriate control of design inputs, outputs, verification, configuration, and design changes and technical and administrative interfaces are implemented.</i> • Criterion 4 <i>to 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</i> • Criterion 4 <i>to ensure that processes for verification of design activities are implemented</i> 	
	<p>For updating the Project Data Sheet, is Criterion 4 (QA Documents and Records) being implemented to ensure that:</p> <ul style="list-style-type: none"> • Processes for preparation, review, approval, issuance, use, and revision of documents are implemented? • Processes for specification, preparation, review, approval, and maintenance of records are implemented? (CD-2.8) 	

ID #	Performance Objectives and Criteria ^{2 3}	Met?
	<p>For conducting design review of Preliminary Design, are the following expectations being implemented? (CD-2.9)</p> <ul style="list-style-type: none"> • Criterion 5 (Design) to ensure that: <ul style="list-style-type: none"> ○ 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 ○ the necessary design inputs from interfacing organizations were specified in the design documents • Criterion 4 (Documents and Records) to ensure that processes for preparation, review, approval, issuance, use, and revision of documents are implemented • Criterion 10 (Independent Review) to ensure that persons conducting reviews are technically qualified and knowledgeable in the areas to be reviewed • Criterion 10 to ensure that persons conducting independent reviews have sufficient authority and freedom from line management • Criterion 2 (Personnel Training and Qualification) to ensure that personnel achieve initial proficiency; maintain proficiency; and adapt to changes in technology, methods, or job responsibilities 	
	<p>For preparing the Preliminary Safety Design Report, are the following expectations being implemented? (CD-2.10)</p> <ul style="list-style-type: none"> • Criterion 4 (Documents and Records) to ensure that processes for preparation, review, approval, issuance, use, and revision are implemented? • Criterion 4 to ensure that processes for specification, preparation, review, approval, and maintenance of records are implemented • Criterion 6 (Design) to ensure that design processes that provide appropriate control of design inputs, outputs, verification, configuration and design changes, and technical and administrative interfaces are implemented • Criterion 6 to ensure that processes for verification of design activities are implemented 	
	<p>For updating the Preliminary Security Vulnerability Assessment Report, is Criterion 4 (QA Documents and Records) being implemented to ensure that processes for preparation, review, approval, issuance, use, and revision of documents are implemented? (CD-2.11)</p>	
	<p>For updating the Initial Cyber Security Plan, is Criterion 4 (Documents and Records) being implemented to ensure that processes for preparation, review, approval, issuance, use, and revision of the Initial Cyber Security Plan are implemented? (CD-2.12)</p>	

ID #	Performance Objectives and Criteria ^{2 3}	Met?
	<p>For preparing the Preliminary Safety Validation Report (PSVR), are the following expectations being implemented? (CD-2.13)</p> <ul style="list-style-type: none"> • Criterion 1 (Program) to ensure that the PSVR follows DOE-STD-1104 • Criterion 4 (Document and Records) to ensure that the processes for preparation, review, approval, issuance, use, and revision of the PSVR are implemented and followed DOE-STD-1104 <p>For incorporating High Performance Sustainable Building design provisions into Preliminary Design and Design Review, is Criterion 6 (Design) being implemented to ensure that the applicable design inputs are controlled? (CD-2.14)</p> <p>For finalizing and obtaining approval of NEPA documentation, is Criterion 4 (Documents and Records) being implemented to ensure that processes for preparation, review, approval, issuance, use, and revision of the NEPA documents are implemented? (CD-2.15)</p>	
Approval of Start of Construction		
CD-3	<p>Are the QA activities integrated into the project activities being implemented for CD-3 approval for start of construction?</p> <p><i>GENERAL: Criterion 4 Verify that processes for preparation, review, approval and issuance, use and revision of documents that prescribe processes requirements and designs are implemented.</i></p> <p><i>Verify that processes (which adequately addresses hazards) for grading the application of requirements are implemented.</i></p> <p><i>Criterion 4 - Ensure that the processes for specification, preparation, review, approval, and maintenance of records are implemented</i></p> <p><i>Verify that suspect/counterfeit item process prevention is developed and implemented in accordance with the Corporate DOE Office of Environmental Management Quality Assurance Program.</i></p>	

ID #	Performance Objectives and Criteria ^{2 3}	Met?
	<p>For activities regarding to completing and reviewing the Final Design or determining if the design is sufficiently mature to start procurement or construction, are the following expectations being implemented? (CD-3.1)</p> <ul style="list-style-type: none"> • Criterion 2 (Personnel Training and Qualification) <i>to ensure that processes are implemented for personnel to achieve initial proficiency; maintain proficiency; and adapt to changes in technology, methods, or job responsibilities</i> • Criterion 6 (Design) to ensure that applicable design inputs are controlled • Criterion 6 to <i>Verify that design inputs (such as design bases, conceptual design reports, performance requirements, regulatory requirements, codes and standards) are controlled and documented and changes from approved design inputs and reasons for the changes are identified, approved, documented and controlled.</i> • Criterion 6 to ensure that processes for conducting design reviews are implemented to ensure that: <ul style="list-style-type: none"> ○ 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 • Criterion 6 to ensure that design processes: <ul style="list-style-type: none"> ○ <i>use sound engineering/scientific principles and appropriate standards;</i> ○ <i>incorporate applicable requirements and design bases in design work and design changes;</i> ○ <i>identify and control design interfaces;</i> ○ <i>verify/validate the adequacy of design products using individuals or groups other than those who performed the work; and</i> ○ <i>verify/validate work before approval and implementation of the design</i> • Criterion 6 to ensure that processes for verification of design activities are implemented 	
	<p>For activities regarding the updating of CD-2 project management documents (including PEP, Performance Baseline, Risk Management, etc), is Criterion 4 (Documents and Records) being implemented to ensure that:</p> <ul style="list-style-type: none"> • Processes for preparation, review, approval, issuance, use, and revision of the project management documents are implemented • Processes for document preparation, review, approval, and change control are implemented? (CD-3.2) 	

ID #	Performance Objectives and Criteria ^{2 3}	Met?
	<p>For performing independent review for construction readiness and readiness assessment, is Criterion 10 (Independent Assessment) being implemented to ensure that:</p> <ul style="list-style-type: none"> • <i>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?</i> • <i>Persons conducting reviews are technically qualified and knowledgeable in the areas to be reviewed?</i> • <i>Persons conducting independent reviews have sufficient authority and freedom from line management?</i> (CD-3.3) 	
	<p>For preparing the Preliminary Documented Safety Analysis (PDSA), are the following expectations being implemented? (CD-3-4)</p> <ul style="list-style-type: none"> • Criterion 1 (Program) to ensure that the PDSA follows the guidance of DOE-STD-1189 and DOE-STD-3009? • <i>Criterion 1 to ensure that the processes for specification, preparation, review, approval, and maintenance of records are implemented?</i> • Criterion 4 (Document and Records) to ensure that processes for preparation, review, approval, issuance, use, and revision of the PDSA are implemented? • Criterion 6 (Design) to ensure that design processes that provide appropriate control of design inputs, outputs, verification, configuration and design changes, and technical and administrative interfaces are implemented? 	
	<p>For updating the Security Vulnerability Assessment Report, is Criterion 4 (Documents and Records) being implemented to ensure that processes for preparation, review, approval, issuance, use, and revision of the Security Vulnerability Assessment Report are implemented? (CD-3.5)</p>	
	<p>For updating the Cyber Security Plan, is Criterion 4 (Documents and Records) being implemented to ensure that:</p> <ul style="list-style-type: none"> • Processes for preparation, review, approval, issuance, use, and revision of the Cyber Security Plan are implemented • Process for specification, preparation, review, approval, and maintenance of records are implemented? (CD-3.6) 	
	<p>For preparing the Safety Evaluation Report (SER), are the following expectations being implemented? (CD-3.7)</p> <ul style="list-style-type: none"> • Criterion 1 (Program) to ensure DOE-STD-1104 guidance are met? • Criterion 4 (Documents and Records) to ensure that processes for preparation, review, approval, issuance, use, and revision of the SER are implemented? • Criterion 4 to ensure that process for specification, preparation, review, approval, and maintenance of records are implemented? 	
	<p>For preparing the Construction Project Safety and Health Plan, is Criterion 4 (QA Documents and Records) being implemented to ensure that processes for preparation, review, approval, issuance, use, and revision of the plan are implemented? (CD-3.8)</p>	

ID #	Performance Objectives and Criteria ^{2 3}	Met?
	<p>For incorporating the final High Performance Sustainable Building design provisions into the Final Design, is Criterion 6 (Design) being implemented to ensure that applicable design inputs are controlled? (CD-3.9)</p> <p>In updating the QAP for construction, field design changes and procurement activities, are the following expectations being implemented? (CD-3.10)</p> <ul style="list-style-type: none"> • Criterion 1 (Program) to 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 • Criterion 9 (Management Assessment) to 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 	
Approval of Start of Operations and Project Completion		
CD-4	<p>Are the QA activities integrated into the project activities prior to CD-4 approval and into post-CD-4 activities?</p> <p><i>GENERAL: Verify that processes for preparation, review, approval, issuance, use and revision of documents that prescribe processes, requirements, and design are implemented (including change control for revision).</i></p> <p><i>to ensure that actions are planned and carried out by qualified personnel using approved procedures, instructions, and equipment under administrative, technical, and environmental controls</i></p> <p><i>Verify that design processes that provide appropriate control of design inputs, outputs, verification, configuration and design changes, and technical and administrative interfaces are implemented.</i></p> <p>When verifying Key Performance Parameters or Project Completion Criteria have been met and mission requirements achieved, are the following expectations being implemented? (CD-4.1)</p> <ul style="list-style-type: none"> • Criterion 3 (Quality Improvement) to ensure that processes to identify, control, and correct items, services, and processes that do not meet established requirements are implemented • Criterion 5 (Work Processes) to 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. 	

ID #	Performance Objectives and Criteria ^{2 3}	Met?
	<p>When conducting Readiness Assessment or Operational Readiness Review, are the following expectations being implemented? (CD-4.2)</p> <ul style="list-style-type: none"> • Criterion 3(Quality Improvement) <i>to ensure that processes to identify, control, and correct items, services, and processes that do not meet established requirements are implemented</i> • Criterion 5 (Work Processes) <i>to 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</i> • Criterion 10 (Independent Assessment) <i>to ensure that persons conducting reviews are technically qualified and knowledgeable in the areas to be reviewed</i> 	
	<p>For preparing the Checkout, Testing, and Commissioning Plan, are the following expectations being implemented? (CD-4.3)</p> <ul style="list-style-type: none"> • Criterion 4 (Documents and Records) <i>to ensure that processes for preparation, review, approval, issuance, use, and revision of the plan are implemented</i> • Criterion 8 (Inspection and Acceptance Testing) <i>to ensure that performance expectations, acceptance criteria, inspections and tests, and hold points, and calibration of measuring and testing equipment are addressed</i> 	
	<p>For preparing the Project Transition to Operations Plan, are the following expectations being implemented? (CD-4.4)</p> <ul style="list-style-type: none"> • Criterion 1 (Program) <i>to ensure that processes to implement a quality management approach are established and implemented</i> • Criterion 4 (Documents and Records) <i>to ensure that processes for preparation, review, approval, issuance, use, and revision of the plan are implemented</i> 	
	<p>For preparing the updated Quality Assurance Plan (QAP), are the following expectations being implemented? (CD-4.5)</p> <ul style="list-style-type: none"> • Criterion 1 (Program) <i>to ensure that processes to implement a quality management approach are established and implemented</i> • Criterion 4 (Documents and Records) <i>to ensure that processes for preparation, review, approval, issuance, use, and revision of the QAP are implemented</i> • <i>Verify that the QA program describes the established organizational structure, functional responsibilities, levels of authority and interfaces for those managing, performing and assessing the work.</i> • <i>Verify the process to implement a quality management approach are established and implemented.</i> • <i>Determine 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.</i> 	

ID #	Performance Objectives and Criteria ^{2 3}	Met?
	<p>For preparing the Environmental Management System (EMS), are the following expectations being implemented? (CD-4.6)</p> <ul style="list-style-type: none"> • Criterion 4 (Documents and Records) to ensure that processes for preparation, review, approval, issuance, use, and revision of the EMS are implemented • Criterion 5 (Work Processes) <i>to ensure that actions are planned and carried out by qualified personnel using approved procedures, instructions, and equipment under administrative, technical, and environmental controls</i> 	
	<p>For preparing the Documented Safety Analysis (DSA) and Technical Safety Requirements (TSR), are the following expectations being implemented? (CD-4.7)</p> <ul style="list-style-type: none"> • Criterion 4 (Documents and Records) to ensure that processes for preparation, review, approval, issuance, use, and revision of the DSA and TSR documents are implemented • Criterion 6 (Design) to ensure that applicable design inputs are controlled 	
	<p>For preparing the updated Construction Project Safety and Health Plan, are the following expectations being implemented? (CD-4.8)</p> <ul style="list-style-type: none"> • Criterion 4 (Documents and Records) to ensure that processes for preparation, review, approval, issuance, use, and revision of the plan are implemented • Criterion 5 (Work Processes) to ensure that actions are planned and carried out by qualified personnel using approved procedures, instructions, and equipment under administrative, technical, and environmental controls 	
	<p>For preparing the final Security Vulnerability Assessment Report, is Criterion 4 (Documents and Records) being implemented to ensure that processes for preparation, review, approval, issuance, use, and revision of the report are implemented? (CD-4.9)</p>	
	<p>For preparing the final Cyber Security Plan, is Criterion 4 (Documents and Records) being implemented to ensure that:</p> <ul style="list-style-type: none"> • Processes for preparation, review, approval, issuance, use, and revision of the plan are implemented • <i>Processes for specification, preparation, review, approval, and maintenance of records are implemented?</i> (CD-4.10) 	
	<p>For preparing the Safety Evaluation Report (SER), are the following expectations being implemented? (CD-4.11)</p> <ul style="list-style-type: none"> • Criterion 4 (Documents and Records) to ensure that processes for preparation, review, approval, issuance, use, and revision of the SER are implemented • Criterion 5 (Work Processes) to ensure that actions are planned and carried out by qualified personnel using approved procedures, instructions, and equipment under administrative, technical, and environmental controls 	

ID #	Performance Objectives and Criteria ^{2 3}	Met?
	<p>For performing Final Administrative and Financial Closeout and preparing the Final Project Closeout Report, are the following expectations being implemented? (CD-4.12)</p> <ul style="list-style-type: none"> • Criterion 3 (Quality Improvement) to ensure that organization has established, implemented, and documented processes to detect and prevent quality problems and that problems have been corrected • Criterion 4 (Documents and Records) to ensure that processes for preparation, review, approval, issuance, use, and revision of the documents are implemented 	
	<p>For preparing the Lessons Learned Report, are the following expectations being implemented? (CD-4.13)</p> <ul style="list-style-type: none"> • Criterion 3 (Quality Improvement) <i>to ensure that processes to detect and prevent quality problems are implemented</i> • Criterion 4 (Documents and Records) to ensure that processes for specification, preparation, review, approval, and maintenance of records are implemented 	
	<p>For preparing the Project Required Operational Documentation, is Criterion 4 (QA Documents and Records) being implemented to ensure that processes for specification, preparation, review, approval, and maintenance of records are implemented? (CD-4.14)</p>	
	<p>For conducting Post Implementation Review, is Criterion 9 (Management Assessment) being implemented to 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? (CD-4.15)</p>	