Focus Area #5 – Line Management Understanding of QA and Oversight

Top Right Quadrant: Quality Assurance

Point of Contact: Sandra Waisley

- **Issues:** Users will provide current or on-going QA issues of concern that impact work being done correctly, timely, and safely. Input could be from recent assessments, trends, Performance Metrics, number of open action items, recurring issues, etc. *Example: Issue #1: Training database was not updated for a 60 day period following termination of training coordinator*

- **Risks:** Users will identify risks that impact the project (can be related to "issues" [above] or any other FPD identified risk) being done correctly, timely, and safely. *Example: Risk #1: Unqualified personnel may have performed hazardous work unsafely or incorrectly during this period*

- **Planned Actions:** Users will provide planned actions to address QA issues or project risks into the New Quad Chart template, especially the yellow and red areas. *Example: Planned Action #1: Contractor will re-verify training records of all operations personnel, review work performed to and update database by 4/5/09*

QUALITY ASSURANCE

Criteria		Previous Period	Current Period
Management	Criteria 1 - 4		
Performance	Criteria 5 - 8		
Assessment	Criteria 9 - 10		

Issues:

Risks:

Planned Actions:

The following indicators are used by the Federal Project Directors (FPD) to convey a summary evaluation of the health and implementation of the project's QA Program. The FPD's evaluation may be based on a number of data points such as: EM Corporate Performance Metrics, recent assessments, contractor performance, trend data, number of open action items, performance related to completed assessments, recurring issues, etc.

Summary QA Program Implementation Status	Rating
The program is not fully documented and/or implemented for the Criteria. The program has significant deficiencies which require extensive corrective actions or compensatory measures.	
The program is documented and implemented for the Criteria; however, evaluation of implementation has identified a significant number of issues that could indicate serious performance problems or adverse trends.	
The program is fully documented and implemented for the Criteria. The program has been independently evaluated within the last year and/or periodically assessed. Program effectively implemented, however, there were findings which required more extensive corrective actions to correct program deficiencies.	
The program is fully documented and implemented for the Criteria. The program has been independently evaluated within the last year and/or periodically assessed. Program effectively implemented, however, there were findings identified which required administrative actions to correct	
The program is fully documented and implemented for the Criteria. The program has been independently evaluated within the last year and/or periodically assessed. Program effectively implemented with only minor issues identified	

The 10 Criteria of DOE O 414.1C which are evaluated for the QPR:

Criterion 1 - Program
Criterion 2 – Personnel Training and Qualification
Criterion 3 – Quality Improvement
Criterion 4 – Documents and Records
Criterion 5 – Work Processes
Criterion 6 - Design
Criterion 7 - Procurement
Criterion 8 – Inspection and Acceptance Testing
Criterion 9 – Management Assessment
Criterion 10 – Independent Assessment

Department of Energy
Washington, DC 20585

November 5, 2008

MEMORANDUM FOR DISTRIBUTION

FROM: INÈS TRIAY
PRINCIPAL DEPUTY ASSISTANT SECRETARY FOR
ENVIRONMENTAL MANAGEMENT

SUBJECT: Issuance and Lmplementation of the Office of Environmental Management (EM) Quality Assurance Program (QAP)

In December 2007, the National Academy of Public Administration (NAPA) issued a report to Congress titled "Office of Environmental Management: Managing America's Defense Nuclear Waste." Several observations regarding the implementation of Quality Assurance (QA) across the EM complex were identified in the report. Specifically, NAPA identified that improvements are needed to increase the emphasis upon QA within EM by ensuring the appropriate QA requirements flow down across all EM contractors and subcontractors. To provide some guidelines in this area, a Corporate Quality Policy Statement and EM Quality Assurance Program (QAP) have now been established for the EM complex (see Attachments 1 and 2). The development and review of this QAP were assisted by numerous professionals from EM HQ, DOE Chief Nuclear Safety Office, EM field sites, National Laboratories, and the DOE contractor community. In addition, the EM QA Corporate Board in its last meeting endorsed this QAP after review and discussion.

Our first priority is to "do work safely." In concert with this, it is also essential to "do work correctly" or both safety and quality are jeopardized. This QAP provides the basis to achieve quality across the EM complex for all mission-related work while providing a consistent approach to QA. This will allow for grading based on the importance to the EM mission and safety, and for site-specific requirements.

We have adopted the American Society of Mechanical Engineers (ASME) NQA-1-2004 Quality Assurance Requirements for Nuclear Facility Applications, as the national consensus standard for implementing the EM QAP due to the high hazards and costs of our activities and facilities. The requirements contained within this document apply to EM (HQ), EM Field/Project Offices, and contractors as applicable to the work being performed by each entity. For those projects that are using NQA-1-2000 due to contract requirements, we are requesting the following: 1) Considering the project life cycle stages, identify and inform the Office of Standards and Quality Assurance (EM-64) of the gaps in

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your project between NQA-1-2000 and 2004 requirements; and 2) Incorporate, in consultation with EM-64, those aspects of NQA-1-2004 that would be beneficial to your project.

Using a graded approach, each HQ and Field organization shall prepare a Quality Assurance Implementation Plan (QIP) identifying procedures and documents that directly implement the applicable requirements of the QAP. The QIP will demonstrate how the QAP requirements are being implemented. Specific instructions for developing and approving QIPs can be found in the QAP. To assist in developing the QIP, organizations should perform a gap analysis to determine the procedures and documents needed to meet the QAP. However, EM HQ intends to provide more detailed direction on implementation of this QAP in first quarter 2009 fiscal year.

The effective implementation date for the EM QAP is June 30,2009. Please note that EM HQ plans to conduct a self assessment and a gap analysis to facilitate implementing the EM QAP at HQ by the June date. If you have any further questions, please call me at (202) 586-5216 or Dae Y. Chung, Deputy Assistant Secretary for Safety Management and Operations, at (202) 586-5151.

Attachments

cc:
C. Anderson, EM-3
K. Goodwin, EM-3.1
B. Smith, EM-3.2
D. Crouther, EM-3.3
J. Fiore, EM-6
F. Marcinowski, EM-10
M. Gilbertson, EM-20
M. Sykes, EM-30
D. Cochran, EM-40
J. Surash, EM-50
D. Chung, EM-60
G. Boyd, OR
E. Sellers, ID
T. Vero, BNL
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R. Schassburger, Oakland Projects Office
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Richard B. Provencher, Deputy Manager, Idaho Operations Office (ID)
Shirley Olinger, Manager,,Office of River Protection (ORP)

.Departmentof Energy
Washington, DC 20585

DEC 0 9 2008

MEMORANDUM FOR DISTRIBUTION

FROM: DAE Y. CHUNG
DEPUTY ASSISTANT SECRETARY FOR
SAFETY MANAGEMENT AND OPERATIONS
ENVIRONMENTAL MANAGEMENT

SUBJECT: Additional Direction for Issuance and Implementation of the Office of Environmental Management Quality Assurance Program

The following information outlines my expectations regarding effectively implementing the new Office of Environmental Management (EM) Corporate Quality Assurance Program (QAP). In the November 5,2008, memorandum, Dr. Ines Triay, in her position as Principal Deputy Assistant Secretary, approved the issuance and implementation of the EM Corporate QAP. However, effective integration and implementation of the Corporate QAP will not be possible without a strong commitment of support from you, your management team and your workers. I encourage each of you to continue support of this effort.

Program Attributes. The salient attributes of the EM Corporate QAP and our implementation approach are summarized below:

- Implementation of the QAP is based upon ASME NQA-1, 2004, including addenda through 2007;
- Headquarters (HQ), Field sites, and site contractors will perform a gap analysis prior to initiating the Corporate QAP implementation;
- A newly developed or site modified QAP along with a Quality Implementation Plan (QIP) will be based on the gap analysis and reflect the mission, project life cycle, and risk of the work scope;
  The QAP/QIP is graded to nuclearinon-nuclear operations;
- EM HQ, Field sites, and site contractors have the ability to tailor and grade QAP requirements; and
- QIPs will be submitted to the respective approval authority for review and approval prior to implementation.

Program Expectations. As detailed in the attached "EM Corporate QAP Implementation Roadmap" each site and corresponding support contractors should immediately initiate preparation of a site/project specific gap analysis. The gap analysis should be designed to identify differences between your current site QAP and the requirements of the Corporate QAP. Those discrepancies that you have identified that are not beneficial or are too costly for your site or project,

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particularly for the capital construction projects, should be vetted through my office for exemption consideration. Once the gap analysis is completed any discrepancies should be addressed through updating your current site QAP to meet or exceed the requirements of the Corporate QAP. Subsequently, each site/project is responsible for preparing a QIP to identify the procedures and documents that directly implement the applicable requirements of the updated QAP. Specific instructions for developing and approving QIPs can be found in the EM Corporate QAP.

Program Path Forward. As stated in the November 5,2008, memorandum, the effective implementation date for the EM QAP is June 30,2009. For those sites and contractors that currently implement a NQA-1 QAP the target date for completing the gap analysis, updating the QAP, and developing a QIP will remain June 30,2009. Final review and approval of your QIP is targeted for September 30,2009. For those sites, however, that do not currently implement a NQA-1 QAP your target date for developing a QAPIQIP is September 30, 2009. Final review and approval date of that QIP is required by December 31,2009. The technical resources of my office are available to you to ensure that your site meets the targeted QAPIQIP development dates.

Further, each site manager should ensure that the federal and contractor workforce is knowledgeable of the corporate quality requirements and adequately trained to meet them. Having a knowledgeable workforce with access to the necessary resources to address quality requirements will greatly impact implementation success. Finally, implementing a structured system to monitor the implementation of your QAPIQIP will provide an effective way of gauging the effectiveness of your quality program by identifying the areas needing improvement.

In closing, our priority is to "do work safely" in concert with "doing work correctly" or both safety and quality are jeopardized. The Corporate QAP provides a consistent approach to achieve quality across the EM complex for all mission-related work. I encourage all of you to make the implementation of the EM Corporate QAP your top priority in fiscal year 2009.

Please contact me or Sandra Waisley, Director of the Office of Standards and Quality Assurance, at (202) 586-5151, if you have any questions concerning the development of your QAPIQIP.

Attachment

cc:
I. Triay, EM-1 (Acting)
J. Owendoff, EM-3
B. Smith, EM-3.2
D. Crouther, EM-3.3
J. Fiore, EM-6
F. Marcinowski, EM-10
M. Gilbertson, EM-20
M. Sykes, EM-30
D. Cochran, EM-40
J. Surash, EM-50
D. Chung, EM-60
G. Boyd, OR
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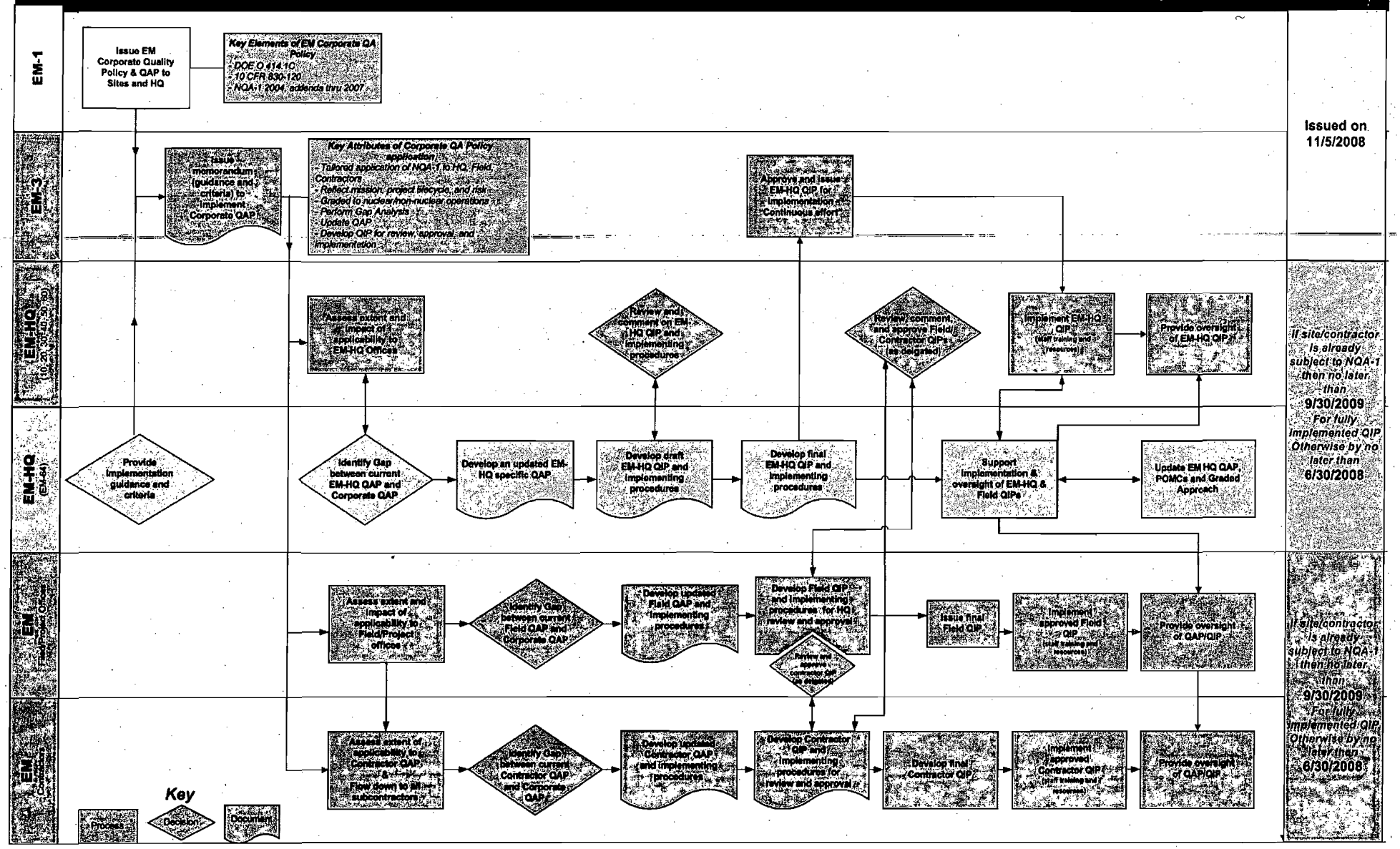
William E. Murphie, Manager, Portsmouth/Paducah Project Office (PPPO)
Shirley Olinger, Manager, Office of River Protection (ORP)
Cynthia Anderson, Deputy Chief Operations Officer EM-3
Richard B. Provencher, Deputy Manager, Idaho Operations Office (ID)

EM Corporate QAP Implementation Roadmap

November 21, 2008



Department of Energy
Washington, DC 20585

AUG 2 4 2009

MEMORANDUM FOR DISTRIBUTION

FROM: DR. STEVEN L. KRAHN
ACTING DEPUTY ASSISTANT SECRETARY FOR
SAFETY MANAGEMENT AND OPERATIONS

SUBJECT: Additional Clarification for Issuance and Implementation of the Office of Environmental Management Quality Assurance Program

In her November 5, 2008 memorandum, Dr. Ines Triay, in her position as Principal Deputy Assistant Secretary, approved the issuance and implementation of the Office of Environmental Management (EM) Corporate Quality Assurance Program (QAP). Mr. Dae Chung, in his former position as Deputy Assistant Secretary for Safety Management and Operations, issued additional guidance in December 2008, with respect to EM's corporate expectations regarding effective implementation of the EM Corporate QAP (EM-QA-001, Revision 0, 10/20/2008). All direction to date, with the exception discussed below, should continue to be followed. The following provides clarification and additional information with respect to the use of the American Society of Mechanical Engineers (ASME) Nuclear Quality Assurance-1 (NQA-1), *Quality Assurance Requirements for Nuclear Facility Applications*, during implementation of EM-QA-001.

Briefly, the EM Corporate QAP adopts the ASME NQA-1-2004 (including addenda through 2007) as the national consensus standard to facilitate consistent implementation of quality assurance across all of EM's activities. To ensure cost-effective and efficient application of NQA-1 to the diverse range of activities undertaken by the EM complex, the QAP promotes a graded approach. The graded approach enables EM elements to tailor their QA program to ensure QA requirements and expectations are met as effectively and efficiently as possible.

Several EM sites and projects have inquired about continuing to use different versions of NQA-1 to demonstrate their implementation of the EM Corporate QAP. The inquires have specifically focused on using alternative versions of NQA-1, other than NQA-1-2004, under existing contracts with the understanding that new, revised or re-competed contracts would incorporate and reference the latest version of the EM Corporate QAP requirements and expectations. The Office of Standards and Quality Assurance (EM-64) has evaluated all the inquiries to date. The corporate policy decision regarding this issue is to consider implementation of the EM Corporate QAP through the application of NQA-1-2000, or subsequent editions of NQA-1, as long as a risk-informed evaluation is performed that clearly demonstrates that any identified gaps between the site or project's current QAP and NQA-1-2004 (including NQA-1 addenda through 2007) do not represent any additional risks to quality of EM work, products, and services. The sites

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are asked to use the attached standardized EM-HQ Exemption/Exception Variance process to formally submit their requests. Please submit the completed forms to Sandra Waisley, Director, Office of Standards and Quality Assurance (EM-64).

For those sites that are currently implementing or choose to implement NQA-1-2008, a variance or exemption request is not needed to use it as your basis for implementation of the EM Corporate QAP. In addition, for those sites that have contracts that will close within the next 12 months, including any extensions, and the contractors are not performing nuclear activities, also do not need a variance or exemption request. If the contractors are performing nuclear related activities, an exemption or variance would still need to be considered by EM-64.

In closing, our priority is to "do work safely" in concert with "doing work correctly." The Corporate QAP provides a consistent set of requirements and management expectations to achieve quality across the EM complex for all mission-related work. I thank all of you for your continued effort in making the implementation of the EM Corporate QAP our top priority.

Please contact me or Sandra Waisley, EM-64, at (202) 586-5151, if you have any questions concerning this direction.

Attachment

cc:
I. Triay, EM-1
D. Chung, EM-2
C. Anderson, EM-2.1
J. Owendoff, EM-3
B. Smith, EM-3.2
D. Crouther, EM-3.3
J. Fiore, EM-5/6
F. Marcinowski, EM-10
M. Gilbertson, EM-20
M. Sykes, EM-30
D. Cochran, EM-40
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Bryan Bower, Director, West Valley Demonstration Project Office (WVDP)
Donald Metzler, Director, Moab Federal Project Office (MOAB)
Dennis Miotla, Acting Manager, Idaho Operations Office (ID)
Gerald Boyd, Manager, Oak Ridge Office (OR)

Framework for a Consistent EM-HQ Review of Quality Assurance (QA) Variance and Exemption Requests

Risk-Informed Process for HQ Review of QA Exemption/Variance Requests				
Requesting Organization: DOE Site/Contractor:				
Specifics of Variance/Exemption/Exception Request	EM QAP Requirement	Delta (from Baseline Requirement)	Risk Analysis/Impacts	EM-60 or Designee Recommendation
Document specifically the nature of the variance and/or exemption requested, specific facility or process or operation that will be affected, and the main drivers and justifications for the request	Identify specific section(s) or aspects of QA requirements from which the variance and/or exemption is being requested	Discuss the extent to which request deviates from the objective of the EM QAP and intent of the requirement—discuss issues such as equivalency or non-applicability due to the nature of the situation and circumstances	Provide a qualitative analysis of any potential impacts on project success, if any, including safety and health implications, readiness including Critical Decision (CD) milestones, product quality, cost, schedule, regulatory implications, and any other attributes as applicable *Note: Impacts can be categorized as HIGH, MEDIUM, LOW and must be tied to qualitative analysis*	Provide a risk-informed judgment on EM-HQ acceptability of any anticipated risks as the result of variance and/or exemption request

Risk-Informed Process for HQ Review of QA Exemption/Variance Requests				
Requesting Organization: DOE Site/Contractor:				
Specifics of Variance/Exemption/Exception Request	EM QAP Requirement	Delta (from Baseline Requirement)	Risk Analysis/Impacts	EM-60 or Designee Recommendation
			provided by requestor	

QA Awareness and Status Report

Office of Environmental Management
Project & Contract Management Workshop
July 21-23, 2009

Robert Toro,
Office of Standards and Quality Assurance, EM-64

EM Environmental Management
safety ❖ performance ❖ cleanup ❖ closure

Overview

- **Background and drivers**
- **Corporate Initiatives**
- **Basic Overview of QA Requirements**

How do we support the EM Complex?

Provide the mechanisms, tools, and resources to support Projects implement an effective QA Program

Examples of Initiatives To date

- Industry Partnership to enhance the availability of and access to qualified QA expertise, e.g., Suppliers events
- Outreach & Awareness in terms of QA training, orientation, and informative booklets e.g., Training aimed at the Nuclear supplier community, Federal and contractor QA personnel, complex-wide resource survey to right size project-specific QA needs
- Policies and Procedures to clearly define EM's QA corporate requirements and expectations, e.g., QA Policy, Corporate Quality Assurance Program (QAP)
- Enhanced Decision-making Framework to ensure transparency and technical rigor in critical decision (CD) review and approval, EM Standard Review Plan (SRP) Review Modules
- Improved Operational Awareness to ensure timely and effective identification of QA issues and closure of corrective actions, e.g., Performance-based QA audits, *EM-QA HUB* to track status of corrective action plans

Corporate Value-Added to EM-Complex

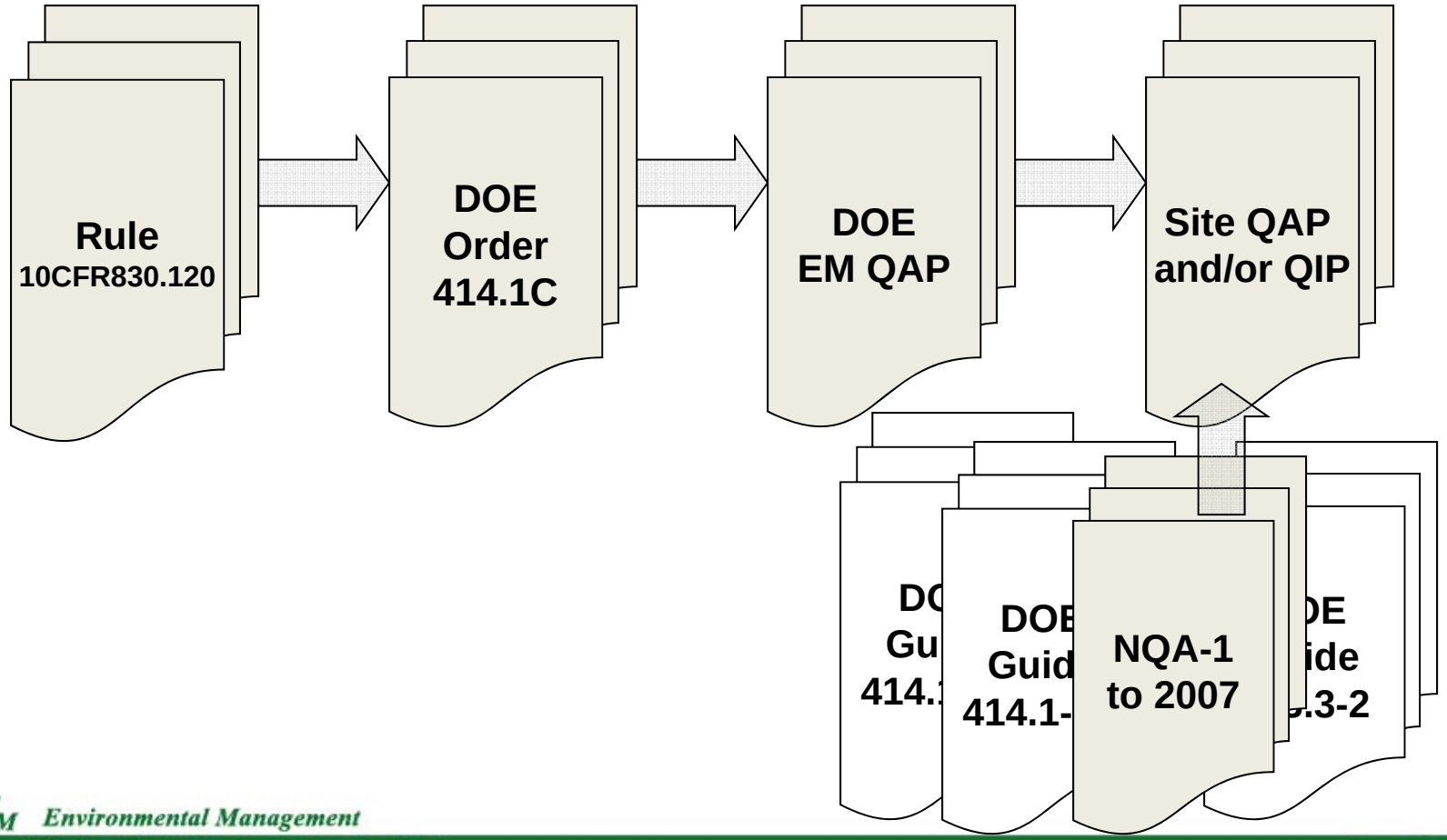
- Clarity and consistency of requirements and expectations
- Stability and predictability in decision-making process
- A more robust integration of QA integration in Projects and day-to-day activities
  - Enhance safety and reliability
  - Improve cost and schedule

Basic Overview of QA Requirements

E M Environmental Management

safety ❖ performance ❖ cleanup ❖ closure

DOE/EM QA Requirements



Quality Assurance Program Requirements (the Rule)

The Rule- 10 CFR 830.120 (10 CFR 830 Subpart A):

- Establishes QA requirements for contractors conducting activities, including providing items or services, affecting nuclear safety of DOE facilities
- Requires contractors to conduct work in accordance with the QA criteria in 10 CFR 830.122
- Requires contractors to integrate the QA criteria with the Safety Management System
- Requires contractors to describe how they ensure subcontractors and suppliers satisfy the QA criteria of 830.122
- Requires contractors, responsible for a DOE nuclear facility, to submit their QA program to DOE for approval
- Enforcement is established via the Price-Anderson Amendments Act

Quality Assurance Program Requirements (The QA Order)

DOE O 414.1C, *Quality Assurance*:

- Requires development of QA program
- Establishes QA Program requirements in 10 criteria
- Applies to primary DOE organizations and their associated field elements (except the Bonneville Power Administration)
- Applies to NNSA organizations (except NNSA Naval Reactors Program)
- Applies to more than nuclear safety-related items /components addressed by NQA-1. **NQA-1-2004 plus addenda thru 2007** expands on the different applications of DOE O 414.1 C.
- (EM has adopted **NQA-1-2004 plus addenda thru 2007** as the consensus standard for all nuclear and non-nuclear work using the graded approach)

Mapping of DOE QA Order to ASME NQA-1 Requirements

Management

Performance

Assess

DOE O 414.1C Performance Criteria	NQA-1 Requirement Section
Criterion 1 - Program	Requirement 1 (Organization) Requirement 2 (Quality Assurance Program)
Criterion 2 - Personnel Training & Qualification	Requirement 2 (Quality Assurance Program)
Criterion 3 - Quality Improvement	Requirement 16 (Corrective Action)
Criterion 4 - Documents & Records	Requirement 5 (Instructions, Procedures & Drawings) Requirement 6 (Document Control) Requirement 17 (Quality Assurance Records)
Criterion 5 - Work Processes	Requirement 8 (Identification & Control of Items) Requirement 9 (Control of Special Processes) Requirement 10 (Inspection)
Criterion 6 - Design	Requirement 3 (Design Control)
Criterion 7 - Procurement	Requirement 4 (Procurement Document Control) Requirement 7 (Control of Purchased Items & Services)
Criterion 8 - Inspection & Acceptance Testing	Requirement 10 (Inspection) Requirement 11 (Test Control) Requirement 12 (Control of Measuring & Test Equipment) Requirement 14 (Inspection, Test & Operating Status) Requirement 15 (Control of Nonconforming Items)
Criterion 9 - Management Assessment	Requirement 2 (Quality Assurance Program)
Criterion 10 - Independent Assessment	Requirement 18 (Audits)

Quality Assurance Program Requirements (the Guides)

- **DOE G 414.1-1B** **Management and Independent Assessments**
- **DOE G 414.1-2A** **QA Management System Guide**
- **DOE G 414.1-3** **Suspect/Counterfeit Items**
- **DOE G 414.1-4** **Safety Software Guide**
- **DOE G 414.1-5** **Corrective Action Program Guide**
- **DOE G 413.3-2** **QA Guide for Project Management**

Quality Assurance Program Requirements (the Guides)

DOE G 413.3-2, *QA Guide for Project Management*:

- Provides guidelines, notes, suggestions, for example, for developing a QA Program
- Discusses QA Program development and implementation by Critical Decisions (DOE G 413.3A)
- Module 4 contains additional discussions regarding QA requirements associated with each Critical Decision.

Graded Approach to QA

Considerations for grading:

- 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

Effective Integration of Quality Assurance (QA) Program in Management and Execution of EM Capital Projects

July CM/PM Workshop

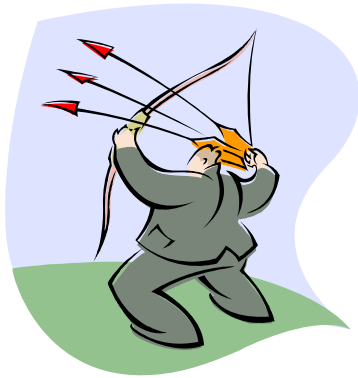
Bob Toro

EM Environmental Management

safety ❖ performance ❖ cleanup ❖ closure

Presentation Layout

- **Introduction**
- **Roles and Responsibilities**
- **DOE/EM Quality Assurance (QA) Program Requirements**
- **Critical Decision (CD) Requirements**



Introduction

Recent Quality Assurance Initiatives

April 26, 2006 - Secretary Bodman released the memorandum, "Improving Quality Assurance," asking for a report on Quality Assurance implementation by July 30, 2006.

"The Department has several examples* where the quality of the work has negatively impacted the mission resulting in rework, delays, and cost growth, all in a time of limited resources."

***Refer to Module 5 "Lessons Learned"**

Deputy Assistant Secretary, Office of Safety Management and Operations - "Field Assist Reviews revealed programmatic weaknesses in several of the key criteria"

REQUIREMENTS/CRITERIAS		CONTRACTOR RESULTS							
		Project 1	Project 2	Project 3	Project 3	Project 5	Project 6	Project 7	Project 8
1	Organization								
2	Quality Assurance Program								
3	Design Control				N/A				
4	Procurement Document Control							N/A	
5	Instructions, Procedures, and Drawings			N/A					N/A
6	Document Control							N/A	N/A
7	Control of Purchased Items and Services							N/A	
8	Identification and Control of Items			N/A	N/A	N/A	N/A	N/A	N/A
9	Control of Special Processes			N/A	N/A	N/A	N/A	N/A	N/A
10	Inspection				N/A	N/A	N/A	N/A	N/A
11	Test Control				N/A	N/A	N/A	N/A	N/A
12	Control of Measuring and Test Equipment			N/A	N/A	N/A	N/A	N/A	N/A
13	Handling, Storage, and Shipping			N/A	N/A	N/A	N/A	N/A	N/A
14	Inspection, Test, and Operating Status			N/A	N/A	N/A	N/A	N/A	N/A
15	Control of Nonconforming Items			N/A	N/A	N/A	N/A	N/A	N/A
16	Corrective Action					N/A	N/A	N/A	N/A
17	Quality Assurance Records							N/A	N/A
18	Audits								
19	Software								

BLUE – Exceeds Requirements of ASME NQA-1, 2004

GREEN – Meets Requirements of ASME NQA-1, 2004

YELLOW – At Risk to not meeting Requirements of ASME NQA-1, 2004

RED – Does not meet Requirements of ASME NQA-1, 2004

N/A – Not Applicable or these areas were not evaluated

In September of 2007, Deputy Assistant Secretary, Dae Y. Chung Announced EM Quality Assurance Improvement Initiatives

EM QA Initiatives:

- **Management and Organizational Focus**
- **Industry Partnership**
- **Oversight Program**
- **Federal QA Resource and Competencies**
- **Standard Review Plan**
- **QA Project Plan Development**
- **QA Corporate Board**

WHY ARE WE HERE???

QA Corporate Board

Project Executive Committee

EFCOG

Project Managers

#1 – Requirements Flow Down

#2 – Adequate NQA-1 Suppliers

#3 – Commercial Grade Item and Services Dedication Implementation and Nuclear Services

#4 – Graded Approach to Quality Assurance

#5 – Line Management Understanding of QA and Oversight

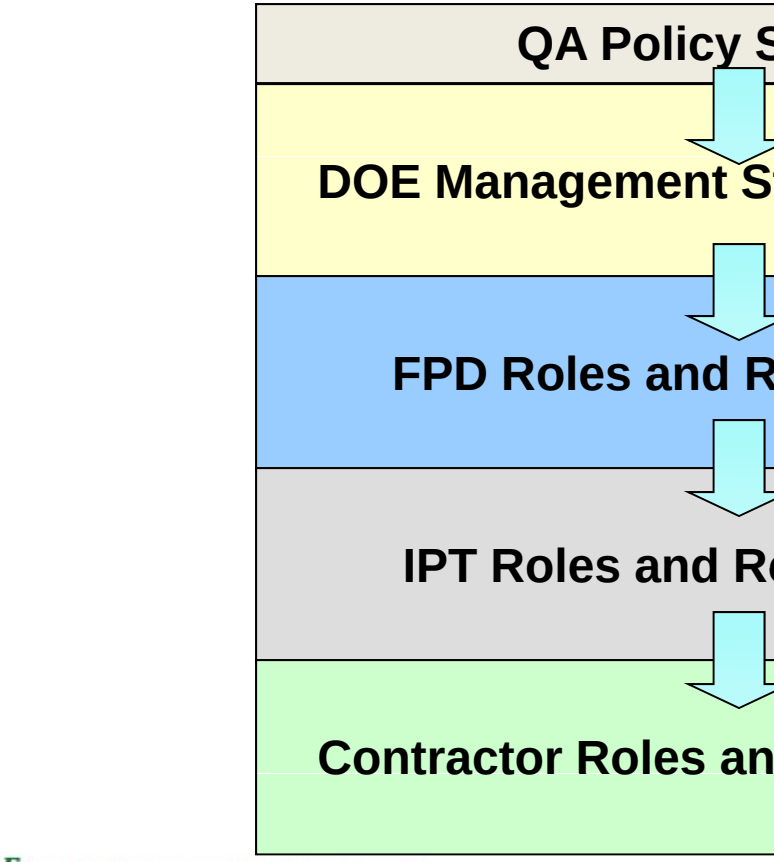
You are here!

Federal Project Director & Integrated Project Team Roles and Responsibilities

EM Environmental Management

safety ❖ performance ❖ cleanup ❖ closure

Responsibilities are Defined in DOE G 413.3-2



Strategy & Policy

Plan and Implement a Project QA Program:

- Organization or project-specific QA plan
  - Maximize use of site-wide programs
  - If project is extremely large or complex, site program use may be impractical
- Identify the applicable QA requirements from DOE Order O 414.1C, 10 CFR 830, Subpart A, or 10 CFR 63.142, and additional voluntary consensus standards for use.

(EM Corporate QAP mandates NQA-1-2004 as a minimum for all nuclear and non-nuclear projects applied in a graded approach.)

Strategy & Policy

- Ensure adequate personnel to support the QA program (Federal and Contractor) including personnel to properly develop, review, implement and conduct oversight of each aspect of the QA program
- Identify key QA leaders in DOE and contractor organizations
- Ensure that the QA organization is independent from Line Management

Strategy & Policy

- Ensure QA requirements are documented in subcontracts
- Ensure implementing procedures are developed & implemented before work is performed
- Evaluate adequacy of project QA program

  (Consider using a gap analysis between existing QA programs and project QA requirements, if appropriate)

Organizational Structure Roles and Responsibilities

Ensure the Contractor Has Assigned Roles and Responsibilities that:

- Identify major project key participants
- Identify work assignment for each participant
- Define project organizational structure
- Define individual's responsibilities and authorities
- Define specific QA oversight responsibilities

FPD Federal Organization Roles and Responsibilities

- Ensure that project efforts comply with:
  - Contract
  - Public Law
  - Regulations
- Ensure that safety, security, environmental and quality are implemented and integrated
- Apply DOE QA program
- Recommend approval of contractor QA program to approval authority

IPT Federal Organization Roles and Responsibilities

- Perform monthly reviews and assessments:
  - Project performance & status vs. performance parameters, baselines, milestones and deliverables
- Plan and participate in project reviews, audits and appraisals
- Review & comment on deliverables
- Review change requests

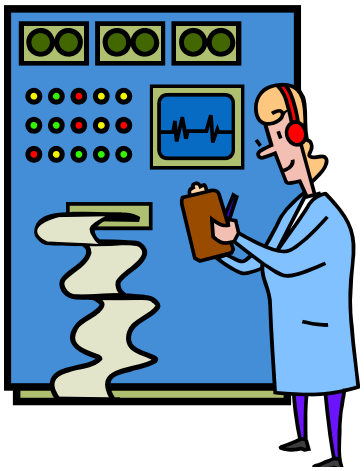
Contractor Organization Roles and Responsibilities

Quality Assurance Function:

- Assist with interpretation of project-specific QA program requirements
- Verify program implementation
- Evaluate effectiveness by surveillances and audits

Contractor Organization Roles and Responsibilities

Quality Control Function:



- Quality verification,
- Inspection,
- Documentation, and
- Surveillance of hardware

[including Structures, Systems, and Components (SSCs) and services]

Contractor Organization Roles and Responsibilities

Quality Engineering Function:

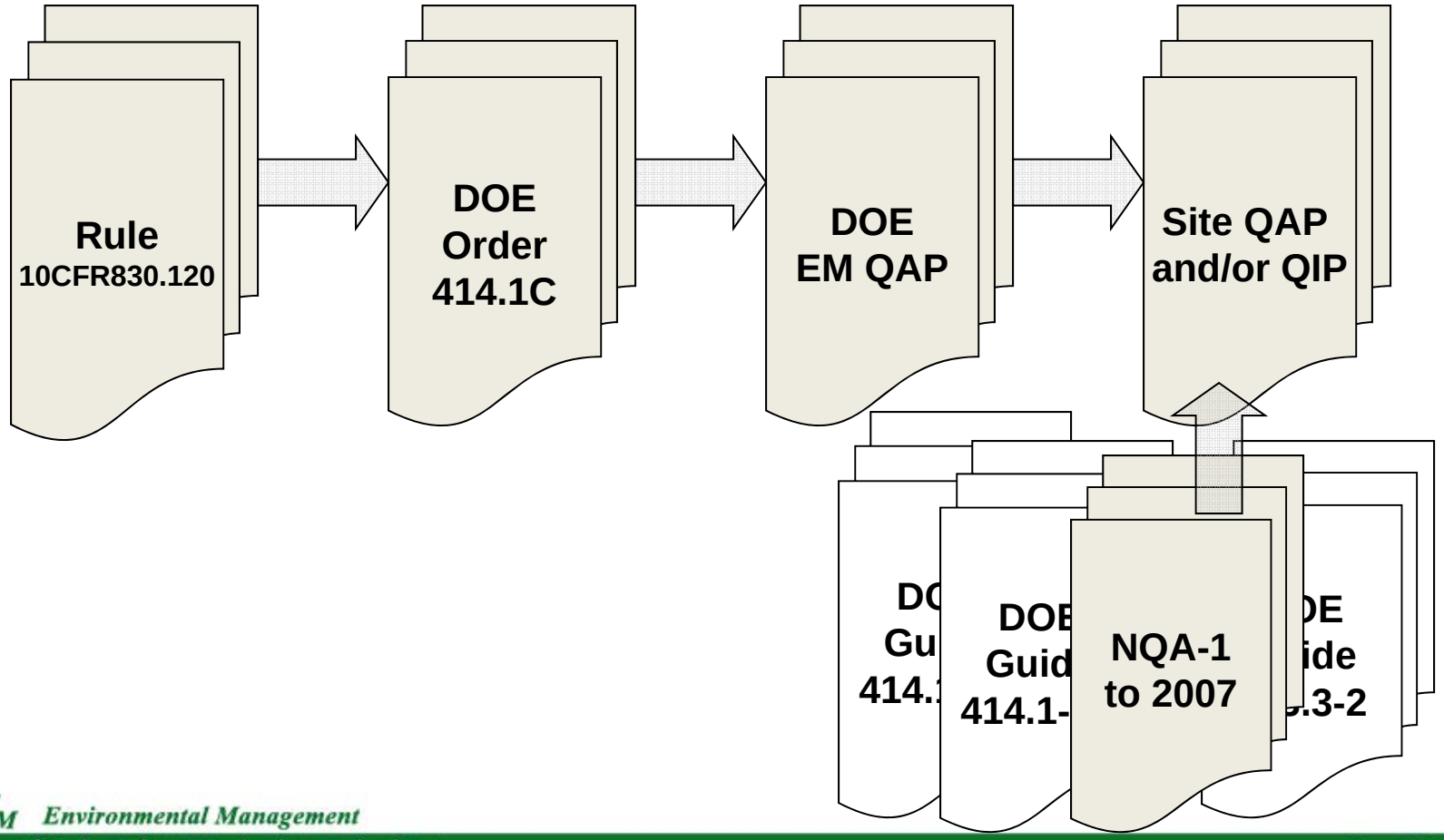
- Design
- Procurement
- Installation
- Test
- Inspection acceptance criteria
- Turnover control system

DOE Quality Assurance Program Requirements Overview

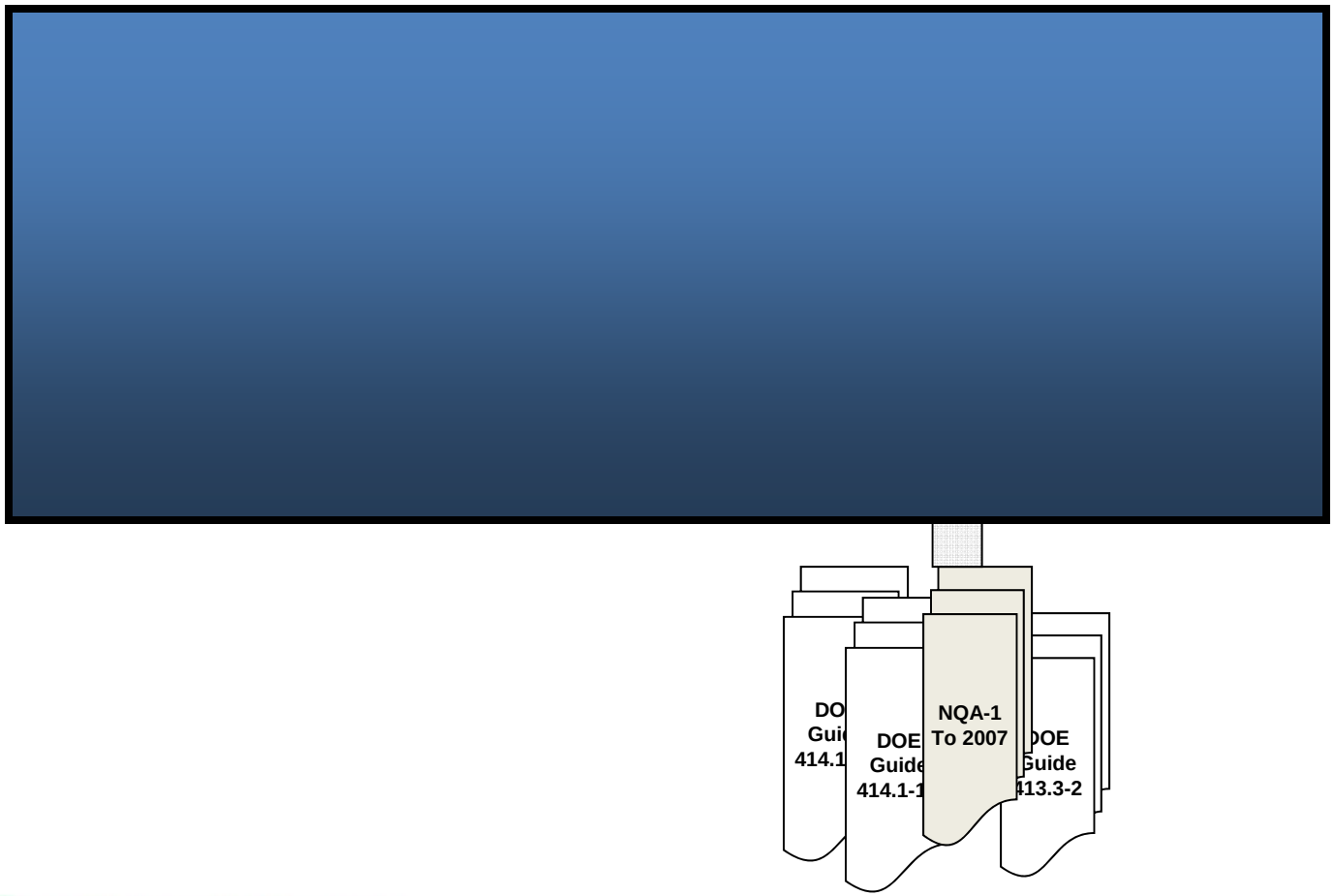
*E*M *Environmental Management*

safety ❖ performance ❖ cleanup ❖ closure

Flow Down of Requirements



QA Enforcement



Quality Assurance Program Requirements (the Rule)

The Rule- 10 CFR 830.120 (10 CFR 830 Subpart A):

- Establishes QA requirements for contractors conducting activities, including providing items or services, affecting nuclear safety of DOE facilities
- Requires contractors to conduct work in accordance with the QA criteria in 10 CFR 830.122
- Requires contractors to integrate the QA criteria with the Safety Management System
- Requires contractors to describe how they ensure subcontractors and suppliers satisfy the QA criteria of 830.122
- Requires contractors, responsible for a DOE nuclear facility, to submit their QA program to DOE for approval
- Enforcement is established via the Price-Anderson Amendments Act

Quality Assurance Program Requirements (the Order)

DOE O 414.1C, Quality Assurance:

- Requires development of QA program
- Establishes QA Program requirements in 10 criteria
- Applies to primary DOE organizations and their associated field elements (except the Bonneville Power Administration)
- Applies to NNSA organizations (except NNSA Naval Reactors Program)
- Applies to more than nuclear safety-related items /components addressed by NQA-1. **NQA-1-2004 plus addenda thru 2007** expands on the different applications of DOE O 414.1 C.
- (EM has adopted **NQA-1-2004 plus addenda thru 2007** as the consensus standard for all nuclear and non-nuclear work using the graded approach)

DOE QA Order Criteria vs. ASME NQA-1 Requirements

	DOE O 414.1C Performance Criteria	NQA-1 Requirement Section
Management	Criterion 1 - Program	Requirement 1 (Organization) Requirement 2 (Quality Assurance Program)
	Criterion 2 - Personnel Training & Qualification	Requirement 2 (Quality Assurance Program)
	Criterion 3 - Quality Improvement	Requirement 16 (Corrective Action)
	Criterion 4 - Documents & Records	Requirement 5 (Instructions, Procedures & Drawings) Requirement 6 (Document Control) Requirement 17 (Quality Assurance Records)
Performance	Criterion 5 - Work Processes	Requirement 8 (Identification & Control of Items) Requirement 9 (Control of Special Processes) Requirement 10 (Inspection)
	Criterion 6 - Design	Requirement 3 (Design Control)
	Criterion 7 - Procurement	Requirement 4 (Procurement Document Control) Requirement 7 (Control of Purchased Items & Services)
	Criterion 8 - Inspection & Acceptance Testing	Requirement 10 (Inspection) Requirement 11 (Test Control) Requirement 12 (Control of Measuring & Test Equipment) Requirement 14 (Inspection, Test & Operating Status) Requirement 15 (Control of Nonconforming Items)
Assess	Criterion 9 - Management Assessment	Requirement 2 (Quality Assurance Program)
	Criterion 10 - Independent Assessment	Requirement 18 (Audits)

Quality Assurance Program Requirements (the Guides)

- **DOE G 414.1-1B** — **Management and Independent Assessments**
- **DOE G 414.1-2A** — **QA Management System Guide**
- **DOE G 414.1-3** — **Suspect/Counterfeit Items**
- **DOE G 414.1-4** — **Safety Software Guide**
- **DOE G 414.1-5** — **Corrective Action Program Guide**
- **DOE G 413.3-2** — **QA Guide for Project Management**

Quality Assurance Program Requirements (the Guides)

DOE G 413.3-2, QA Guide for Project Management:

- Provides guidelines, notes, suggestions, for example, for developing a QA Program
- Discusses QA Program development and Implementation by Critical Decisions (DOE G 413.3A)
- Module 4 contains additional discussions regarding QA requirements associated with each Critical Decision.

Integrating Quality with ISMS

- **The DOE fundamental quality expectation is that all work meets established requirements. In this regard, the quality management system ensures compliance with the approved safety standards set, so that the expectation for safe work within controls is met.**

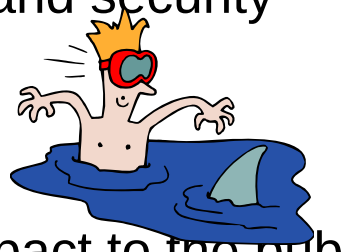
Identify the Right Safety Standards	**+**	**Doing it Right to those Standards**	**=**	**Doing it Safely**

Application of Graded Approach

The Graded Approach is documented In your Quality Implementation Plan and your Quality Assurance Plan.

Grade based on:

- 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



Application of Graded Approach

"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."

DOE Project Critical Decision QA Requirements

E M Environmental Management

safety ❖ performance ❖ cleanup ❖ closure

Requirements for 6 Key Areas

Requirement	DOE O 414.1C Criteria	NQA-1 Criteria
Document Development & Control	4, Documents & Records	5, Instructions, Procedures & Drawings 6, Document Control 17, Quality Assurance Records
Design	6, Design	3, Design Control
Training & Qualification	2, Personnel Training & Qualification	2, Quality Assurance Program
Review/Assessments	6, Design 9, Management Assessment 10, Independent Assessment	3, Design Control 18, Audits
Work Processes	5, Work Processes	8, Identification & Control of Items 9, Control of Special Processes 10, Inspection
QA Program	1, Program	1, Organization 2, Quality Assurance Program

The Standard Review Plan

EM Portal

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Project Management

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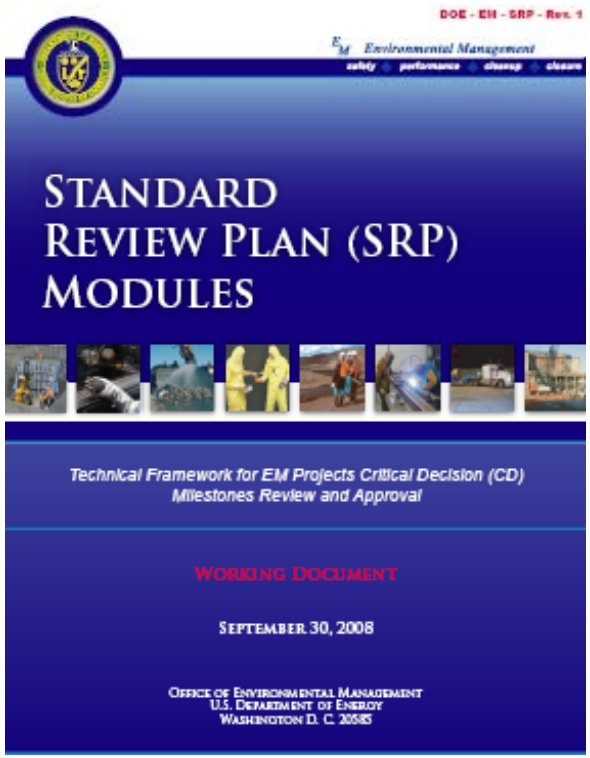
Standard Review Plans And Associated Review Modules



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Master Roadmap for EM Projects *(Key Documents for Critical Decision Approval Review)*

Working Document - CNS

	CD-0 Approval on Mission Need	CD-1 Approval on Alternative	CD-2 Approval on Performance Baseline	CD-3 Approval on Start of Construction	CD-4 Approval on Start of Operations
Project Management	Mission Need Statement	Project Execution Plan Risk Management Plan Alternatives Analysis document Acquisition Strategy Long Lead Procurement documents, if applied Integrated Project Team Charter	Updated Project Execution Plan Detailed Resource Loaded Schedule Detailed Cost and Schedule Estimates Risk Management Plan Contingency Analysis and Plan Earned Value Management System documents Acquisition Strategy/Plan Funding Profile documents Startup Plan, when appropriate EIR report on Performance Baseline Validation	Updated Project Execution Plan Updated Detailed Resource Loaded Schedule Updated Detailed Cost Estimate Updated Risk Management Plan Updated Value Management and Engineering Report Updated Acquisition Strategy Updated Funding Profile documents Updated Startup Plan, when appropriate EIR report on Construction Readiness Review	Documents on verification of Key Performance Parameters or Project Completion Criteria Project Transition to Operations Plan Final Project Closeout Report Lessons Learned Report Documents on operations procedures Post Implementation Review report
Engineering and Design	None at this CD stage	Technology Readiness Assessment Conceptual Design Report Conceptual Design Review Report Project Data Sheet for design	Drawings, specifications and design lists System Functions and Requirements documents (Design Criteria) Preliminary Design Report Preliminary Design Review documents Updated Project Data Sheet	Design Code of Record *(initiated in CD-1)* Construction planning documents Final Design documents, including drawing and specs Final design review documents Checkout, Testing and Commissioning Plan	
Nuclear and Facility Safety	Documentation of major potential hazards and safety/risk implication as part of Mission Need Statement	Safety Design Strategy Conceptual Safety Design Report Conceptual Safety Validation Report Preliminary Hazard Analysis Report for non-nuclear project DOE review of PHA Report ISM documents	Updated Safety Design Strategy Preliminary Safety Design Report Preliminary Safety Validation Report Hazard Analysis Report (non nuclear) DOE review of Hazard Analysis Report	Updated Safety Design Strategy Preliminary Documented Safety Analysis report Safety Evaluation Report Updated Hazard Analysis Report (non nuclear) DOE review of Hazard Analysis Report	Documented Safety Analysis with Technical Safety Requirements Safety Evaluation Report Updated Hazard Analysis Report (non nuclear) DOE review of Hazard Analysis Report Readiness Review or Operational Readiness Review Report
Worker Safety	None at this CD stage	ISM documents	Hazard Analysis Report and approval (see Nuclear Safety)	Construction Project Safety and Health Plan Updated Hazard Analysis Report and approval (see Nuclear Safety)	Updated Construction Project Safety and Health Plan Updated Hazard Analysis Report and approval (see Nuclear Safety)
Environment	None at this CD stage	Permit applications NEPA documents High Performance Sustainable Building considerations documents	Final NEPA documents Sustainable Building considerations documents	Final Sustainable Building considerations documents	Environment Management System
Security	None at this CD stage	Preliminary Security Vulnerability Assessment Report, if applied Initial Cyber Security Plan, if applied	Updated Preliminary Security Vulnerability Assessment Report, if applied Updated Cyber Security Plan, if applied	Updated Preliminary Security Vulnerability Assessment Report, if applied Updated Cyber Security Plan, if applied	Security Vulnerability Assessment Report, if applied Cyber Security Plan, if applied
Quality Assurance	None at this CD stage	QA Plan	Updated QA Plan	Updated QA Plan for construction	Updated QA Plan

Note: Long-Term plan is to develop a SRP Review Module for each of the key documents and associated activities listed above.

Figure 2

Master Roadmap for EM Projects *(Crtitical Decision Approval Prerequisite Activities)*

Working Document - CNS

	CD-0 Approval on Mission Need	CD-1 Approval on Alternative	CD-2 Approval on Performance Baseline	CD-3 Approval on Start of Construction	CD-4 Approval on Start of Operations
Project Management	Perform Pre-conceptual Planning activities Prepare Mission Need Statement Prepare a Tailoring Strategy if required Perform a Mission Validation Independent Project Review Evaluate projects for Information Technology elements within the Departmental Enterprise Architecture framework	Prepare a preliminary Project Execution Plan Prepare an Acquisition Strategy Comply with the One-for-One Replacement legislation Approve appointment of the Federal Project Director Establish and charter an Integrated Project Team Approve Long-Lead Procurements, if necessary	Update the Project Execution Plan Establish Performance Baseline Employ an Earned Value Management System Perform a Performance Baseline Validation External Independent Review or a Performance Baseline Validation Independent Project Review Develop an Independent Cost Estimate or perform an Independent Cost Review for Major System Projects	Update all CD-2 project documentation and required approvals to reflect any changes resulting from final Design, including Project Data Sheet, etc Perform an External Independent Review for Construction or Execution Readiness (OECM) Issue a Project Transition to Operations Plan	Verify Key Performance Parameters or Project Completion Criteria have been met and mission requirements achieved Perform final administrative and financial closeout and prepare a Final Project Closeout Report Prepare a Lessons Learned Report Conduct Post Implementation Review Complete project required Operational Documentation
Engineering and Design	None at this CD stage	Prepare a Project Data Sheet Prepare a Conceptual Design Report Conduct Conceptual Design Review	Update the Project Data Sheet, if applicable Prepare a Preliminary Design Conduct a Preliminary Design Review	Issue a Checkout, Testing, and Commissioning Plan Prepare Final Design Conduct Final Design Review Develop Design Code of Record	No activities required by DOE O 413.3A
Nuclear and Facility Safety	Determine major potential hazards and safety/risk implication	Prepare a Safety Design Strategy for projects subject to DOE STD 1189 Prepare a Conceptual Safety Design Report for Hazard Category 1, 2, and 3 nuclear facilities Prepare a Conceptual Safety Validation Report Prepare a Preliminary Hazard Analysis Report for facilities that are below Hazard Category 3 threshold Implement Integrated Safety Management	Update the Safety Design Strategy for projects subject to DOE STD 1189 Prepare a Preliminary Safety Design Report Prepare a Preliminary Safety Validation Report Prepare a Hazard Analysis Report and obtain DOE approval	Update the Safety Design Strategy for projects subject to DOE STD 1189 Prepare the Preliminary Documented Safety Analysis Prepare a Safety Evaluation Report Update the Hazard Analysis Report and obtain DOE approval Complete a Readiness Assessment or an Operational Readiness Review. As a precursor to ORR, conduct an Management Self-Assessment	Prepare the Documented Safety Analysis with Technical Safety Requirements Prepare a Safety Evaluation Report Finalize the Hazard Analysis Report and obtain DOE approval
Worker Safety	None at this CD stage	Implement Integrated Safety Management (see nuclear safety)	None defined	Prepare a Construction Project Safety and Health Plan and obtain DOE approval as defined in 10 CFR 851	Update the Construction Project Safety and Health Plan
Environment	Initiate National Environmental Policy Act strategy and analyses	Document High Performance Sustainable Building considerations Prepare environmental documents including National Environmental Policy Act strategy and analyses, and permit applications	Incorporate Preliminary Sustainable Environmental Stewardship-High Performance Sustainable Building provisions into the preliminary design and design review Complete (or obtain approval of) final National Environmental Policy Act documentation, which must be completed prior to the start of final design	Incorporate Sustainable Environmental Stewardship-High Performance Sustainable Building provisions into the Final Design and the External Independent Review Revise the Environmental Management System to ensure that it incorporates new environmental aspects related to turnover and operations	No activities required by DOE O 413.3A
Security	None at this CD stage	Prepare a Preliminary Security Vulnerability Assessment Report Prepare an Initial Cyber Security Plan	Update the Preliminary Security Vulnerability Assessment Report Update the Initial Cyber Security Plan	Update the Preliminary Security Vulnerability Assessment Report Update the Cyber Security Plan	Finalize the Security Vulnerability Assessment Report Finalize the Cyber Security Plan for Information Technology projects and complete the Certification and Accreditation, as required
Quality Assurance	None at this CD stage	Determine that the Quality Assurance Program is acceptable	Determine that the Quality Assurance Program is acceptable and continues to apply	Issue an updated Quality Assurance Plan to address testing, identified deficiencies, and startup, transition, and operation activities	Update the Quality Assurance Program for operations

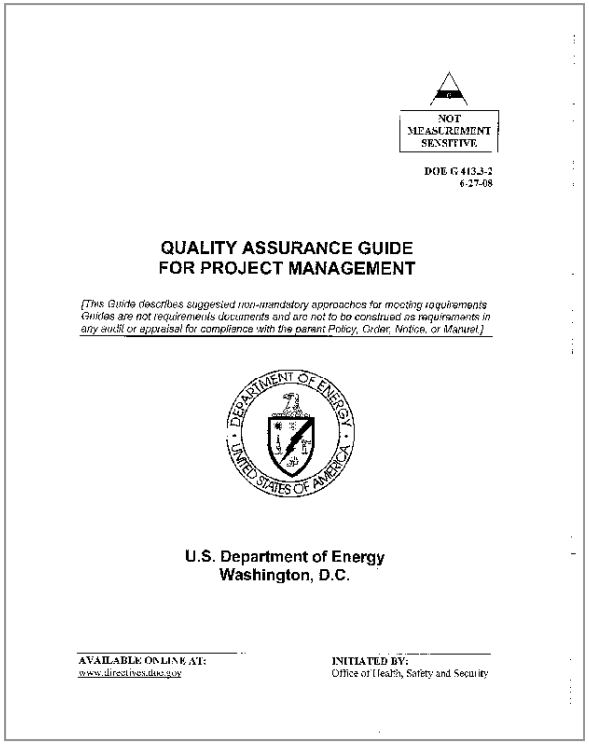
Figure 1

The Quality Assurance Guide

DOE Directives, Regulations And Standards Portal Homepage

DOE G 413.3-2 Quality Assurance Guide For Project Management

http://www.directives.doe.gov/pdfs/doe/doetext/neword/413/g4133-2.pdf



NOT MEASUREMENT SENSITIVE

DOE G 413.3-2
6-27-08

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.

AVAILABLE ON LINE AT:
www.directives.doe.gov

INITIATED BY:
Office of Health, Safety and Security

Key Elements of the Quality Assurance Guide

- 4.1 Quality Assurance Sources
- 4.2 Developing a Quality Assurance Strategy and Policy
- 4.3 Developing a Quality Assurance Program
- 4.4 Quality Assurance Program Development and Implementation by DOE O 413.3A Critical Decisions
- Appendix C, Quality Assurance Attributes/Characteristics, and Identification of Value Added Matrix
- Appendix D, Suggested QA Activities to Support Critical Decision Requirements

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

DOE O 414.1C and 10 CFR 830 Subpart A QA Criterion	Attributes/Characteristics	Value Added	ISO 9001:2000	NQA-1-2000
WORK PROCESSES Perform work consistent with technical standards, administrative controls, and hazard controls adopted to meet regulatory or contract requirements using approved instructions, 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	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 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	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 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	7.5.1 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 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	5. Instructions, Procedures and Drawings 8. Identification and Control of Items 12. Control of Measuring and Test Equipment 13. Handling, Storage and Shipping 14. Inspection, Test and Operating Status Part 1 Introduction

Appendix D – Suggested QA Activities to Support Critical Decision Requirements

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.

DOE Implementation Guide, QAP Guide, has been completely revised; no revision bars are used.

Summary of QA Activities For CD-1 to CD-4 Requirements

DOE G 413.3-2, Quality Assurance Guide for Project Management, Appendix D

- **137 QA Activities associated with 56 Requirements/Deliverables**
- **110 QA Activities are in 6 Key Areas**
  - Document Development & Control
  - Design
  - Training & Qualification
  - Review/Assessments
  - Work Processes
  - QA Program

Assessment Expectations Developed by the QA EFCOG Project Managers

EM QA Corporate Board

Project Executive Committee

EFCOG

Project Managers

#1 – Requirements Flow Down

#2 – Adequate NQA-1 Suppliers

#3 – Commercial Grade Item and Services Dedication Implementation and Nuclear Services

#4 – Graded Approach to Quality Assurance

#5 – Line Management Understanding of QA and Oversight

QA Training

Assessment Expectations

Other Deliverables

Assessment Expectations Developed by the QA EFCOG Project Managers

Assessment Expectations for FPDs and IPTs
Review Attributes/Characteristics

CD-3 Requirements – Quality Assurance Activities			
DOE G 413.3-2	**QA Criterion (DOE O 414.1C)**	**CD-3 Requirements**	**Performance Objectives, Measures & Commitments (POMC)**
CD-3, Approval of the Start of Construction	Program Personnel Training & Qualification Documents & Records Design	Final Design CD-2 Project Documentation Preliminary Documented Safety Analysis Report DOE Approval of Updated Hazard Analysis Report Updated Preliminary Security Vulnerability Assessment Report Updated Cyber Security Plan for IT Projects Safety Evaluation Report Preparation Construction Project Safety and Health Plan Preparation Final Environmental Stewardship	Verify 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.
			Verify that applicable 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.
			Verify that processes for preparation, review, approval, issuance, use, and revision of documents that prescribe processes, requirements, and design are implemented.
			Verify that processes (which adequately addresses hazards) for grading the application of requirements are implemented.
			Verify that processes for specification, preparation, review, approval, and maintenance of records are implemented.
			Verify the processes are implemented for personnel to achieve initial proficiency; maintain proficiency; and adapt to changes in technology, methods, or job responsibilities.
CD-3, Approval of the Start of Construction	Management Assessment Independent Assessment	External Review for Construction or Execution Readiness QA Program for Construction, Field Design Changes, and	Verify 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.
			Verify that persons conducting reviews are technically qualified and knowledgeable in the areas to be reviewed.
			Verify that persons conducting independent reviews have sufficient authority and

Phase I Project Requirements – Quality Assurance Activities – Quality Program Definition				
Objective	**QA Criterion (DOE O 414.1C)**	**DOE G 414.1-2A, Attachment 1**		**Performance Criteria (DOE QA Program; NQA-1 Part IV, Subpart 4.5)**
QA Program is approved. The graded approach to Quality is applied. Approved documents exist to implement the DOE QA criterion.	Criterion 1: Management/ Program	Review Area 1 — Program	a.	Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing work.
			b.	Establish management processes including, planning, scheduling, and providing adequate resources for the work
			c.	Define a process for grading the application of QA requirements for activities that identifies consequences, requirements, and depth/extent/rigor necessary in application of those requirements.
	Criterion 2: Management/ Personnel Training and Qualification	Review Area 2 — Personnel Training and Qualification	a.	Train and qualify personnel to be capable of performing their assigned work.
			b.	Provide continuing training to personnel to maintain their job proficiency.
	Criterion 3: Management/ Quality Improvement	Review Area 3 — Quality Improvement	a.	Establish and implement processes to detect and prevent any conditions adverse to quality.
			b.	Identify, control, and correct items, services, and processes that do not meet established requirements.
			c.	Identify the causes of all conditions adverse to quality and work to prevent recurrence as part of correcting the problem.
			d.	Review item characteristics, process implementation, deficiencies and other quality-related information to identify items, services, and processes needing improvements.
	Criterion 4: Management/ Documents and Records	Review Area 4 — Documents and Records	a.	Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design.
			b.	Specify, prepare, review, approve, and maintain records.

Phase II Project Requirements – Quality Assurance Activities –Quality Program Performance				
Objective	**QA Criterion (DOE O 414.1C)**	**DOE G 414.1-2A, Attachment 1**		**Performance Criteria (DOE QA Program; NQA-1 Part IV, Subpart 4.5)**
Approved implementing documents are used to control work affecting quality.	Criterion 5: Performance/ Work Processes.	Review Area 5 — Work Processes	a.	Perform all work consistent with technical standards, administrative controls, and hazard controls adopted to meet regulatory or contract requirements using approved instructions, procedures, etc.
			b.	Identify and control items to ensure their proper use.
			c.	Maintain items to prevent their damage, loss, or deterioration.
			d.	(d)Calibrate and maintain equipment used for process monitoring or data collection.
	Criterion 6: Performance/ Design.	Review Area 6 — Design	a.	Design items and processes using sound engineering/scientific principles and appropriate standards.
			b.	Incorporate applicable requirements and design bases in design work and design changes.
			c.	Identify and control design interfaces.
			d.	Verify/validate the adequacy of design products using individuals or groups other than those who performed the work.
			e.	Verify/validate work before approval and implementation of the design.
	Criterion 7: Performance/ Procurement	Review Area 7 — Procurement	a.	Procure items and services that meet established requirements and perform as specified.
			b.	Evaluate and select prospective suppliers on the basis of specified criteria.
			c.	Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.
	Criterion 8: Performance/ Inspection and Acceptance Testing	Review Area 8 — Inspections and Acceptance Testing	a.	Inspect and test specified items, services, and processes using established acceptance and performance criteria.
			b.	Calibrate and maintain equipment used for inspections and tests.

Phase III Project Requirements – Quality Assurance Activities –Quality Program Improvement				
Objective	**QA Criterion (DOE O 414.1C)**	**DOE G 414.1-2A, Attachment 1**		**Performance Criteria (DOE QA Program; NQA-1 Part IV, Subpart 4.5)**
QA Program is assessed to identify and correct problems, to enable continuous improvement.	Criterion 9: Assessment/ Management Assessment	Review Area 9 — Management Assessment	a.	Assess the management processes and identify and correct problems that hinder the organization from achieving its objectives.
			b.	Management Assessment implements the intent, focus and concepts described in DOE Guide, G 414.1-1A, Management Assessment and Independent Assessment Requirements of 10 CFR 830.120 and DOE-O-414.1 Quality Assurance.
	Criterion 10: Assessment/ Independent Assessment	Review Area 10 — Independent Assessment	a.	Plan and conduct independent assessments to measure item and service quality and the adequacy of work performance and to promote improvement.
			b.	Establish sufficient authority and freedom from line management for independent assessment teams.
			c.	Ensure that persons conducting independent assessments are technically qualified and knowledgeable in the areas to be assessed.
			d.	Independent Assessment implements the intent, focus and concepts described in DOE Guide, G 414.1-1A, Management Assessment and Independent Assessment Requirements of 10 CFR 830.120 and DOE-O-414.1 Quality Assurance.

Assessment Expectations for FPDs and IPTs
Review Attributes/Characteristics

CD-0 Requirements – Quality Assurance Activities					
DOE G 413.3-2	**QA Criterion (DOE O 414.1C)**	**CD-0 Requirements**	**Performance Objectives, Measures & Commitments (POMC)**		
CD-0, Approval of Mission Need	Program Documents & Records Design Independent Assessment	Mission Need Statement Pre-Conceptual Planning Tailoring Strategy Program Requirements Document Mission Validation Independent Project Review	Determine that a Mission Need Statement has been developed and approved.		
			Determine whether adequate resources have been identified to describe management processes for planning, scheduling, and providing funding for the work.		
			Determine that processes for preparing, reviewing, approving, issuing, using, and revising documents that prescribe processes, requirements, and design are implemented. Verify that a design process is implemented.		
			Verify that the process for conducting the project review is developed and implemented using independent and qualified personnel.		

CD-1 Requirements – Quality Assurance Activities			
DOE G 413.3-2	**QA Criterion (DOE O 414.1C)**	**CD-1 Requirements**	**Performance Objectives, Measures & Commitments (POMC)**
CD-1, Approval of Alternative Selection and Cost Range	Work Processes Documents & Records Design Procurement	Conceptual Design Report Acquisition Strategy Preliminary Project Execution Plan Line-Item Projects and Long-Lead Procurements	Verify that processes for preparing, reviewing, approving, issuing, using, and revising the Conceptual Design Report, Acquisition Strategy, Preliminary Project Execution Plan, line-item projects/long-lead procurements are described and implemented.
			Determine that a design process is implemented providing control of design inputs, outputs, verification, and configuration and design changes, including technical and administrative interfaces. Determine that design activities are verified and documented. Determine that significant QA participation is emphasized in the development and review of the Preliminary Project Execution Plan.
			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. Verify that QA personnel are utilized to assist with procurement (acquisition) planning.

			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.
CD-1, Approval of Alternative Selection and Cost Range	Personnel Training & Qualification	Federal Project Director Appointment Integrated Project Team	Verify that policies and procedures that describe personnel selection, training, and qualification requirements for a Federal Project Director and the Integrated Project Team (IPT) are developed and implemented. Ensure that a QA representative is a member of the IPT.
			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.
CD-1, Approval of Alternative Selection and Cost Range	Work Processes Documents & Records	Environmental Documents and Permit Applications Hi-Performance Building Considerations Security Vulnerability Assessment Report IT Projects Conceptual Safety Design Report for Hazard 1, 2, & 3 Nuclear Facilities Preliminary Hazard Analysis Report Preliminary Safety Validation Report	Verify that processes for preparing, reviewing, approving, issuing, using, and revising documents that prescribe processes, requirements, and design are described and implemented.
			Verify that procedures, work instructions, or other appropriate means used to define work processes are documented and controlled.
			Verify that processes for specification, preparation, review, approval, and maintenance of records are developed and implemented.
CD-1, Approval of Alternative Selection and Cost Range	Program Management Assessment	QA Program Acceptability/ Applicability	Verify that the QA Program describes the organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work. Verify the adequate resources have been identified for quality program activities,

			such as planning, auditing, supplier qualification, technical document review, inspection, calibration, etc. Verify 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.

CD-2 Requirements – Quality Assurance Activities			
DOE G 413.3-2	**QA Criterion (DOE O 414.1C)**	**CD-2 Requirements**	**Performance Objectives, Measures & Commitments (POMC)**
CD-2, Approval of Performance Baseline	Program Work Processes Documents & Records Design	Performance Baseline Project Execution Plan Cost Estimate for Major System Projects Preliminary Design Preliminary Safety Design Hazard Analysis Preliminary Security Vulnerability Assessment Report IT Projects Safety Validation Report Preliminary Environmental	Verify that the QA Program describes the organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work.
			Verify that processes (which adequately addresses hazards) for grading the application of requirements are implemented.
			Verify the processes are implemented for personnel to achieve initial proficiency; maintain proficiency; and adapt to changes in technology, methods, or job responsibilities.
			Verify that processes for document preparation, review, approval, and change control are implemented. Verify that processes for specification, preparation, review, approval, and maintenance of records are implemented.
			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.
			Verify that processes for appropriate control of design inputs, outputs, verification, configuration and design changes, and technical and administrative interfaces are implemented. Verify that processes for verification of design activities are implemented.

		Stewardship Final NEPA Documentation QA Program	
CD-2, Approval of Performance Baseline	Management Assessment Independent Assessment	Performance Baseline Validation Independent Cost Review for Major System Projects Design Review of Preliminary Design QA Program Acceptability/ Applicability Quality Improvement	Verify the adequate resources have been identified for quality program activities, such as planning, auditing, supplier qualification, technical document review, inspection, calibration, etc. Verify that persons conducting reviews are technically qualified and knowledgeable in the areas to be reviewed. Verify that persons conducting independent reviews have sufficient authority and freedom from line management. Verify 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. Verify that processes for specification, preparation, review, approval, and maintenance of records are developed and implemented.

CD-3 Requirements – Quality Assurance Activities			
DOE G 413.3-2	**QA Criterion (DOE O 414.1C)**	**CD-3 Requirements**	**Performance Objectives, Measures & Commitments (POMC)**
CD-3, Approval of the Start of Construction	Program Personnel Training & Qualification Documents & Records Design	Final Design CD-2 Project Documentation Preliminary Documented Safety Analysis Report DOE Approval of Updated Hazard Analysis Report	Verify 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. Verify that applicable 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.

		Updated Preliminary Security Vulnerability Assessment Report Updated Cyber Security Plan for IT Projects Safety Evaluation Report Preparation Construction Project Safety and Health Plan Preparation Final Environmental Stewardship	Verify that processes for preparation, review, approval, issuance, use, and revision of documents that prescribe processes, requirements, and design are implemented.
			Verify that processes (which adequately addresses hazards) for grading the application of requirements are implemented.
			Verify that processes for specification, preparation, review, approval, and maintenance of records are implemented.
			Verify the processes are implemented for personnel to achieve initial proficiency; maintain proficiency; and adapt to changes in technology, methods, or job responsibilities.
CD-3, Approval of the Start of Construction	Management Assessment Independent Assessment	External Review for Construction or Execution Readiness QA Program for Construction, Field Design Changes, and Procurement Activities	Verify 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.
			Verify that persons conducting reviews are technically qualified and knowledgeable in the areas to be reviewed.
			Verify that persons conducting independent reviews have sufficient authority and freedom from line management.
			Verify 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.

CD-4 Requirements – Quality Assurance Activities			
DOE G 413.3-2	**QA Criterion (DOE O 414.1C)**	**CD-4 Requirements**	**Performance Objectives, Measures & Commitments (POMC)**
CD-4, Approval of the Start of Operations or	Quality Improvement Work Processes	Verification of Key Performance Parameters	Verify that processes to identify, control, and correct items, services, and processes that do not meet established requirements are implemented.
			Verify that work is performed consistent with technical standards, administrative

Project Completion	Independent Assessment	Readiness Assessment or Operational Readiness Review	controls, and hazard controls adopted to meet regulatory or contract requirements using approved instructions, procedures, etc.
			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.
			Verify that persons conducting reviews are technically qualified and knowledgeable in the areas to be reviewed.
CD-4, Approval of the Start of Operations or Project Completion	Program Documents and Records Work Processes Design Inspection and Acceptance Testing	Checkout, Testing, and Commissioning Plan Transition to Operations Plan Update of QA Plan Environmental Management System Revision Safety Analysis Reports Preparation Construction Project Safety & Health Plan Update Final Hazard Analysis Report Final Security Vulnerability Assessment Report Final Cyber Security Plan	Verify that processes for preparation, review, approval, issuance, use, and revision of documents that prescribe processes, requirements, and design are implemented.
			Verify that actions are planned and carried out by qualified personnel using approved procedures, instructions, and equipment under administrative, technical, and environmental controls.
			Verify that applicable 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.
			Verify that design processes that provide appropriate control of design inputs, outputs, verification, configuration and design changes, and technical and administrative interfaces are implemented.
			Verify that processes for specification, preparation, review, approval, and maintenance of records are implemented.
			Verify 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 test equipment.
			Verify that processes to implement a quality management approach are established and implemented.
			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.
			Verify that processes to implement a quality management approach are established and implemented.

			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.

Post CD-4 Requirements – Quality Assurance Activities			
DOE G 413.3-2	**QA Criterion (DOE O 414.1C)**	**Post CD-4 Requirements**	**Performance Objectives, Measures & Commitments (POMC)**
Post CD-4, Project and Operations Completion	Quality Improvement Documents and Records	Final Project Closeout Report Lessons Learned Report to the Office of Engineering and Construction Management Operational Documentation	Verify that organization established, implemented, and documented processes to detect and prevent quality problems and that problems have been corrected.
			Verify that processes for preparation, review, approval, issuance, use, and revision of documents that prescribe processes, requirements, and design are implemented.
			Verify that processes for specification, preparation, review, approval, and maintenance of records are implemented.
Post CD-4, Project and Operations Completion	Management Assessment	Post Implementation Review for IT Projects	Verify that processes to plan and conduct review to measure and item and service quality and the adequacy of work performance and to promote improvement are implemented.

Department of Energy
Washington, DC 20585

FEB 1 7 2010

MEMORANDUM FOR DISTRIBUTION

FROM: DR. STEVEN L. KRAHN
DEPUTY ASSISTANT SECRETARY FOR
SAFETY AND SECURITY PROGRAM
ENVIRONMENTAL MAIVAGEMENT

SUBJECT: Protocol for EM-HQ Review/Field Self-Assessment of Site Specific Quality Assurance Plans Quality Assurance Implementation Plans dated February 2010

The Office of Environmental Management (EM) issued its Corporate Quality Assurance Program (QAP), EM-QA-001, in November 2008. The EM Corporate QAP serves as the Quality Assurance (QA) roadmap to ensure that the EM mission is accomplished safely, correctly, and efficiently. Using a graded approach, Headquarters (HQ) and each Field organization is required to prepare a Quality Assurance Implementation Plan (QIP) identifying procedures and documents that directly implement the applicable requirements of the QAP.

This memorandum serves to transmit the Protocol for EM Review/Field Self-Assessment of Site-Specific QAP/QIP. The subject document is developed as part of continued efforts to ensure technical consistency, transparency, and clarity of QA requirements and expectations. The purpose of the document is to present the review protocol and lines of inquiry that were developed for use by EM-HQ to perform the technical review and approval of site-specific QAP/QIP. The review protocol and lines of inquiry are also designed to be used by EM Field Offices, sites, and projects to conduct internal self-assessment of effectiveness of their QAP/QIP development and implementation.

Each field office with a HQ Phase I approval or conditional approval of their QAP/QIP should now be engaged in the process of implementing the document. Once implementation is complete (including any corrections from the Phase I review), each field office should initiate Phase II of the approval process. Phase II requires the validation and verification of implementation via self assessments and HQ review. In order to facilitate this validation effort, an Office of Standards and Quality Assurance (EM-23) representative will participate in each field office self assessment. Please have your staff coordinate with Bob Toro, EM-23, to ensure a HQ representative participates in each of your implementation validation self assessments. Mr. Toro can be reached at 202-586-3359. Each site is also required to provide EM-23 a monthly update on the status of the implementation beginning in March 2010. These updates may be informal (e.g., phone, email) and should be provided to Kriss Grisham (EM-23) at (310)-903-8478 or at kriss.grisharn@hq.doe.gov.

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The Field led self-assessments coupled with QA assist visits by the EM-23, represent a critical element of the overall Fiscal Year 2010 corporate strategy to ensure QA is integrated in every aspect of the EM mission, including projects funded by the American Recovery and Reinvestment Act.

If you have any questions, please contact me at (202) 586-5151.

Attachment

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Jack Craig, Director, Consolidated Business Center Ohio (CBC)
John Moon, Acting Director, Office of Small Site Completion
Joanne Lorence, Acting Director, Office of Large Site Support

Site	Site QAP Status
Richland	Conditionally Approved
River Protection	Conditionally Approved
Carlsbad	Extension Granted
Oak Ridge	Approved
Savannah River	Conditionally Approved
Idaho	Approved
Portsmouth/Paducah	Conditionally Approved
EMCBC	Conditionally Approved

The *Office of Environmental Management (EM) Quality Assurance Program (QAP)* document (EM-QA-001) can be found online at http://www.hss.energy.gov/nuclearsafety/qa/docs/Signed-EM_QAP.pdf

The *Protocol for EM-HQ Review/Field Self-Assessment of Site-Specific Quality Assurance Programs (QAPs)/Quality Implementation Plans (QIPs)* can be found online at http://www.em.doe.gov/pages/safety.aspx (under the "Standard Review Plan" link on the page).

The *Quality Assurance for Critical Decision Reviews Module* can be found online at http://www.em.doe.gov/pages/safety.aspx (under the "Standard Review Plan" link on the page).