EM QUALITY ASSURANCE CORPORATE BOARD MEETING
Denver, Colorado
July 29 -30, 2008

Key Workshop Objectives:

1. Inform Board Members of Ongoing and Future EM QA Initiatives.

2. Review and Discuss the Draft EM/EFCOG Project Action Plan for the Top Five Priority Issues Identified by Site Federal and Contractor Executives in 1st EM QA Board Meeting in March 2008.

3. Brief and Discuss with Board Members the Proposed EM Corporate Performance Metrics System Concept and Approach.

4. Review the Progress of EM HQ and Sites to Establish QA Managers and to Allocate Adequate QA Resources.

Desired Outcomes:

1. Executive Board Members Vote on Draft EM/EFCOG Project Action Plan and Associated Milestone Schedules for the Five Priority Issues.

2. Executive Board Members Vote on the Proposed EM Corporate Performance Metrics System Concept and Approach.

3. Select Location and Date of Next EM QA Corporate Board Meeting.

EM QUALITY ASSURANCE CORPORATE BOARD MEETING

Meeting Location: Hyatt Regency Tech Center, 7800 East Tufts Avenue Denver, Colorado 80237 Main Number: 303-779-1234		
Room: Windriver		
AGENDA for July 29, 2008		
8:00	**COFFEE**	**ALL**
8:30	Welcome and Opening Remarks	Dae Chung (EM/HQ) Joe Bader, DNFSB
9:00	Introduction of Board Members and Other Participants; Agenda; and Logistics	Sandra Waisley (EM/HQ)
9:15	EM QA Initiatives Update	Sandra Waisley (EM/HQ)
9:30	Draft EM Corporate Quality Assurance Program Plan (QAPP) Overview/ Discussion	Kriss Grisham (EM/HQ)
10:00	**Break**	**ALL**
10:15	EM/EFCOG Quality Assurance Improvement Project Overview and Discussion: Top Five Focus Areas: • #1: Requirements Flow Down Project Action Plan • #2: Adequate NQA-1 Suppliers Project Action Plan	Sandra Waisley (EM/HQ) Dave Tuttel (EFCOG/WSRC) Butch Huxford(EM/HQ) Alice Doswell (Parsons) Bill Rowland (EM/SRS) Rich Campbell, (Energy*Solutions*) Jeffrey Allison (EM/SRS)
11:45	**LUNCH**	**ALL**
1:00	EM/EFCOG Quality Assurance Improvement Project Overview and Discussion: Five Focus Areas (Cont'd): • #3: Commercial Grade Dedication Implementation Project Action Plan • #4: Graded Approach to Quality Assurance Project Action Plan • #5: Line Management Understanding of QA and Oversight Project Action Plan	Pat Carier (EM/ORP) Shelby Turner (FLUOR) Steve Piccolo (URS/WGI) Al Hawkins (EM/RL) Rich Higgins (CH2M Hill) TJ Jackson (EM/CBC) Jon Hoff (URS/WIPP)
3:00	**Break**	**ALL**
3:30	Board Members Vote on EM/EFCOG Quality Assurance Improvement Project Action Plan	Dae Chung (EM/HQ)
4:00	Corporate QA Performance Metrics Discussion	Sandra Waisley (EM/HQ)
5:00	**Adjourn: End Full Board Session**	**Dae Chung**

EM QUALITY ASSURANCE CORPORATE BOARD MEETING

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Room: Windriver		
AGENDA for July 30, 2008		
8:00	**COFFEE**	**ALL**
8:30	Opening Remarks	Dae Chung, (EM/HQ) Shirley Olinger (EM/ORP)
8:45	FY 2008 Integrated Annual ISMS and QA Effectiveness Review and Declaration	Dae Chung (EM/HQ)
9:15	Site QA Resources (Federal and Contractor) Progress Report and Discussion	Sandra Waisley (EM/HQ)
10:15	**Break**	**ALL**
10:30	Additional Site QA and Oversight Issues and Concerns	Sandra Waisley (EM/HQ)
11:30	Next Steps/Actions • Discuss/Finalize High Priority Action Items • Discuss next Meeting date/Logistics	Dae Chung (EM/HQ)
12:00	**Adjourn: End Full Board Session**	**Dae Chung**

EM Corporate Quality Assurance Program

Kriss Grisham

Quality Assurance Specialist
Office of Standards and Quality Assurance

July 29, 2008

Briefing Topics

- **EM Corporate QA Program**
  - Rationale
  - Development
  - Implementation

Background

- EM Headquarters (HQ) QA Program revised in 2004 and 2008 and approved by EM-1

- Continuous EM QA Improvement Initiative in 2007 and 2008 - Develop EM Corporate QA Program

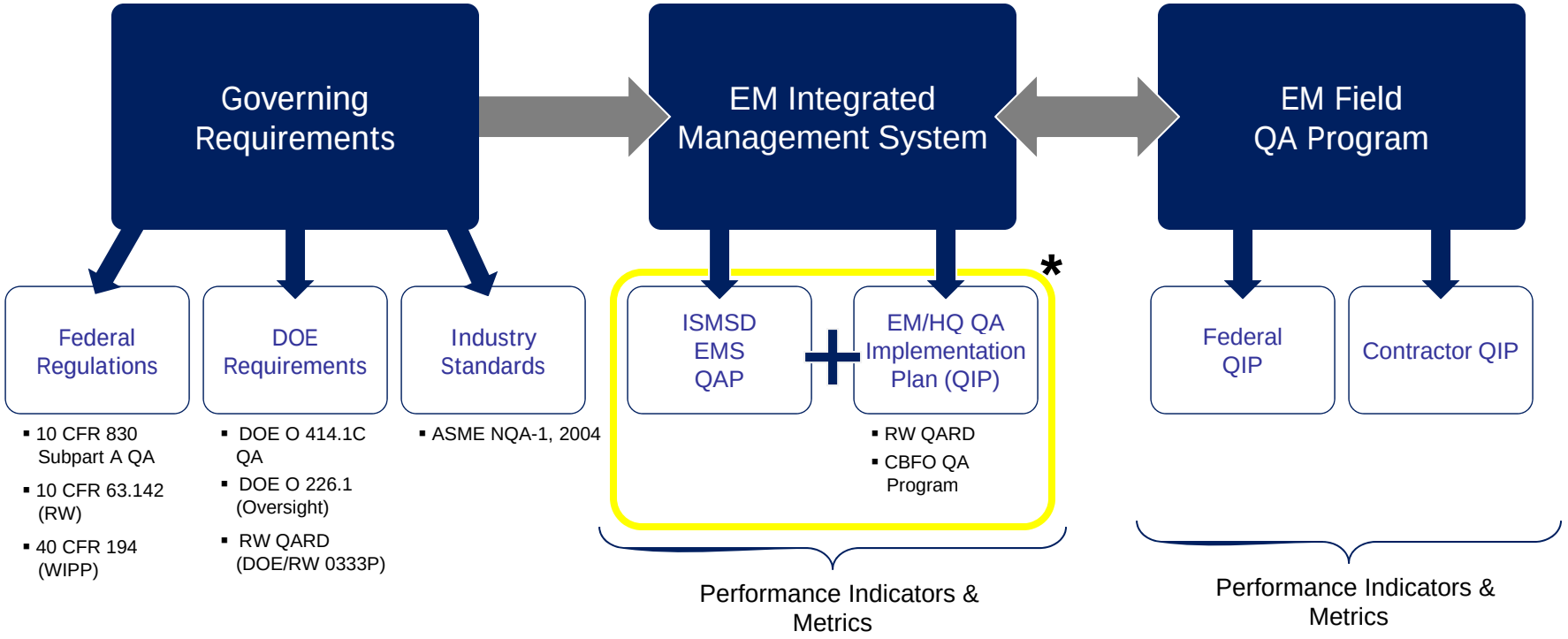
EM-Complex QA Vision

- **EM Corporate Objective:**
  - Perform mission work safely AND correctly
- **EM Strategy:**
  - Establish a single, integrated EM-Complex QA program and ensure consistent implementation across all EM assets
    - Consistent interpretation and implementation of DOE O 414.1C
    - EM QA Corporate Board (institutionalization of QA)
    - QA managers established at major sites
    - Flow down of QA requirements and EM-1 expectation from federal to contractor staff
    - EM Centralized Training Platform or Academy

EM-Complex QA Vision (Cont'd)

- Establish a systematic approach for QA Program oversight
  - QA system evaluation and declaration process
  - QA performance metrics system
  - Rigorous assessment and audit process and corrective action
  - Culture of accountability, continuous improvement, and feedback

Integrated EM Corporate QA Program Structure



* **EM Priority:**

Integration of QA and EM Safety Management Systems ----including Development of Corporate Performance

Integrated Quality Management System

Integrated Quality Management System EM Corporate QAP	
- Purpose and Objective	
- Scope	
- EM Management Commitments & Expectations	
- Roles and Responsibilities	
- Implementation	
- Quality Performance Objectives, Measures, and Commitments (POMCs)	
DOE Order 414.1C Criteria	
Program	Design
Personnel Training and Qualification	Procurement
Quality Improvement	Inspection and Acceptance Testing
Documents and Records	Management Assessment
Work Processes	Independent Assessment
EM HQ QIP EM Field - Federal QIP EM Field - Contractor QIP	

Integration Approach

- **Crosswalk ISM, DOE Order 414.1C/10 CFR 830, and NQA-1**
  - Adopt NQA-1, 2004 as EM Corporate QA consensus standard
  - Use established approved crosswalk to integrate ISM and QA
    - ISMSD, Table 2
    - NQA-1, 2004
      - Subpart 4.5, Table 400

Integration Approach (Cont'd)

- **Establish EM Corporate QA Expectations**
- **Define QA Program Requirements/Criteria**
- **Define QA Program Implementation Requirements**

Impacts

- **EM Corporate QA Program**
  - Written to ensure minimal impact to existing NQA-1 based QA Programs
  - Written to easily accommodate existing specialty QA Programs (e.g., RW QARD, WIPP)
  - Non-NQA-1 Programs may require additional steps to achieve compliance
  - Contract changes will be necessary to incorporate EM Corporate QAP implementation

QA Program (QAP) vs. QA Implementation Plan (QIP)

- Use EM Corporate QAP requirements throughout EM Complex
- Gap Analysis performed by EM Field Federal & Contractor staff between the EM Corporate QAP and their current QA Programs
- All EM Participants establish individual QIPs describing implementation of the EM Corporate QAP
- Implement EM Corporate QAP using QIPs

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Energy Facility Contractors Group

Quality Assurance Improvement Project Plan

EM QA Corporate Board Meeting

Denver, Colorado

July 29, 2008

Agenda

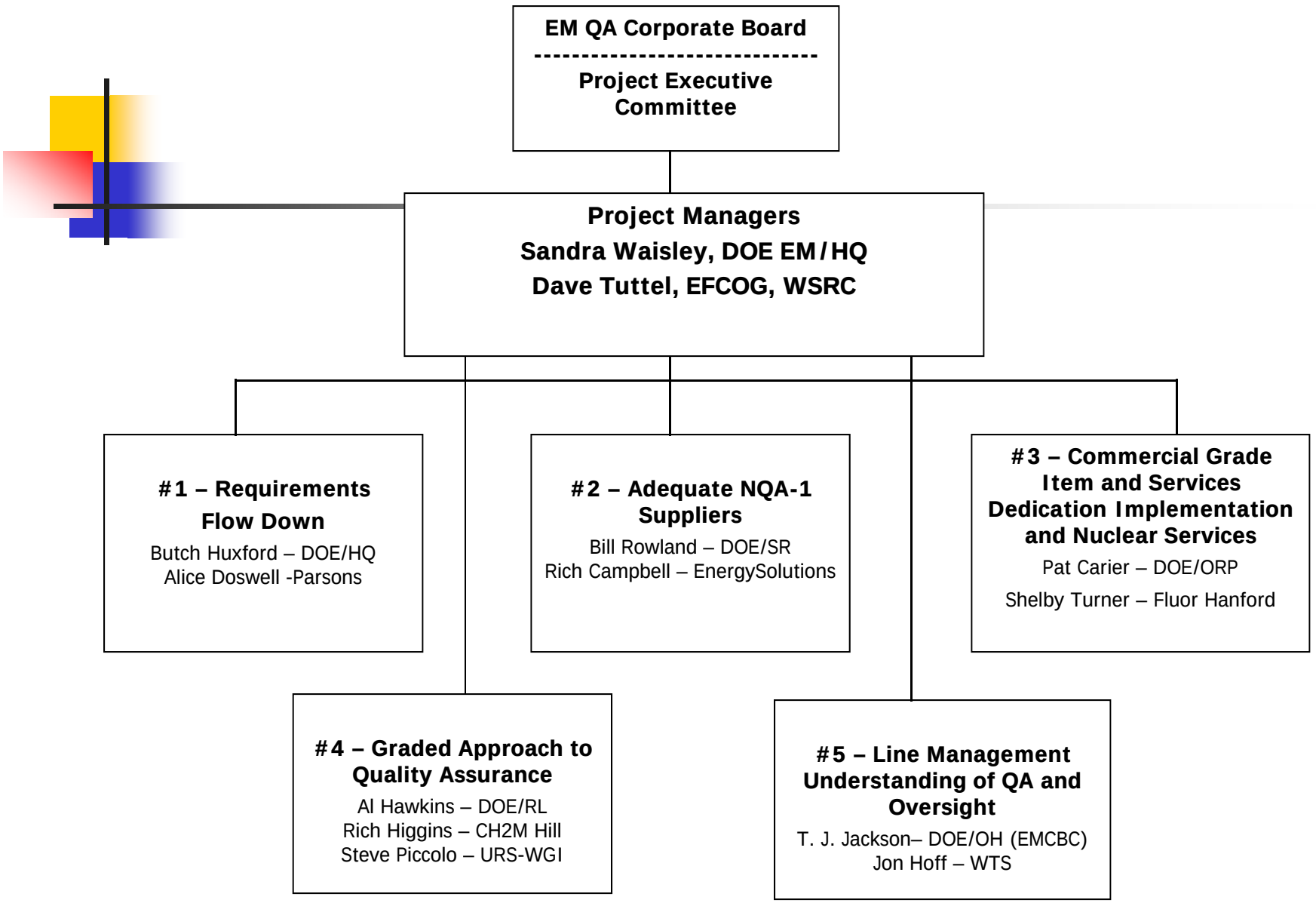
- Project Plan Overview
- Quality Assurance Project Focus Areas
  - Team 1: Requirements Flow Down
  - Team 2: Adequate NQA-1 Suppliers
  - Team 3: Commercial Grade Item and Services Dedication Implementation and Nuclear Services
  - Team 4: Graded Approach to Quality Assurance
  - Team 5: Line Management Understanding of QA and Oversight
- Questions / Comments

Project Plan Overview

- Introduction
- Scope
- Project Organization
- Key Roles and Responsibilities
- Project Execution and Performance Management
- Communications
- Project Termination
- Project Status

Project Organization

- Project Managers:
  - Sandra Waisley, Director, Office of Standards & Quality Assurance, EM/HQ
  - Dave Tuttel, QA Program Manager, WSRC, EFCOG
- Executive Committee:
  - James Owendoff, Chief Operations Officer, EM/HQ
  - Dave Chung, Deputy Assistant Secretary of the Office of Safety Management and Operations, EM/HQ
  - Dave Amerine, Senior Vice President, Parsons, EFCOG Board of Directors
  - Joe Yanek, Executive Director ESHQ, Fluor, EFCOG Board of Directors
  - Norm Barker, Energy Solutions, Chair EFCOG ISM/QA Working Group


EM QA Corporate Board
Project Executive Committee
Project Managers
Sandra Waisley, DOE EM/HQ
Dave Tuttel, EFCOG, WSRC
#1 – Requirements Flow Down
Butch Huxford – DOE/HQ
Alice Doswell -Parsons
#2 – Adequate NQA-1 Suppliers
Bill Rowland – DOE/SR
Rich Campbell – EnergySolutions
#3 – Commercial Grade Item and Services Dedication Implementation and Nuclear Services
Pat Carier – DOE/ORP
Shelby Turner – Fluor Hanford
#4 – Graded Approach to Quality Assurance
Al Hawkins – DOE/RL
Rich Higgins – CH2M Hill
Steve Piccolo – URS-WGI
#5 – Line Management Understanding of QA and Oversight
T. J. Jackson– DOE/OH (EMCBC)
Jon Hoff – WTS

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Project Area #1

QA REQUIREMENTS FLOW DOWN

EM QA Corporate Board Meeting
Denver, Colorado
July 29-30, 2008

Team Members

- William “Butch” Huxford – DOE Chair
- Alice C. Doswell – Contractor Chair, Parsons
- Amy Ecclesine – LANL
- Don Paine – Fluor

Background

Deficiencies Observed in DOE's Quality Assurance (QA) Programs by Major Contractors

- Deficiencies not usually due to a lack of prime contractors' program descriptions or procedural guidance
- Result of a failure to implement the procurement requirements
- Inadequate oversight by the prime contractor of its supply chains

It is the Responsibility of Line Management to Ensure that:

- Requirements are clear
- Acceptance/Inspection Criteria identified
- Requirements are flowed down to suppliers and subcontractors
- Suppliers and subcontractors understand the requirements
- Procurement processes are flexible

Scope

Provide EM with Recommendations

- Identify the process for ensuring appropriate technical Quality Assurance program requirements are flowed down to suppliers and subcontractors; and
- Develop approaches to provide increased assurance of the effectiveness of requirement flow-down processes

Actions/Status

Task	Milestone	Status
1.1	Questionnaire	June 16, 2008 - Completed
1.2	EM Contractors	July 7, 2008 – 10 responses received
1.3	Commercial Nuclear Contractors	August 1, 2008 - Ongoing
1.4	Contractor' Briefing	August 15, 2008 – Target Date
1.5	Analysis DOE/Commercial Processes	August 15, 2008 - Final
1.6	Develop Composite Flow Down	August 30, 2008 – Still on Target
1.7	Project Area #4 – Graded Approach to QA Implementation	September 15, 2008, Still on Target

Challenges/Barriers

Preliminary Survey Results

The DOE Contractual Requirements for QA Programs vary by Location and Project Type

Examples:

- Hanford, ISOTEK and SWPF QA requirements are based on 10 CFR 830.120 and DOE Order 414.1C
- WIPP QA Requirements are based upon WIPP Quality Assurance Program Document

Contractors use Different Vintages of Quality Consensus Standards (e.g., NQA-1-1989, 2000, or 2004)

Challenges/Barriers

Various Means for Flow Down of QA Requirements Throughout the Procurement Process

- QA Specifications
- Quality Assurance Program Documents
- Statement of Work
- Identification of Applicable Standards (National/Int'l)
- Quality Levels/Grading System Based Upon Safety/Functional Class

Varied Approach for Incorporating QA Documentation Requirements into Procurement Documents

- Technical and QA Specifications
- Specific Sections of Purchase Orders/Sub Contracts
- QA Clauses

Challenges/Barriers

Differing Means for Flow Down Requirements in Project Documents

- Design Specifications
- Procedures (QA/Procurement)
- Purchase Orders/Subcontract Packages

Differing Approaches for Flow Down of QA Requirements to Suppliers and Sub-tier Suppliers

- Dependent on Functional Classification
- Dependent on Supplier Scope of Work
- Dependent on Procurement Documents Terms and Conditions

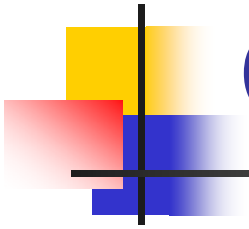
Challenges/Barriers

Varied Approaches for QA Assessment of Suppliers and Sub-tier Suppliers

- Dependent on Project Type
- Dependent on Work Scope
- Dependent on Adequacy of Supplier/Sub-tier QA Program
- Dependent on Suppliers and Sub-tier Supplier Qualified Personnel Availability

Next Steps/Issues

- Developing a consensus model that addresses the diversity in current Contractor's QA Program Requirements (e.g., consistent use of Quality Consensus Standards and vintage)
- Establishing consistency in DOE contractual requirements



Questions & Comments

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Project Area #2

Adequate NQA-1 Suppliers

EM QA Corporate Board Meeting
Denver, Colorado
July 29-30, 2008

Team Members

- Team Leads:
  - Bill Rowland, DOE – SRS
  - Rich Campbell, Energy*Solutions*
- Team members:
  - Lynne Drake, WSRC
  - Cathy Nesser, WTS
  - Steven Stein, DOE - BNL

Background

- The issue is three-fold:
  - Difficulty of contractors finding adequate NQA-1 suppliers;
  - Contractors duplicating supplier audits adding to overall project costs as felt by vendor/supplier shops; and,
  - Suppliers not trained and qualified to common criteria based on national standards.
- An additional issue that needs consideration is the expansive DOE mandated selection process that must be followed to select a supplier of equipment or services.
- Qualified suppliers are decreasing for various reasons such as retirement and working overseas.

Background (Cont'd)

- Past and continuing weaknesses in supplier evaluations conducted by DOE contractors have resulted in:
  - Project cost overages; schedule delays;
  - Decrease in safety margins; and,
  - Regulatory enforcement civil penalties.
- Contractor supplier evaluation issues include:
  - Absence of or poorly performed supplier evaluations;
  - Redundant supplier evaluations by multiple DOE contractors which has resulted in multiple reviews of the same supplier by each contracting organization instead of a coordinated review;
  - Inconsistent training and qualification of assessors; and,
  - Assessments conducted without rigorous criteria based on national standards.

Scope

- Perform research and evaluation to identify methods for expanding the number of willing and qualified suppliers for nuclear grade items and services within EM. Provide recommendations for promoting information sharing, resource sharing and standardization of efforts within EM to improve quality, safety and cost associated with identifying, qualifying and maintaining suppliers.

Actions / Status

- Task 2.1: Request a current list of commodities/ items/services from major EM contractors

  Status: Complete

- Task 2.2: Request a list of the current points of contact for supplier quality assurance from each of the major EM contractors

  Status: In Progress

Actions / Status

- Task 2.3: Attend the NEI Manufacturing Outreach Workshop in June 2008 to gain insight into NEI efforts to attract nuclear suppliers

  Status: Complete

- Task 2.4: Request the names of current suppliers that are providing nuclear grade (Safety Class, Safety Significant, and Important to Safety) materials, equipment, items and services from each major EM contractor

  Status: Complete (list will be used for evaluation in Tasks 2.9 & 2.11)

Actions / Status

- Task 2.5: Request the procedures used for qualifying nuclear grade suppliers from each major EM contractor

  Status: Complete

- Task 2.6: Evaluate procedures being used by major EM contractors for consistency

  Status: In Progress

Actions / Status

- Task 2.7: Evaluate the feasibility of EM hosting a Nuclear Vendor Day, possibly in conjunction with other groups such as EFCOG and NEI

  Status: Hold the DOE Nuclear Suppliers Outreach Event on July 31, 2008 in partnership with NNSA and EFCOG. Complete

- Task 2.8: Evaluate impact of “Buy American” clause on efforts to expand the supplier base within EM Program

  Status: Not Started

Actions / Status

- Task 2.9: Evaluate the applicability and completeness of the common commodities/items/ services listing provided by the major EM contractors

  Status: In Progress

- Task 2.10: Determine the feasibility of EM contractors performing joint audits of common suppliers. If feasible, recommend procedure and checklist requirements that would be needed to implement

  Status: Not Started

Actions / Status

- Task 2.11: Evaluate inputs to determine if there are common suppliers being used for nuclear grade procurements within EM. Identify redundant supplier audits being performed by major EM contractors

  Status: Not Started

- Task 2.12: Determine the feasibility of issuing a consolidated nuclear grade supplier list for EM. Evaluation should include legal and liability issues as well as any restrictions that would be needed on use of list by EM contractors

  Status: Not Started

Actions / Status

- Task 2.13: Evaluate the possibility of integrating EM procurement activities with other supplier initiatives such as NEI, NIAC, and NASA

  Status: Not Started

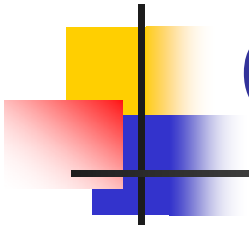
- Task 2.14: Provide final draft deliverable and/or recommendations to EM-60 for review and approval.
  Status: Not Started

Challenges / Barriers

- Maintaining momentum, focus and resources to complete task (all volunteer resources).
- Obtaining buy-in from EM contractors to change process.
- Convincing new suppliers to enter nuclear supply chain. DOE percentage of business may not justify additional cost for new programs.

Challenges / Barriers (Cont'd)

- Establishing an EM Approved Supplier List: address/evaluate the legal issues and liabilities involved.



Questions & Comments

SUPPLIER AUDITING CONCERNS

Jeff Allison

Manager, DOE-SR

Background

- Vendor is long-term supplier of nuclear components to SRS and other DOE sites
- Employee concern investigation team concluded in Feb 2008 that vendor was not meeting NQA-1 requirements
- Contradicted many prior vendor audits from WSRC and others
- Enhanced vendor audit was performed in June 2008 with participation from WSRC, DOE-SR and EM-64

Results of Enhanced June 2008 Audit

- At the time of the audit, the vendor did not have a qualified, experienced QA Manager or QA organization
- QA Program was not adequately documented or implemented
- No internal audits or management assessments had been conducted in last two years
- QA requirements were not flowed down to sub-vendors
- Materials and services were purchased from non-qualified suppliers for safety-related components
- Deficient M&TE control and calibration program

Fallout

- Suspension was issued by WSRC for ongoing work in vendor's shop
- Vendor was removed from WSRC Approved Supplier List
- All EM organizations are reviewing supporting documentation for past orders from vendor
- DOE-IG and DOJ have opened a formal investigation into the vendor's activities

Conclusion

(Preliminary – Root Cause Analysis Underway)

- WSRC vendor auditing programs were less than adequate
- Preliminary cause – insufficient staffing and focus (compliance vs. performance) for vendor audit teams and DOE oversight group
- Possible contributor – lull in commercial nuclear industry construction and fabrication led to nuclear experience deficit in vendor's shop

Path Forward

- WSRC root cause analysis underway
- Extent of condition reviews underway for previous procurements
- Increase in contractor staff assigned to vendor auditing
- Shift in audit focus to performance vs. compliance
- Additional DOE oversight for vendor auditing efforts
- Emphasis on identifying and developing alternate suppliers

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EFCOG *Energy Facility Contractors Group*

Project Area #3

Commercial Grade Item and Services Dedication Implementation

EM QA Corporate Board Meeting
Denver, Colorado
July 29-30, 2008

Team Members

Pat Carier	ORP	DOE Team Lead
Shelby Turner	FH	EFCOG Team Lead
David Faulkner	EM	
Scott Spencer	FH	
Michael McElroy	CH2M Hill	
Herb Berman	CH2M Hill	
Tony Hawkins	WSRC	
Jerry Southard	BEA	
Steven Foelber	BNI	

Background

- Suppliers with Nuclear QA Programs are limited
- CGI Dedication use is more prevalent

Scope

- Provide EM with a recommended baseline scope and approach for the application of Commercial Grade Item (CGI) Dedication and acceptance of nuclear services within EM consistent with code requirements (NQA-1, 2000)

Actions / Status

Task 3.1: Complete a survey of selected EM contractors requesting them to identify the process and basis for their CGI dedication program including safety classification of items being dedicated for nuclear applications within their facilities.

Task 3.2: Complete a survey of selected EM contractors requesting them to identify the process and basis for the process used to accept nuclear services.

Status: Contractor surveys have been completed; nine contractors responded.

Actions / Status (Cont'd)

Task 3.3: Conduct benchmarking activities of operating reactor plants to review CGI dedication and acceptance of nuclear services processes.

Status: Best-in-class benchmarking activities being pursued within travel budgets ECD 9/30/08

Task 3.4: EFCOG QA Working Group prepare a tutorial on what is/is not allowed by the ASME NQA-1 code (NQA-1, 2000) relative to dedication of commercial grade items and acceptance of services for nuclear applications (i.e., SC, SS, ITS, etc).

Status: Not started ECD 10/30/08

Actions / Status (Cont'd)

Task 3.5 – 3.6: Provide EM with recommended baseline requirements/guidance actions considered necessary for implementation of effective CGI dedication and acceptance of services processes within EM nuclear facilities.

Status: Not started ECD: 11/21/08

Survey Results for CGI Dedication

- Seven contractors providing responses utilize CGI dedication for SC/SS applications
- What we do for item dedication is consistent
- How we do it has wide variation

What We Do for CGI Dedication is Consistent

- NQA-1 and EPRI standards are widely used as a basis for CGI dedication
- Organizational responsibility for program is defined
- Acceptance methods are defined
- Written guidance is provided for defining critical characteristics
- Receipt inspections are performed

How We Do CGI Dedication Varies

- Organizational responsibility for the process varies
- Multiple versions of industry standards are used
- Two responders use CGI for safety related applications in addition to SC/SS
- Design output documents used for documenting CGI use vary considerably
- Six responders utilize engineering/quality assurance to accept CGIs for use
- One responder allows responsible functional organization to accept CGIs for use
- Special form records are utilized by 4 responders to document CGI acceptance

Survey Results for Acceptance of Services

- Five responders accept commercial grade services for nuclear applications
- Organizational responsibility for acceptance of services varies
- Only three responders have written guidance on selection of critical characteristics for services
- Documentation method for critical characteristics varies

WTP Project CGD Lessons Learned

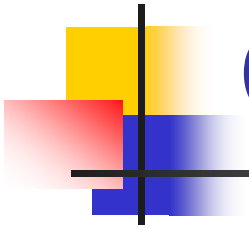
- Tailor CGD program requirements and work processes to the scope of work
  - The process is different for new items for an Engineering-Procurement-Construction (EPC) project versus replacement items for operating plants
  - WTP Project tailored NQA-1 2004 and utilized EPRI and NRC guidance
- Formal CGD training is beneficial
  - Include all groups that are involved in CGD (e.g. Engineering, QA, Procurement)
  - Include workshops with “real world” examples
- Utilization of nuclear industry CGD experts provides value

WTP Project CGD Lessons Learned (cont'd)

- Procurement strategy and execution
  - Improve market research to identify potential qualified suppliers
  - Engineering and QA perform supplier technical and quality reviews early in the process
  - Use CGD where appropriate based on cost, technical feasibility, and supplier NQA-1 maturity
  - Good Commercial Material suppliers who upgraded their QA programs to NQA-1 were often problematic
- Develop onsite NQA-1 testing capabilities based on projected scope and schedule needs

Challenges / Barriers

- CGI dedication is a disciplined process that may not always be expeditious
- Developing high level guidance and expectations that can be tailored to the scope of work (e.g. operating facility vs Engineering-Procurement-Construction project)
- Developing and providing training on application of the process



Questions & Comments

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Project Area #4

Graded Approach to Quality Assurance

EM QA Corporate Board Meeting
Denver, Colorado
July 29-30, 2008

Team Members

- Al Hawkins EM/RL
  Rich Higgins CH2M Hill Hanford

- Phyllis Bruce ATL
  Vince Grosso WSRC
  Clif Hoover FH
  Dave Shugars CWI
  David Faulkner EM-64
  Mike Hassell WCH
  Dave Jantosik BNI
  Sam Vega EM/ORP
  Cathy Nesser Washington TRU Solutions
  Dale Cottingham Isotek Systems LLC

Background

- EM needs consistency in the application of the graded approach. EM lacks a common understanding of why DOE policy allows grading and a standard process for how grading may be accomplished.
- Consistent definitions and examples of successful application from across the complex are also needed.

Scope

- The graded approach team will provide the EM Program with a model process for application of a graded approach for QA in both contractor and federal QA programs. This includes framing the graded approach process, considering its multiple uses and interfaces, and providing examples of successful application from across the complex.

Actions/Status

Task 4.1: List processes warranting application of formal graded approach

Status: Complete – identified need to define elements of a single standard process. Compiled examples of graded approach from across EM and complex

Actions/Status

Task 4.2: Draft EM position paper

Status:

- Requirements and definitions gathered, Action Plan issued
- Group formed, decision to work by consensus
- Working teleconferences held resulting in consensus agreement on 80+% of approach
- On schedule for September 2008 deliverable

Actions/Status

Task 4.3: Provide draft DOE Standard

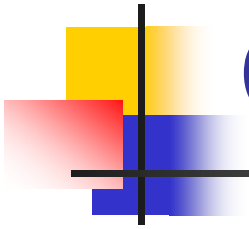
Status: Not started (due 3/31/09)

Key Graded Approach Elements

- Must be written down - approved by DOE
- Applies to items services, and activities
- Not flowed down to subcontractors
- Cost effectiveness is examined
- Line management responsibility
- Deviations (but not exemptions) allowed
- Preferred terminology and roles defined

Challenges / Barriers

- Developing single approach applicable to the diverse situations found in EM (e.g., construction vs. labs)
- Resolving “what ifs” (e.g., what if engineering specification cannot be verified)
- Grading and Tailoring
- Agreeing to common set of EM definitions



Questions & Comments

EM Environmental Management

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Project Area #5

Line Management Understanding of QA and Oversight

EM QA Corporate Board Meeting
Denver, Colorado
July 29-30, 2008

Team Members

- **DOE Lead: T. J. Jackson, DOE EMCBC**
- **EFCOG Lead: Jon E. Hoff – URS / Washington TRU Solutions**

- Bryan Bower, WVDP,
- Jack Zimmerman, PPPO
- Bob Toro, DOE EM,
- Kriss Grisham, DOE EM

Background

- To understand quality and to instill a quality culture in the EM-complex, all EM federal and contractor organizations must:
  - Define the importance of Quality as it pertains to each organization in achieving its mission, goals, and objectives;
  - Emphasize line ownership and accountability in implementing a quality program;
  - Have management commitment and support to develop and implement a standardized EM QA Program; and
  - Exhibit the EM values (e.g. Safety, Integrity, Quality, Teamwork, Accountability, and Continuous Improvement) needed to establish a quality culture and quality program throughout the EM complex.

Scope

- Provide a QA management system, training, and assessment expectations for line management to instill “consistency” in application, awareness, and performance of QA principles for both federal workers and contractor staff.

Actions/Status

- Task 5.1: Add interim QAP Performance/Risk data to the agenda of every Quarterly Performance Review (QPR).

  Status: QPR Quad Chart has a place holder for QA Performance/Risk Data. Expectations for Performance/Risk Data are under development. Develop final QPR Quad Chart by 9/30/08.

- Task 5.2: Obtain commitment of all EM site managers on QA qualifications/training for assigned project QA staff.

  Status: QA Resources table/Analysis has been compiled per the May 13, 2008 EM-2 memo (distributed at this meeting). Training will be completed by 12/31/08.

Actions/Status

- Task 5.3: Develop an EM QA Program (QAP) that will be applicable to all EM sites.

  Status: Draft QAP is out for review/comment (7/21/08). Finalized QAP – 9/30/08

- Task 5.4: EM-1, 2 provides direction and guidance to EM field sites to promulgate EM Corporate QAP.

  Status: Memorandum to issue QAP - 10/31/08

- Task 5.5: Develop Training modules on the value of a strong QA Program

  Status: Various modules being developed (many class offerings from ½ day sessions to 40 hour sessions). 3 modules undergoing dry run at WIPP (8/18/08). Ready for

Actions/Status

- Task 5.6: Complete QA training for all FPDs and IPT participants to reinforce consistent performance expectations

  Status: Due by 12/31/08. Focus will be on ensuring IPTs understand the importance of a rigorous QA Program.

- Task 5.7: Establish assessment expectations for FPDs and IPTs (e.g., Phase I, Phase II, annual reviews, performance measures, lessons learned).

  Status: Draft assessment expectations document to be issued for review/comment by 12/31/08 focused on phase of the project (CD-1, 2, 3, etc....consistent with new QA for Project Management guidance document DOE G 413.3-2). Another important change will be “an annual QA declaration” and PhaseI/Phase II/Annual evaluation process to ensure effective QA Program implementation similar to the evaluation process for ISMS (Line management ownership)

Actions/Status

Task 5.8: Following EM QA Program promulgation, associated Project Execution Plans, procedures, implementation plans, and charters will be developed to ensure adequate and consistent implementation of the QAP.

Status: Due 3/3/1/09. Sites to deliver procedure set to approval authority.

Challenges/Barriers

- Getting “buy in” from the entire EM complex – this initiative has the support of many projects, but there will be challenges (similar to ISMS roll out in the 90s) to ensure consistent application/performance
- Proposed cost to implement by some contractors and vendors (though this should not be a big consideration since they all should have a 10 CFR 830 compliant program)
- Short time frame so all of these actions need high level attention
- Instilling a Quality culture similar to the safety one takes time

Questions & Comments

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Proposed EM Corporate Performance Metrics System

Sandra L. Waisley

EM QA Corporate Board Meeting

July 29 – 30, 2008

Denver, Colorado

Background

- EM HQ QA Improvement Initiative Established Early CY 2007
- Office of Environmental Management Initiatives and NAPA Actions Adopted Late CY 2007
  - ✓ Development of 1st EM Corporate QA Performance Metrics System
- EM QA Corporate Board Established and Identified Five Top Priority Issues

Philosophy

- Instill a Quality Culture in EM Complex by Identifying and Fixing Legacy Organizational Weaknesses
- Quality Culture Must Emphasize Problem Prevention, Problem Correction, and Continuous Improvement
- Measures or Indicators Should Be Linked to Requirements and Line Management Expectations
- Line Management is Primarily Responsible and Accountable for Scope and Implementation of a QA Program and Should Know if Their QA Program is Healthy.
- Procurement Process Should Produce Good Quality in Products and Services
- Proactive not Reactive Approach (Preventative): Not Focused Primarily on Process-Type Activities

Overall Approach

- Consistent with ISMS Verification Process and Annual Declaration
- Conforms to ASME NQA-1 and 10 CFR 830.120 Requirements
- Measurement Over Time (Compare to a Baseline)
- Need to be Able to Distinguish Between Systematic and Isolated (one-of-a-kind) Causes
- Focus on Feedback and Continuous Improvement

Overall Approach (Cont'd)

- Three Categories of Program Criteria: Management, Performance, and Assessment
- Three Levels: Phase I (Assessments), Phase II (Audits), and Feedback & Continuous Improvement (Annual Validation Process)
- Performance Objectives, Measures, and Commitments (POMCs): Indicators that Allow for Response, Correction, and Prevention
- POMCs Weighted to Determine Overall Score for Specific Criteria
- Continue to Re-evaluate and Refine POMCs and Incorporate Line Feedback Annually

QA Performance Metrics System Levels of Measurement

- Evaluation of Criteria by Site Managers:
  - ✓ Site-Wide
  - ✓ Project Baseline Summaries (PBSs)
  - ✓ Major Projects
- Scoring: Good (Green); Yellow (Investigate); Red (Define Actions)
- Score on Quarterly Basis
- Trend Report: A Measure of the Quarterly Changes in Performance Compared Over a Rolling 12 Month Period

Next Steps

- Obtain Comments from EM QA Corporate Board Membership
- Establish Final EM Corporate Performance Metrics System by September 30, 2008.
- Seek Volunteers from EM Field Sites for Pilot Tests of New System
- Initiate Implementation of Pilot Tests at EM Field Sites

Site QA Resources Summary Analysis

Sandra L. Waisley

EM QA Corporate Board Meeting

July 29 – 30, 2008

Denver, Colorado

Background

- Secretary Bodman Memorandum “Improving Quality Assurance” in April 2006
- Dae Chung Memorandum “EM QA Initiative Evaluation Plan” in March 2007
- Office of Environmental Management Initiatives and NAPA Recommendation A/PM-224 Adopted Late CY 2007
  - ✓ Assessing staffing requirements and levels performing QA functions
- Dr. Ines Triay Memorandum “Establishing QA Manager Positions at Major EM Sites and the Consolidated Business Center” in May 2008

May 13, 2008 EM-2 Direction Memo

- Establish QA Managers at Headquarters, major EM sites, and the Consolidated Business Center (CBC)
- Designate a site QA Manager with independent reporting responsibilities to sufficient levels of the organization (Site Manager or Deputy Manager)
- Empower designated Site QA Manager within organization's site management
- Allocate additional QA resources to site QA functions, including hiring new staff
- Qualify/Certify existing QA staff to QA and Software QA Technical Qualification Programs (TQPs), and as NQA-1 2004 Auditor/ Lead Auditor
- Designate mitigating agent if Site QA Manager is not NQA-1 qualified

Summary

- QA Managers designated at Headquarters, major and small EM Sites, and the Consolidated Business Center (CBC) with sufficient authority and independence
- QA Resources identified for EM large and small sites and the CBC with active hiring program at 3 major EM sites
- Designated QA Managers qualified or in-process to NQA-1 requirements
- Existing QA staff qualified or in-process of being qualified to QA and Software QA TQPs
- Existing QA Staff certified/qualified or in-process as NQA-1 2004 Auditor/Lead Auditor, respectively

Summary (Cont'd)

- New EM Centralized Training Academy is designed for new QA professionals or other staff who desire QA training; existing qualified QA staff are "grandfathered" in and do not need to attend this training

- Number of Federal QA Professionals (existing and projected to be hired soon) in HQ and the Field Sites total about 49 FTES – about 3.5% of total EM workforce (commercial sector average for operating projects is 4 – 7%)

EM Corporate Performance Metrics Concept

Quality Program Criteria

I. MANAGEMENT					
10 CFR 830	**ASME NQA-1, 2004**	**Supported ISM Guiding Principles**	**Performance Objectives, Measures & Commitments (POMC)**	**WEIGHT**	**LEVEL/ SCORE**
1. Program	1. Organization 2. Quality Assurance Program	Line Management Responsibility Clear Roles and Responsibilities Competence Commensurate with Responsibilities	A Does the quality management system (QMS) define and document the established organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work including overall expectations for effective implementation of the quality assurance program?	40%	II
			B Does the QMS describe a quality assurance organization that has sufficient resources and qualifications to perform its functions?	30%	
			C Does the QMS define a process for grading the application of requirements? Does this process adequately address hazards and mission?	30%	
2. Personnel Training and Qualification	2. Quality Assurance Program	Line Management Responsibility Clear Roles and Responsibilities Competence Commensurate with Responsibilities	A Is the methodology described for establishing requirements to indoctrinate, train and qualify personnel performing or managing activities affecting quality?	30%	
			B Have adequate resources been identified to support the selection, training, and qualification of personnel conducting work?	30%	
			C Are the requirements defined and implemented for the qualification and/or certification of personnel in the various functional areas (e.g., audit personnel, subject matter experts, inspection and test personnel, welders, etc.)?	40%	

Level	Evaluation
I	Program (Phase I Assessments)
II	Performance (Phase II Audits)
III	Feedback & Continuous Improvement (Annual Validation Process)

Score color
Good
Investigate
Define Actions

EM Corporate Performance Metrics Concept

Quality Program Criteria

I. MANAGEMENT					
10 CFR 830	**ASME NQA-1, 2004**	**Supported ISM Guiding Principles**	**Performance Objectives, Measures & Commitments (POMC)**	**WEIGHT**	**LEVEL/ SCORE**
3. Quality Improvement	2. Quality Assurance Program 15. Control of Nonconforming Items 16. Corrective Action	Operations Authorization	A Has the organization established, implemented, and documented processes and leading indicators to detect and prevent quality problems such as conditions adverse to quality and nonconforming items?	20%	
			B Does the QMS describe methods for addressing cause, extent, and remedial and preventative actions for continuous improvement of quality problems?	20%	
			C Is a process defined to review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement?	20%	
			D Do controls provide for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, and for notification to affected organizations?	10%	
			E Are conditions adverse to quality identified promptly and corrected as soon as practicable and in the case of a significant condition adverse to quality, is the cause of the condition determined and corrective action taken to preclude recurrence?	20%	
			F Is a nonconformance and corrective action tracking and trending program in place and is it effective?	10%	

Level	Evaluation
I	Program (Phase I Assessments)
II	Performance (Phase II Audits)
III	Feedback & Continuous Improvement (Annual Validation Process)

Score color
Good
Investigate
Define Actions

EM Corporate Performance Metrics Concept

Quality Program Criteria

I. MANAGEMENT						
10 CFR 830	**ASME NQA-1, 2004**	**Supported ISM Guiding Principles**	**Performance Objectives, Measures & Commitments (POMC)**		**WEIGHT**	**LEVEL/ SCORE**
4. Documents and Records	5. Instructions, Procedures, and Drawings 6. Document Control 17. Quality Assurance Records	Balanced Priorities Identification of Safety Standards Hazard Controls Tailored to Work Operations Authorization	A	Are functions and activities affecting quality and services effectively described and performed in approved, documented, and controlled instructions, procedures, or drawings that include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished?"	30%	
			B	Are quality assurance records traceable to associated items and completed work activities from applicable documents, such as design specifications, procurement documents, test procedures, and operational procedures; properly identified classified and specified; authenticated, controlled and maintained; and their final disposition specified?	30%	
			C	Have documents been developed and effectively implemented that prescribe processes to oversee contractors and suppliers?	20%	
			D	Does the QMS describe how procedures are prepared, reviewed, approved, issued, used, and revised to prescribe processes, specify requirements, or establish design?	20%	

Level	Evaluation
I	Program (Phase I Assessments)
II	Performance (Phase II Audits)
III	Feedback & Continuous Improvement (Annual Validation Process)

Score color
Good
Investigate
Define Actions

EM Corporate Performance Metrics Concept

Quality Program Criteria

II. PERFORMANCE					
10 CFR 830	**ASME NQA-1, 2004**	**Supported ISM Guiding Principles**	**Performance Objectives, Measures & Commitments (POMC)**	**WEIGHT**	**LEVEL/ SCORE**
5. Work Processes	5. Instructions, Procedures, and Drawings 8. Identification and Control of Items 9. Control of Special Processes 12. Control of Measuring and Test Equipment 13. Handling, Storage, and Shipping 14. Inspection, Test, and Operating Status Subpart 2.7 SQA	Balanced Priorities Identification of Safety Standards Hazard Controls Tailored to Work Operations Authorization	A Are the core functions and guiding principles of the DOE Integrated Safety Management System addressed consistent with DOE O 450.1, DOE P 450.4 and applicable chapters in DOE O 5480.19 such that work is performed consistent with technical standards, administrative controls, and other hazard controls adopted to meet regulatory or contract requirements using approved instructions, procedures, or other appropriate means.?	20%	
			B Does the quality management system provide methods to identify and control items to ensure their proper use consistent with DOE G 414.1-3 and does it address suspect counterfeit items?	20%	
			C Is the method to maintain items to prevent their damage, loss, or deterioration adequately described? Does this method address the requirements (e.g., DOE O 433.1, Maintenance Management Program for DOE Nuclear Facilities, dated 6-1-01)?	20%	
			D Are special processes that control or verify quality, such as those used in welding, heat treating, and nondestructive examination, performed by qualified personnel using approved procedures or instructions compliant with the requirements of applicable codes and standards, including acceptance criteria for the process?	20%	
			E Are tools, gauges, instruments and other measuring and test equipment used for activities affecting quality, controlled and calibrated at specific periods, adjusted and maintained to required accuracy limits?	10%	

Level	Evaluation
I	Program (Phase I Assessments)
II	Performance (Phase II Audits)
III	Feedback & Continuous Improvement (Annual Validation Process)

Score color
Good
Investigate
Define Actions

EM Corporate Performance Metrics Concept

Quality Program Criteria

II. PERFORMANCE					
10 CFR 830	**ASME NQA-1, 2004**	**Supported ISM Guiding Principles**	**Performance Objectives, Measures & Commitments (POMC)**	**WEIGHT**	**LEVEL/ SCORE**
5. Work Processes (cont)			F Is the status of inspection and test activities identified either on the items or in documents traceable to the items where it is necessary to ensure that required inspections and tests are performed and to ensure that items which have not passed the required inspections and tests are not inadvertently installed, used, or operated?	10%	
6. Design	3. Design Control Subpart 2.7 SQA	Balanced Priorities Identification of Safety Standards Hazard Controls Tailored to Work Operations Authorization	A Does the quality management system describe a process for design verification and/or validation for design products including software related to safety systems, before approval and implementation of the design? Does the process require the use of individuals or groups other than those who performed the work?	20%	
			B Do design items and processes use sound engineering/scientific principles and appropriate Standards and Orders (i.e., DOE O 420.1A)? Does the process address change control (changes to design inputs, final designs, field changes and temporary and permanent modifications to operating facilities)?	20%	
			C Are design interfaces identified and controlled, within the design authority and externally with customers and suppliers, including subcontractors?	20%	
			D Is the extent of the design verification a function of importance to safety, complexity of the design, degree of standardization, state-of-the-art, and similarity with previously proved designs?	10%	
			E Are procedures implementing configuration management requirements established and documented at the earliest practical time prior to facility operation, including authority and responsibilities of the organizations whose functions affect the configuration of the facility, such as operations, design, maintenance, construction, licensing, and procurement?	10%	

Level	Evaluation
I	Program (Phase I Assessments)
II	Performance (Phase II Audits)
III	Feedback & Continuous Improvement (Annual Validation Process)

Score color
Good
Investigate
Define Actions

EM Corporate Performance Metrics Concept

Quality Program Criteria

II. PERFORMANCE					
10 CFR 830	**ASME NQA-1, 2004**	**Supported ISM Guiding Principles**	**Performance Objectives, Measures & Commitments (POMC)**	**WEIGHT**	**LEVEL/ SCORE**
6. Design (cont)			F Are software design requirements identified and documented and their selection reviewed and approved (operating system, function, interfaces, performance requirements, installation considerations, design inputs, and any design constraints of the computer program)?	20%	
7. Procurement	4. Procurement Document Control 7. Control of Purchased Items and Services Subpart 2.7 SQA	Balanced Priorities Identification of Safety Standards Hazard Controls Tailored to Work Operations Authorization	A Are the requirements for the procurement of items and services established? Do the requirements include performance and quality specifications provided by the design authority and quality organization and do the requirements ensure that procured items and services will meet established requirements and perform as expected?	30%	
			B Is there a system to evaluate and select prospective suppliers based on specified criteria?	30%	
			C Are processes in place to ensure that approved suppliers continue to provide acceptable items and services established and implemented? Is it graded to ensure safety-related items and mission critical items are subject to more rigorous methods (e.g., inspection and testing at the manufacturer and upon receipt)?	40%	
8. Inspection & Acceptance Testing	8. Identification and Control of Items 10. Inspection 11. Test Control 12. Control of Measuring and Test Equipment Subpart 2.7 SQA	Operations Authorization	A Are inspections and tests specified for items, services, and processes? Are acceptance and performance criteria established and used?	40%	
			B Is there a system for documenting the results of inspections and tests?	30%	
			C Is inspection and test equipment controlled by a process to ensure it is calibrated and maintained?	30%	

Level	Evaluation
I	Program (Phase I Assessments)
II	Performance (Phase II Audits)
III	Feedback & Continuous Improvement (Annual Validation Process)

Score color
Good
Investigate
Define Actions

EM Corporate Performance Metrics Concept

Quality Program Criteria

III. ASSESSMENT					
10 CFR 830	**ASME NQA-1, 2004**	**Supported ISM Guiding Principles**	**Performance Objectives, Measures & Commitments (POMC)**	**WEIGHT**	**LEVEL/ SCORE**
9. Management Assessment	2. Quality Assurance Program 18. Audits	Operations Authorization	A Does the QMS describe how managers, at all levels, assess their management processes?	30%	
			B Does the QMS provide for the identification and correction of problems that hinder the organization from achieving its objectives?	30%	
			C Do managers take responsibility for, and directly participate in, the assessments?	40%	
10. Independent Assessment	1. Organization 2. Quality Assurance Program 10. Inspection 11. Test Control 15. Control of Nonconforming Items 16. Corrective Action 18. Audits	Operations Authorization	A Are independent assessments (e.g., audits) planned and conducted to measure item and service quality, to measure the adequacy of work performance, and to promote improvement?	30%	
			B Does the organization act on assessments in a manner that results in continuous improvement?	30%	
			C Does the group performing independent assessments have sufficient authority and freedom from line management (i.e., not directly responsible for the work being assessed) and are the persons who perform independent assessments technically qualified and knowledgeable in the areas to be assessed?	20%	
			D Does management of the audited organization or activity investigate adverse audit findings, schedule corrective action, including measures to prevent recurrence of significant conditions adverse to quality, and notify the appropriate organization in writing of action taken or planned?	20%	

Level	Evaluation
I	Program (Phase I Assessments)
II	Performance (Phase II Audits)
III	Feedback & Continuous Improvement (Annual Validation Process)

Score color
Good
Investigate
Define Actions

EM Corporate Performance Metrics Concept

Quality Program Criteria

Level definition

Level	Evaluation	
I	Program (Phase I Assessments)	Evaluation of the contractors QA program description
II	Performance (Phase II Audits)	Evaluation of the implementation of a satisfactory QA program description
III	Feedback & Continuous Improvement (Annual Validation Process)	Annual validation of QA program implementation

Summary of EM Federal Site QA Resources
(Percentage of Total Federal Workforce)

Description	Number (FTEs)	Percent of Total EM Federal Workforce (1600 FTEs)
EM HQ/Site QA Managers	13	
EM QA Professional Staff	37.25	
Total	**50.25**	**3.1%**
Projected New Hires	14	
Total	**64.25**	**4.0%**
EM QA Support Services and/or Program Support Contractors **(HQ only)**	6	
EM QA Support Services and/or Program Support Contractors **(Sites only)**	31 (23 – CBFO)	
Total	**101.25**	**6.3%**

Note: Industry averages 4% - 7% of total workforce

EM Corporate QA Policy

This EM Quality Assurance Program recognizes individuals performing work determine whether it is done correctly and quality is achieved. While "do work safely" is our first priority we understand it is also essential to "do work correctly." Although plans, procedures, and instructions are a basic part of any quality program, people make quality happen.

As the Assistant Secretary for Environmental Management, I am responsible to achieve quality within my organization. It is EM policy that doing work correctly is not subordinate to cost or schedule objectives. My expectation is each individual, when properly trained and supported, will achieve the highest quality performance of which he or she is capable.

This Quality Assurance Program provides the basis for the achievement of quality across the EM complex for all EM mission related work. It is EM policy that all EM projects will have a consistent Quality Assurance approach while allowing for grading based on importance to the EM mission and for site-specific requirements. We have adopted ASME NQA-1-2004 as out national consensus standard. It is EM's policy that each EM organization and contractor will have an organization-specific Quality Assurance Implementation Plan demonstrating how they meet the applicable requirements of NQA-1-2004 as addressed in this Quality Assurance Program. It is the members of the line organization who are responsible for implementing the Quality Assurance Program requirements within their areas of responsibility.

As we strive to make EM a "Best-in-Class" organization a strong Quality Assurance Program supports our emphasis on more disciplined management and operational processes. I fully support the implementation of this program and I know I can count on your support of this essential effort.

/s/ Jim Rispoli

Office of Environmental Management (EM)
Subject: EM Quality Assurance Program (QAP)

Policies, Procedures, and Plans

APPROVED: _____
OEM (add Title)

1.0 PURPOSE AND OBJECTIVE

The purpose of this document is to describe the U.S. Department of Energy (DOE), Office of Environmental Management (EM) Quality Assurance Program (QAP). The QAP is the EM management system to ensure we "do work correctly." The QAP meets the requirements of DOE O 414.1C, *Quality Assurance*, and 10 CFR 830 Subpart A "Quality Assurance Requirements." The QAP provides EM expectations for implementing quality assurance (QA) across the EM complex. The QAP demonstrates how QA and the Integrated Safety Management System (ISMS) are fully integrated in EM.

The objective of this QAP is to provide consistent QA implementation across EM while allowing both for grading based on importance to the EM mission and for site-specific requirements to be addressed (e.g., DOE/RW-0333P, *Quality Assurance Requirements and Description*; state permit requirements; etc.).

2.0 SCOPE

This QAP applies to EM Headquarters (HQ), EM Field/Project Offices, and EM contractors. The requirements of the QAP are applied in a graded fashion commensurate with the type of work being performed and the importance of the work contributing to safe completion of the EM mission. EM expects applicable requirements will be passed down to subcontractors. EM adopts American Society of Mechanical Engineers (ASME) NQA-1-2004, *Quality Assurance Requirements for Nuclear Facility Applications*, Part I, and the noted requirements of Part II as its national consensus standard. Other requirements of NQA-1-2004 Part II may be selected as appropriate for the work scope being performed.

The vast majority of EM work involves nuclear materials and/or systems. Therefore, NQA-1 is the appropriate standard to ensure safety and rigor in work activities. Through careful application of the graded approach, NQA-1 is also an acceptable standard to ensure safety and rigor in associated non-nuclear work activities. Thus leveraging efficiencies of standardization for all EM work.

3.0 APPLICABILITY

The requirements contained within this document apply to EM HQ, EM Field/Project Offices, and EM contractors as applicable to the work being performed by each entity. Each organization will have an organizational-specific quality assurance implementation plan (QIP) describing how the applicable requirements of this QAP are implemented and/or passed down to lower-tier organizations. It is expected that EM sites will incorporate additional site-specific and NQA-1 requirements into their QIP based on activities being performed (e.g., Federal repository-related work, transuranic [TRU] waste disposal activities, special processes, inspections, use of measuring and test equipment, etc.).

4.0 REQUIREMENTS & REFERENCES

4.1 REQUIREMENTS

4.1.1 DOE O 414.1C, *Quality Assurance*

4.1.2 ASME NQA-1-2004, *Quality Assurance Requirements for Nuclear Facility Applications*

4.1.3 10 CFR 830, Subpart A, "Quality Assurance Requirements" (i.e., QA Rule)

4.2 REFERENCES

4.2.1 DOE G 414.1-1B, *Management Assessment and Independent Assessment Guide*

4.2.2 DOE G 414.1-2A, *Quality Assurance Management System Guide*

4.2.3 DOE G 414.1-3, *Suspect/Counterfeit Items Guide*

4.2.4 DOE G 414.1-4, *Safety Software Guide*

4.2.5 DOE G 414.1-5, *Corrective Action Program Guide*

4.2.6 DOE P 450.4, *Safety Management System Policy*

4.2.7 Office of Environmental Management Integrated Safety Management System Description (ISMSD), dated April 2007

5.0 DEFINITIONS & ACRONYMS

5.1 No new definitions are created in this document. See requirements/referenced documents for applicable definitions.

5.2 Acronyms are defined upon first usage in this document.

6.0 RESPONSIBILITIES

QAP implementation, assessment, and improvement are senior management responsibilities.

6.1 EM HQ Senior Official, EM Field/Project Office Senior Official, and EM Contractor Senior Official:

6.1.1 Develop and implement an approved QIP governing the work under their purview, including as applicable software development/use, in accordance with requirements defined in this document. Identify the senior management position assigned this responsibility.

6.1.2 Submit their QIP to their organizational reporting office (i.e., Contractor through the DOE Field Office to the DOE HQ Office (unless delegated); DOE Field/Project Office through the DOE HQ Office to the Secretarial Office; DOE HQ Office to the Secretarial Office) for review, comment resolution, and approval.

6.1.3 Review and, if authorized, approve new and revised QIPs for contractors within their purview and as required by applicable contract, QA Rule, and DOE Orders.

NOTE: The scope and rigor of review must be graded based on the status of the contractor's prior quality performance (e.g., past regulatory /contract noncompliance, performance metrics, or third-party certification, etc.). QIPs must be reviewed and approved or rejected within 90 calendar days of receipt.

6.1.4 EM HQ, EM Field/Project Office, and EM contractors will perform a QA effectiveness review and submit an annual declaration report that demonstrates QA implementation similar to the annual ISMS declaration process.

6.2 Office of Safety Management and Operations (EM-60)

6.2.1 EM-60 is responsible for the development and maintenance of this QAP. This includes defining expected annual performance objectives, measures, and commitments (POMC).

6.3 EM HQ, EM Field/Project Office, and EM contractor personnel are responsible for implementing this QAP in accordance with their applicable QIPs.

7.0 EM QA PROGRAM

The following sections define the EM QAP. EM HQ, EM Field/Project Offices, and EM contractors shall prepare QIPs that meet the requirements defined here to demonstrate they are implementing the EM QAP. QIPs may be developed using the sample EM QIP as a template (Attachment G, *Quality Assurance Implementation Plan*). Organizations should perform a gap analysis to determine the procedures and documents needed to meet the EM QAP. When employees comply with the processes, procedures, and other documents identified in their organization's approved QIP, they are implementing the EM QAP. EM-1 retains responsibility for the development, execution, and maintenance of the EM QAP.

The following sections describe the implementation of the 10 QA Criteria from DOE O 414.1C and 10 CFR 830, Subpart A (i.e., QA Rule). They also provide alignment with the 18 requirements of ASME NQA-1 (see Attachment E). The connection between ISMS core functions/guiding principles and QA requirements can be found in the EM-HQ ISMSD, Table 2. The EM graded approach is described in Attachment D. Attachment F defines EM's ISMS expectations.

7.1 PROGRAM

The following are the **Management/Criterion 1 – Program** requirements cited in DOE O 414.1C, Attachment 2 and 10 CFR 830.122, "Quality assurance criteria":

(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 resources for work.

The following table illustrates the relationship between the Management/Criterion 1 – Program requirements and the ASME NQA-1 requirements used to implement them. Implementation of these requirements supports all five ISMS core functions.

Management/Criterion 1 – Program Requirements	ASME NQA-1 Requirements
(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 resources for work.*	**Requirement 1 – Organization** 100 – Basic 200 – 202 Structure and Responsibility 300 – Interface Control **Requirement 2 – Quality Assurance Program** 100 – Basic 200 – 202 Indoctrination and Training 300 – 305 Qualification Requirements 400 – Certification of Qualification 500 – Records

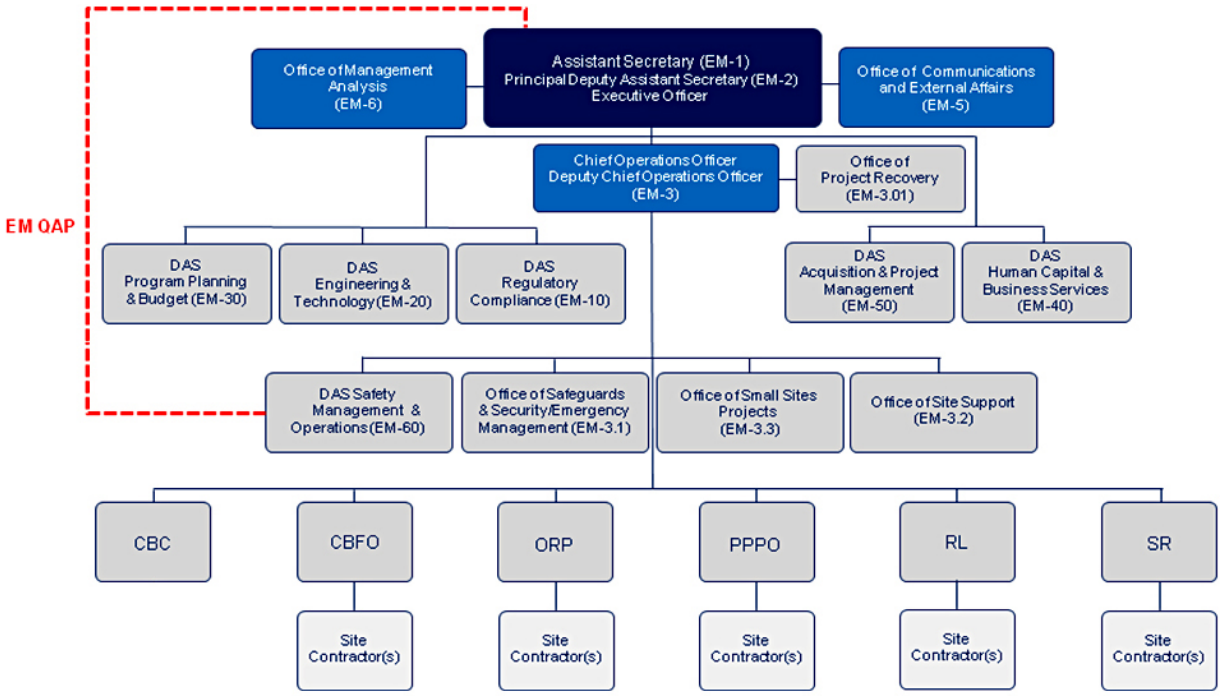
7.1.1 General Information

Management Expectations:

- Employees shall be familiar with and facilitate achievement of the management expectations included in the organizational QIP.
- Management shall establish and implement processes and procedures for EM or EM site mission-related activities in a controlled manner.
- This QAP and associated QIPs shall be maintained current.
- This QAP and associated QIPs should be developed and maintained using the guidance provided in DOE G 414.1-2A, *Quality Assurance Management System Guide*.

Line management for execution of the work extends from EM-3, through the Field/Project Office, to the Contractor. The authority for development and implementation of this EM QAP, as defined in DOE O 414.1C, has been delegated by EM-1 to EM-60.

The EM line management organizational structure is as follows:



Where necessary, EM sites coordinate and integrate activities with EM HQ**.** Lines of communication, feedback mechanisms, and interfaces with stakeholders, regulators, HQ, and support organizations are established and documented. Using the graded approach and consistent with ISMS principles, the Senior DOE Official ensures resources are planned, scheduled, and allocated to accomplish work. The Functions, Responsibilities and Authorities Manual (FRAM) is used to ensure requirements are identified and associated responsibilities are assigned. The QIP defines these linkages to each QA criterion (see Attachment G, *Quality Assurance Implementation Plan*).

7.1.2 Implementation

(a) This QAP complies with DOE 414.1C and with 10 CFR 830 Subpart A (i.e., QA Rule) and aligns with ASME NQA-1 requirements and integrates with the EM ISMSD.

(b) Each associated (both Federal and Contractor) QIP shall reflect the organizational structure (i.e., organization chart), roles/responsibilities, levels of authority, and interfaces in the organization.

(c) A Functions, Responsibilities, and Authorities (FRA) manual for the DOE organizations is provided to ensure requirements and functional responsibilities are identified and assigned. Each organization's (including contractors) QIP will also identify organizational functions and responsibilities.

(d) The Senior DOE or Contractor Official, as identified in the respective organizational chart, is responsible to assure adequate planning, scheduling, and resources are provided to implement the QIP.

Implementing procedures and documents are referenced in the respective organizational QIPs.

7.2 PERSONNEL TRAINING AND QUALIFICATION

The following are the **Management/Criterion 2 – Personnel Training and Qualification** requirements from DOE 414.1C, Attachment 2 and 10 CFR 830.122:

(a) Train and qualify personnel to be capable of performing assigned work.

(b) Provide continuing training to personnel to maintain job proficiency.

The following table illustrates the relationship between the Management/Criterion 2 – Personnel Training and Qualification requirements and the ASME NQA-1 requirements used to implement them. Implementation of these requirements supports all five ISMS core functions.

Management/Criterion 2 – Personnel Training and Qualification	**ASME NQA-1 Requirements**
(a) Train and qualify personnel to be capable of performing assigned work. *(b) Provide continuing training to personnel to maintain job proficiency.*	**Requirement 2 – Quality Assurance Program** 100 – Basic 200 – 202 Indoctrination and Training 300 – 305 Qualification Requirements 400 – Certification of Qualification 500 – Records

7.2.1 General Information

Management Expectations:

The success of any organization requires members of the organization to be competent in the work they perform. Training shall be provided to employees to maintain or improve job performance, enhance existing skills, and develop new skills. Managers are responsible for ensuring personnel are fully qualified for their positions. Training identified by the supervisor is made available, if necessary, to improve knowledge or skills specific to the job and/or organization.

Training includes formal and informal training, education, and developmental and other learning assignments. Training also includes the application of acquired knowledge, skills, and experience to workplace responsibilities and can be used as a tool to recruit and maintain a talented, diverse, and versatile workforce. Methods of training include, among others, reading assignments, observation and performance of activities, lessons learned, on-the-job training, feedback from co-workers and managers, briefings, and formal training classes. The extent of training is commensurate with the scope, complexity, and nature of the respective task and as required by the approved QIP. Education, experience, formal, and on-the-job training comprise the basis for qualification.

Employee-specific training needs shall be documented and updated as required to ensure the maintenance of competence required by the position.

Qualifications for specific job categories are based on requirements established by the organization's personnel management, DOE directives, other requirement documents, or management. Management reviews the positions within their organization to determine:

- If critical and unique job functions or tasks require highly technical, specialized skills;

- Whether competency must be demonstrated before performance (e.g., Office of Personnel Management [OPM] minimum qualification requirements, NQA-1 Lead Auditor qualification, etc.) or within a specified timeframe after entering the position (e.g., Technical Qualification Program [TQP] qualification within 18 months of entering the position); and/or
- Whether a specialized certification may be required.

Based on the review, qualification requirements that provide evidence of employee proficiency through a practical and/or written examination process may be established.

7.2.2 Implementation

(a) The method and process for ensuring personnel are trained, qualified and capable of performing assigned work is identified in training and qualification procedures as described in the applicable QIP.

(b) Specific training includes such things as General Employee Training, Job-Specific Training, Assessment and Oversight Training, Lead Auditor Training, Technical Qualification Training (including Safety Software Quality Assurance per Attachment C, *Safety Software Quality Requirements*), and Professional Qualification/Certification Training, as applicable.

7.3 QUALITY IMPROVEMENT

The following are the **Management/Criterion 3 – Quality Improvement** requirements from DOE 414.1C, Attachment 2 and 10 CFR 830.122:

(a) Establish and implement processes to detect and prevent quality problems.

(b) Identify, control, and correct items, services, and processes that do not meet established requirements.

(c) Identify the causes of problems, and include prevention of recurrence as a part of corrective action planning.

(d) Review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement.

The following table illustrates the relationship between the Management/Criterion 3 – Quality Improvement requirements and the ASME NQA-1 requirements used to implement them. Implementation of these requirements supports ISMS Core Function 5.

Management/Criterion 3 – Quality Improvement	**ASME NQA-1 Requirements**
(a) Establish and implement processes to detect and prevent quality problems. *(b) Identify, control, and correct items, services, and processes that do not meet established requirements.*	**Requirement 2 – Quality Assurance Program** 100 – Basic 200 – 202 Indoctrination and Training 300 – 305 Qualification Requirements 400 – Certification of Qualification 500 – Records **Requirement 15 – Control of Nonconforming Items** 100 – Basic

Management/Criterion 3 – Quality Improvement	ASME NQA-1 Requirements
(c) Identify the causes of problems, and include prevention of recurrence as a part of corrective action planning. *(d) Review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement.*	200 – Identification 300 – Segregation 400 – 405 Disposition **Requirement 16 – Corrective Action** 100 – Basic

7.3.1 General Information

Management Expectations:

- Management shall set performance goals and standards.
- Management shall establish metrics that monitor performance to identify processes needing improvement.
- Nonconforming items will be identified, segregated, and dispositioned. Nonconforming items shall be controlled to prevent inadvertent installation or use.
- Corrective/preventive actions shall be developed and implemented for problems/findings related to processes or services. An "Extent of Condition" determination should be conducted, when appropriate.
- Completed corrective/preventive actions shall be independently verified for implementation and closure.

In order for quality improvement to occur, it is necessary to have systems that identify problems. Problem identification can occur as a result of self-assessments, independent or external assessments, anomalous behavior of some measured quantity against a predefined metric, benchmarking, failure to achieve performance goals or accomplish improvement plans, or as a result of the occurrence of an event. Problem identification can also result from unfulfilled expectations of customers served by the organization. In most cases, problems are associated with deviations or inconsistencies with a requirement, or failures to meet customer, or management expectation.

Problems with potential programmatic or safety significance or that are widespread, continuing, multiple, or repetitive in nature should be afforded special attention. Such problems must be entered into a database and identified to management for proper attention.

Responses to findings identified during Independent Oversight; Environment, Safety, and Health evaluations; Security or Cyber Security evaluations; and Emergency Management assessments, Judgments of Need for Type A Accident investigations, and for other sources as directed by the Secretary or Deputy Secretary are subject to the requirements identified in Attachment B, *Corrective Action Management Program.* This includes

requirements to prepare a comprehensive corrective action plan (CAP) and to track and report CAP data to HQ using the DOE Corrective Action Tracking System (CATS).

The EM Issues/Action Management System requires that the receiving organization (e.g., the EM site Senior DOE Official) designate a point-of-contact (POC) for items subject to Attachment B. The POC is required to manage the process in strict compliance with the requirements identified in Attachment B. The designated POC is responsible for coordinating responses, transmitting the CAP, and preparing closeout documentation in accordance with the requirements. Nonconformance and corrective action processes shall meet the requirements of their approved QIP.

Corrective/preventive action should include an analysis of causal factors. Formal root cause analysis should be considered based on the complexity of the identified issue. Root causes should be identified and documented using an authoritative methodology for root cause identification, such as DOE G 231.1-2, *Occurrence Reporting Causal Analysis Guide*, and be performed by root cause analysis-trained personnel.

Quality Improvement requirements may be further defined in oversight plans and associated procedures. Oversight plans contribute to providing accurate technical, business, and operational performance information to management and staff. Improvement processes maintained by this management system include: Self-Assessment, Independent Oversight, Lessons Learned, Performance Metrics, and Performance Analysis.

7.3.2 Implementation

Processes to detect, communicate, and prevent quality problems can be associated with operational awareness activities such as facility tours/walkthroughs, work observation, document reviews, meeting attendance and participation, and ongoing interactions with contractor workers, support staff, and management.

Other processes include assessments/audits of facilities, operations, and programs; assessments/audits of contractor assurance systems; evaluations of contractor performance; and self-assessment of DOE line management functions and performance.

Implementing procedures and documents for quality improvement are defined in the EM HQ, Field/Project Offices, and contractors' QIPs.

7.4 DOCUMENTS AND RECORDS

The following are the **Management/Criterion 4 – Documents and Records** requirements from DOE 414.1C, Attachment 2 and 10 CFR 830.122:

(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.

The following table illustrates the relationship between the Management/Criterion 4 – Documents and Records requirements and the ASME NQA-1 requirements used to implement them. Implementation of these requirements supports ISMS Core Functions 1, 2, 3, and 4.

Management/Criterion 4 – Documents and Records	ASME NQA-1 Requirements
(a) Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design. *(b) Specify, prepare, review, approve, and maintain records.*	**Requirement 5 – Instructions, Procedures and Drawings** 100 – Basic **Requirement 6 – Document Control** 100 – Basic 200 – Document Control 300 – 302 Document Changes **Requirement 17 – Quality Assurance Records** 100 – Basic 200 – Generation of Records 300 – Authentication of Records 400 – 402 Classification 500 – Receipt Control of Records 600 – 603 Storage 700 – Retention 800 – Maintenance of Records

7.4.1 General Information

Management Expectations:

- New or revised requirements shall be analyzed to determine impact on implementing procedures and/or contracts.
- Policies, procedures, and plans shall be maintained current and deployed in a manner that makes the documents readily available to the users.
- Procedures shall identify records that need to be created and maintained.
- Records shall be maintained until they are transferred to permanent storage.
- Records shall be transferred to permanent storage in a timely manner when they are no longer needed by the organization.

Documents

Documents establish requirements or define how work is to be performed. Documents that establish policy, prescribe work, or specify requirements are required to be prepared, reviewed, approved, issued, used, and revised in a controlled manner using appropriate technical, NQA-1, and/or other quality standards.

Requirements typically originate from laws, state or Federal regulations (10 CFR 830, Subpart A), DOE directives (DOE O 414.1C), and selected consensus standards (NQA-1). New or revised requirements documents are analyzed to determine impact on implementing documents and/or contracts.

Documents that describe the methods for implementing the requirements of this QAP are to be identified by each organization (EM HQ, EM Field/Project Offices, and EM contractors) and maintained current.

Records

In general terms, a record is recorded information, in any format, that is created in the course of business, received for action, or needed to document work activities. Records are typically the outcome of implementing documents and reflect what was done. The legal definition of a record includes … *all books, papers, maps, photographs, machine-readable materials, or other documentary materials, regardless of physical form or characteristics, made or received by an agency of the U.S. Government under Federal law or in connection with the transaction of public business and preserved or appropriate for preservation by that agency or its legitimate successor as evidence of the organization, functions, policies, decisions, procedures, operations, or other activities of the Government or because of the informational value of data in them.*[1] EM HQ, Field/Project Offices, and contractor personnel performing work prepare, collect, protect, and retain records in a manner that makes the record retrievable, useable, and auditable. Written procedures govern records required to support ongoing activities (active records) as well as records transferred to records retention areas (inactive records). Records must accurately reflect the work performed, be legible, and be traceable to the applicable work and the responsible personnel.

Completed records are maintained in active files until they are no longer required to support ongoing activities or have met legal retention requirements. While in the custody of the responsible personnel, these records are protected from loss or damage by employing filing equipment suitable for the level of protection required as defined in records management regulations. When records are no longer required to support ongoing activities, the responsible personnel transfer them from active files to long-term, secured storage of the records or as determined by legal requirements. The records management program addresses the lifecycle of records, which is the period of time that records are in the custody of Federal agencies. The lifecycle consists of three stages: creation or receipt; maintenance or use; and disposition.

7.4.2 Implementation

Implementation documents are identified in the applicable QIP.

7.5 WORK PROCESSES

The following are the **Performance/Criterion 5 – Work Processes** requirements from DOE 414.1C, Attachment 2 and 10 CFR 830.122:

(a) Perform work consistent with technical standards, administrative controls, and hazard controls adopted to meet regulatory or contract requirements using approved instructions, procedures, etc.

(b) Identity and control items to ensure their proper use.

(c) Maintain items to prevent their damage, loss, or deterioration.

(d) Calibrate and maintain equipment used for process monitoring or data collection.

The following table illustrates the relationship between the Performance/Criterion 5 – Work Processes requirements and the ASME NQA-1 requirements used to implement them. Implementation of these requirements supports ISMS Core Functions 1, 2, 3, and 4.

[1] United States Code, Title 44, Chapter 33, Sec. 3301, "Definition of records," (44 USC 3301), as amended, et seq.

Performance/Criterion 5 – Work Processes	ASME NQA-1 Requirements
(a) Perform work consistent with technical standards, administrative controls, and hazard controls adopted to meet regulatory or contract requirements using approved instructions, procedures, etc. *(b) Identity and control items to ensure their proper use.* *(c) Maintain items to prevent their damage, loss, or deterioration.* *(d) Calibrate and maintain equipment used for process monitoring or data collection.*	**Requirement 5 – Instructions, Procedures and Drawings** 100 – Basic **Requirement 8 – Identification and Control of Items** 100 – Basic 200 – 202 Identification Methods 300 – 303 Specific Requirements **Requirement 9 – Control of Special Processes** 100 – Basic 200 – 203 Process Control 300 – Responsibility 400 – Records **Requirement 12 – Control of Measuring and Test Equipment** 100 – Basic 200 – Selection 300 – 304 Calibration and Control 400 – 402 Records **Requirement 13 – Handling, Storage, and Shipping** 100 – Basic 200 – Special Requirements 300 – Procedures 400 – Tools and Equipment 500 – Operators 600 – Marking or Labeling **Requirement 14 – Inspection, Test, and Operating Status** 100 – Basic **Requirement NQA-1 Part I – Introduction** **Requirement NQA-1 Part II, Subpart 2.7 – Quality Assurance Requirements for Computer Software for Nuclear Facility Applications** 100 – 102 General 200 – 204 General Requirements 300 – 302 Software Acquisition 400 – 407 Software Engineering Method 500 – Standards, Conventions, and Other Work Practices 600 – 602 Support Software 700 – References

7.5.1 General Information

Management Expectations:

- Management processes that are routinely performed shall be incorporated into each EM HQ, Field/Project Offices, and contractor's QIP.
- Documents shall clearly establish the roles and responsibilities for employees.
- Employees shall follow approved processes when performing assigned tasks.
- Employees shall identify and assist in making changes that improve project processes and documents.
- Safety software shall be managed and controlled in accordance with the requirements of DOE O 414.1 C, Attachment 2, Section 5 (EM contractors) and Attachment 5 (EM HQ and EM Field/Project offices).
- Non-safety, quality-related software for nuclear facility or EM mission critical applications shall be managed and controlled in accordance with the requirements of NQA-1-2004 Part II, Subpart 2.7, "Quality Assurance Requirements for Computer Software for Nuclear Facility Applications."

Work performed by Federal and contractor employees focuses on completing the EM project mission through effective management. Procedures identified in each organization's QIP describe how work will be accomplished. The QIP comprises a set of requirements-based processes, procedures, and program descriptions used by the organization's staff to perform their assigned work activities.

Safety- and quality-related software must have the appropriate controls in place as required by DOE O 414.1C and NQA-1 2004, even if it is off-the-shelf. It is anticipated that only the prime contractors purchase or develop safety- or quality-related software. However, if EM HQ or EM Field/Project Offices should directly purchase or develop safety- or quality-related software, the applicable requirements of DOE O 414.1C and NQA-1-2004 must be implemented. (See also Attachment C, *Safety Software Quality Requirements*.)

Typically, EM HQ or EM Field/Project Offices do not perform work activities applicable under Criterion 5 (b), (c), or (d). EM delegates implementation authority for these activities through contracts and/or technical direction. EM monitors these practices to ensure proper implementation through oversight and assessment activities.

7.5.2 Implementation

Implementing procedures and documents are identified in the organizational QIPs.

7.6 DESIGN

The following are the **Performance/Criterion 6 – Design** requirements from DOE 414.1C, Attachment 2 and 10 CFR 830.122:

(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.

The following table illustrates the relationship between the Performance/Criterion 6 – Design requirements and the ASME NQA-1 requirements used to implement them. Implementation of these requirements supports ISMS Core Functions 1, 2, 3, and 4.

Performance/Criterion 6 – Design	**ASME NQA-1 Requirements**
(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.*	**Requirement 3 – Design Control** 100 – Basic 200 – Design Input 300 – Design Process 400 – 402 Design Analysis 500 – 501.3 Design Verification 600 – 601.9 Change Control 700 – Interface Control 800 – 802.3 Software Design Control 900 – Documentation and Records **Requirement NQA-1 Part II, Subpart 2.7 – Quality Assurance Requirements for Computer Software for Nuclear Facility Applications** 100 – 102 General 200 – 204 General Requirements 300 – 302 Software Acquisition 400 – 407 Software Engineering Method 500 – Standards, Conventions, and Other Work Practices 600 – 602 Support Software 700 – References

7.6.1 General Information

Management Expectations:

- Sound engineering and design principles and standards shall be applied.
- Applicable design bases shall be incorporated.
- Design interfaces shall be identified and controlled.
- Independent design reviews shall be implemented.
- Design work shall be verified before approval and implementation.

7.6.2 Implementation

EM HQ or EM Field/Project Offices do not generally perform work activities applicable under Criterion 6. EM delegates implementation authority for design through contracts and/or technical direction. The role of EM HQ and Field/Project Office organizations is

monitoring contracted design practices to ensure proper implementation through oversight activities.

EM contractors are expected to have and implement a complete design control system as required by DOE O 414.1C and NQA-1-2004 as applicable to the work being performed.

Each organization shall have procedures and documents identified in their QIP describing and controlling the activities for which they are responsible.

7.7 PROCUREMENT

The following are the **Performance/Criterion 7 – Procurement** requirements from DOE O 414.1C, Attachment 2 and 10 CFR 830.122:

(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.

The following table illustrates the relationship between the Performance/Criterion 7 – Procurement requirements and the ASME NQA-1 requirements used to implement them. Implementation of these requirements supports ISMS Core Functions 1, 2, 3, and 4.

Performance/Criterion 7 – Procurement	ASME NQA-1 Requirements
(a) Procure items and services that meet established requirements and perform as specified. *(b) Evaluate and select prospective suppliers on the basis of specified criteria.* *(c) Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.*	**Requirement 4 – Procurement Document Control** 100 – Basic 200 – 207 Content of Procurement Documents 300 – Procurement Document Review 400 – Procurement Document Changes **Requirement 7 – Control of Purchased Items and Services** 100 – Basic 200 – Supplier Evaluation and Selection 300 – Bid Evaluation 400 – Control of Supplier Generated Documents 500 – 507 Acceptance of Item or Service 600 – Control of Supplier Nonconformances 700 – 705 Commercial Grade Items and Services 800 – Records

7.7.1 General Information

Management Expectations:

- Develop and maintain an integrated acquisition strategy to ensure work is accomplished in compliance with applicable laws, acquisition regulations, state/Federal regulations, and DOE Orders and directives.

- Oversight shall focus on verifying that work is being performed at a cost that provides reasonable value to the government and that contract terms and conditions are satisfactorily accomplished.
- Government-furnished services/items (GFS/I) shall be provided according to contract provisions.

The procurement process is defined by the DOE Office of Procurement and Assistance Management through implementation of applicable laws and regulations. Processes include: Acquisition Planning and Management; Contract Management; and Oversight of Contractors.

Procurement functions for EM HQ and EM Field/Project Offices are predominantly related to contract award and administration of contracts for a variety of goods and services. EM contractors conduct contract work scope including associated technical, quality assurance, structural, systems, components, spare/replacement parts and materials procurement activities. Suspect/Counterfeit Items Prevention requirements from DOE O 414.1C, Attachment 3 are addressed in Attachment A of this QAP. The latest information on S/CI awareness can be located at the following DOE website: http://www.hss.energy.gov/csa/csp/sci/).

The procurement process begins with project staff determining the scope of work to be performed, how the work is to be "packaged" (i.e., one contract or multiple contracts and the type of contract that is most beneficial to the government), the duration of the contract, special requirements unique to the scope of work, etc. EM HQ or EM Field/Project Offices may place and administer a variety of procurement vehicles; e.g., contracts for the cleanup work, interagency agreements for services furnished by other government organizations (e.g., Corps of Engineers), and specialty service contracts. The procurement process includes the following:

- Developing program and acquisition strategies and plans;
- Establishing requirements;
- Evaluating and selecting qualified contractors;
- Providing direction to the contractor;
- Reviewing and approving of deliverables;
- Evaluating work performed to ensure it meets contract requirements;
- Performing oversight and assessments to ensure work is completed in a cost-effective, safe, and quality manner; and
- Furnishing GFS/I in a timely manner.

Because of the lead-time required to place a contract, acquisition planning must be performed sufficiently early. Acquisition strategies are developed bringing together procurement specialists and site management. When QA plans or program documents are required as part of an offeror's response to procurement documents, they are reviewed by qualified personnel during the evaluation process.

Contractor performance is monitored on an ongoing basis. Project and supplier monitoring includes facility walkthroughs, observations of contractor activities, reviewing

contractor work products or reports, and formal assessments/surveillances that are planned, performed, and documented, with corrective actions verified. Sites may vary their level of oversight by application of the graded approach depending on: (1) relative importance of the work to the site mission, (2) past performance of contractor, and (3) relative risk of future work. Project mission element monitoring is focused primarily on verification of costs, work progress, implementation of environmental agreements and permits, verifying quality, and verifying/evaluating completion of work in accordance with applicable QIP and contract requirements.

Special oversight activities are performed as needed to respond to circumstances that cannot be foreseen; e.g., events/incidents, employee concerns, degrading performance, adverse trends, etc. Monitoring is also conducted to verify the contractor's integrated safety management system is effective. Projects review performance data and other relevant information quarterly and provide timely GFS/I.

7.7.2 Implementation

The method and processes for ensuring services meet established requirements and performance expectations are evaluated using the following processes including: Acquisition Planning, Vendor Surveys, Bid Evaluations, Contractor Oversight, Contract Administration, Source Evaluation, etc.

Implementation documents are identified in the applicable QIP.

7.8 INSPECTION AND ACCEPTANCE TESTING

The following are the **Performance/Criterion 8 – Inspection and Acceptance Testing** requirements from DOE 414.1C, Attachment 2 and 10 CFR 830.122:

(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.

The following table illustrates the relationship between the Performance/Criterion 8 – Inspection and Acceptance Testing requirements and the ASME NQA-1 requirements used to implement them. Implementation of these requirements supports ISMS Core Function 5.

Performance/Criterion 8 – Inspection and Acceptance Testing	**ASME NQA-1 Requirements**
(a) Inspect and test specified items, services, and processes using established acceptance and performance criteria.	**Requirement 3 – Design Control** 100 – Basic 200 – Design Input 300 – Design Process 400 – 402 Design Analysis 500 – 501.3 Design Verification 600 – 601.9 Change Control 700 – Interface Control 800 – 802.3 Software Design Control 900 – Documentation and Records

Performance/Criterion 8 – Inspection and Acceptance Testing	ASME NQA-1 Requirements
	Requirement NQA-1 Part II, Subpart 2.7 – Quality Assurance Requirements for Computer Software for Nuclear Facility Applications 100 – 102 General; 200 – 204 General Requirements 300 – 302 Software Acquisition; 400 – 407 Software Engineering Method 500 – Standards, Conventions, and Other Work Practices 600 – 602 Support Software 700 – References **Requirement 8 – Identification and Control of Items** 100 – Basic 200 – 202 Identification Methods 300 – 303 Specific Requirements
(8)(b) Calibrate and maintain equipment used for inspections and tests.	**Requirement 10 – Inspection** 100 – Basic 200 – Inspection Requirements 300 – Inspection Hold Points 400 – 402 Inspection Planning 500 – In-Process Inspection 600 – 604 Final Inspections 700 – Inspections During Operations 800 – Records **Requirement 11 – Test Control** 100 – Basic 200 – Test Requirements 300 – Test Procedures (Other Than for Computer Programs) 400 – Computer Program Test Procedures 500 – Test Results 600 – 602 Test Records **Requirement 12 – Control of Measuring and Test Equipment** 100 – Basic 200 – Selection 300 – 304 Calibration and Control 400 – 402 Records **Requirement 14 – Inspection, Test, and Operating Status** 100 – Basic

7.8.1 General Information

Management Expectations:

The contractor will conduct inspections and tests to verify the physical and functional aspects of items, services, and processes to meet requirements and that systems and components are fit for use and acceptable. The procedures that address these processes will be identified in the QIP.

This criterion is generally not applicable to the EM HQ and EM Field/Project Office organizations since Federal employees do not typically perform inspection or testing functions. Oversight or assessment of the contractor's program or implementation thereof, to ensure acceptability of work or items may include:

- Inspection/test planning
- Inspection/test methods
- Inclusion of inspection and test acceptance criteria in work and inspection, test implementing documents
- Calibration and control of inspection and testing equipment
- Documentation and records

7.8.2 Implementation

EM typically delegates implementation authority for inspection and acceptance testing through contracts and/or technical direction. EM monitors inspection and acceptance testing practices through assessment and oversight activities.

QIPs for EM HQ, Field/Project Office, and EM contractors address the oversight functions performed by the DOE organizations and the performance functions performed by the EM contractors by identification of the applicable requirements and reference to the implementing procedures.

7.9 MANAGEMENT ASSESSMENT

The following is the **Assessment/Criterion 9– Management Assessment** requirement from DOE 414.1C, Attachment 2 and 10 CFR 830.122:

> *Ensure that managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.*

The following table illustrates the relationship between the Assessment/Criterion 9– Management Assessment requirements and the ASME NQA-1 requirements used to implement them. Implementation of these requirements supports ISMS Core Function 5.

Performance/Criterion 9 – Management Assessment	**ASME NQA-1 Requirements**
Ensure that managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.	**Requirement 2 – Quality Assurance Program** 100 – Basic 200 – 202 Indoctrination and Training; 300 – 305 Qualification Requirements; 400 – Certification of Qualification 500 – Records

Performance/Criterion 9 – Management Assessment	ASME NQA-1 Requirements
	Requirement 18 – Audits 100 – Basic 200 – Scheduling 300 – 303 Preparation; 400 – Performance 500 – Reporting 600 – Response 700 – Follow-up Action 800 – Records

7.9.1 General Information

Management Expectations:

- Management assessments shall be one of the means for identifying areas needing correction and/or improvement.
- Managers within all organizations (EM HQ, Field/Project Office, and contractor) will assess their organization's performance with regards to such things as safety, quality, mission completion, and performance against technical and financial goals and objectives. Management shall consolidate the ISMS and QA annual validation and declaration activities.
- Results of management assessments shall be documented, and deficiencies identified and tracked with corrective actions taken.
- Management assessments will be consistent with guidance provided in DOE G 414.1-1B, *Management Assessment and Independent Assessment Guide*.

Management assessment is a method used to achieve continuous improvement and/or to identify barriers that hinder improved performance. Managers must periodically evaluate the performance of their organizations in comparison with their mission, responsibilities, and priorities. Management assessments include verifying that roles and responsibilities are known and understood, processes and procedures are effective, appropriate measurement systems are in place and functional, evidence of continuous improvement is readily available, procedures are being complied with, organizational activities are consistent with the mission, and customer requirements and expectations are satisfied.

The assessments include evaluating available quality performance and trend analysis data, such as the results of independent or external assessments and data from issue tracking and corrective action systems. Areas that present the greatest consequences of failure and the greatest benefit from improvements, if implemented, should receive particular emphasis.

Management assessments include an introspective evaluation to determine if the Integrated Safety and Quality Management System effectively meet strategic goals. Therefore, significant personal participation by the manager in the assessment is an essential element. Management assessments also identify opportunities for improving cost, schedule, safety, and/or quality of performance. Assessment results shall be

documented. Assessment results requiring corrective actions shall be tracked until corrective actions have been completed and verified.

Oversight plans and associated assessment procedures include requirements to:

- Document improvement actions
- Process lessons learned, as applicable
- Provide a copy of the final assessment report so that follow-up improvement actions resulting from the assessment can be entered into an issues tracking system for tracking and a record of the assessment can be established

7.9.2 Implementation

Implementation documents and procedures are identified in the applicable QIP.

7.10 INDEPENDENT ASSESSMENT

The following are the **Assessment/Criterion 10– Independent Assessment** requirements from DOE 414.1C, Attachment 2 and 10 CFR 830.122:

(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.

The following table illustrates the relationship between the Assessment/Criterion 10 – Independent Assessment requirements and the ASME NQA-1 requirements used to implement them. Implementation of these requirements supports ISMS Core Function 5.

Performance/Criterion 10 – Independent Assessment	**ASME NQA-1 requirements**
(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.*	**Requirement 1 – Organization** 100 – Basic 200 – 202 Structure and Responsibility 300 – Interface Control **Requirement 2 – Quality Assurance Program** 100 – Basic 200 – 202 Indoctrination and Training 300 – 305 Qualification Requirements 400 – Certification of Qualification 500 – Records **Requirement 10 – Inspection** 100 – Basic 200 – Inspection Requirements 300 – Inspection Hold Points 400 – 402 Inspection Planning 500 – In-Process Inspection 600 – 604 Final Inspections

Performance/Criterion 10 – Independent Assessment	ASME NQA-1 requirements
	700 – Inspections During Operations 800 – Records **Requirement 11 – Test Control** 100 – Basic 200 – Test Requirements 300 – Test Procedures (Other Than for Computer Programs) 400 – Computer Program Test Procedures 500 – Test Results 600 – 602 Test Records **Requirement 15 – Control of Nonconforming Items** 100 – Basic 200 – Identification 300 – Segregation 400 – 405 Disposition **Requirement 16 – Corrective Action** 100 – Basic **Requirement 18 – Audits** 100 – Basic 200 – Scheduling 300 – 303 Preparation 400 – Performance 500 – Reporting 600 – Response 700 – Follow-up Action 800 – Records

7.10.1 General Information

Management Expectations:

- Organizations will develop and implement a comprehensive plan and schedule to independently assess the performance of reporting organizations against technical, programmatic, administrative, and quality program requirements.
- Results of independent assessments shall be documented; deficiencies tracked, corrective action plans reviewed, and corrective actions verified.
- Independent assessments should be consistent with guidance provided in DOE G 414.1-1B, Management Assessment and Independent Assessment Guide.

In the course of issue identification, proposed solutions or alternative courses of action are brought forward with the objective of seeking to improve organizational excellence. Findings, observations, and recommendations are presented in assessment and audit reports that are transmitted formally.

Deficiencies identified as significant (as defined in NQA-1) shall be documented, extent of conditions identified, and corrective/preventive actions implementation verified.

7.10.2 Implementation

Implementation documents are identified in the applicable QIP.

8.0 ATTACHMENTS

Attachment A – Suspect/Counterfeit Items Prevention
Attachment B – Corrective Action Management Program
Attachment C – Safety Software Quality Requirements
Attachment D – Graded Approach
Attachment E – Application of ASME NQA-1
Attachment F – Integrated Management System
Attachment G – Quality Assurance Implementation Plan

ATTACHMENT A – SUSPECT/COUNTERFEIT ITEMS PREVENTION

The following are **DOE O 414.1C, Attachment 3, Suspect/Counterfeit Items (S/CI) Prevention** requirements:

> (2) An S/CI prevention process must be developed and implemented as a part of the organization's quality assurance program (QAP) and commensurate with the facility/activity hazards and mission impact. The QAP must be applied to identifying and analyzing S/CIs, removing them, and preventing S/CIs from being supplied to DOE/[National Nuclear Security Administration]NNSA and its contractors per DOE O 414.1C, Attachment 3 (Contractor Requirements Document, Attachment 2, Paragraph 4).
>
> (3) Work processes must be developed and implemented using available S/CI information per DOE O 414.1C, Attachment 3 (Contractor Requirements Document, Attachment 2, Paragraph 4).

Implementation of these requirements supports ISMS Core Functions 2 and 3.

GENERAL INFORMATION

Management Expectations:

- S/CI prevention processes will meet requirements consistent with guidance provided in DOE G 414.1-3, *Suspect/Counterfeit Items Guide*.
- Use the latest information on S/CI awareness, which can be located at the DOE website: http://www.hss.energy.gov/csa/csp/sci/

IMPLEMENTATION

EM delegates implementation authority for S/CI prevention through contracts and/or technical direction. EM monitors S/CI prevention practices through oversight activities.

Implementation documents are identified in the applicable QIP.

ATTACHMENT B – CORRECTIVE ACTION MANAGEMENT PROGRAM

The following is the DOE O 414.1C, Contractor Requirements Document (CRD) Criterion 3, *Quality Assurance Criteria*, requirement applicable to contractors:

Identify the cause(s) of problems and include prevention of recurrence as a part of corrective action planning

The following are **DOE O 414.1C, Attachment 4, Corrective Action Management Program** requirements applicable to EM HQ and Field/Project Office:

Line managers must perform corrective actions per DOE O 414.1C, Attachment 4, that effectively resolve safety, quality and other issues arising from –

(a) findings identified during Independent Oversight; Environment, Safety, and Health evaluations; Security or Cyber Security evaluations; and Emergency Management assessments (DOE O 470.2B, *Independent Oversight and Performance Assurance Program*);

(b) judgments of need identified by Type A accident investigations (DOE O 225.1A, *Accident Investigations*);

(c) findings identified by the Office of Aviation Management, Office of Management, Budget and Evaluation (DOE O 440.2B, *Aviation Management and Safety*); or

(d) other sources as directed by the Secretary or Deputy Secretary, including crosscutting safety issues.

Implementation of these requirements supports ISMS Core Function 5.

GENERAL INFORMATION

Management Expectations:

- Effectively implement the following requirements consistent with guidance provided in DOE G 414.1-5, *Corrective Action Program Guide*:
  (a) Reporting findings
  (b) Corrective action plan development, approval, and review
  (c) Tracking and reporting implementation
  (d) Corrective action effectiveness review
  (e) Lessons learned
- Comply with nonconformance and corrective action processes in approved QIP.

IMPLEMENTATION

Implementation documents are identified in the applicable QIP.

ATTACHMENT C – SAFETY SOFTWARE QUALITY REQUIREMENTS

The following are DOE O 414.1C, Attachment 5, Safety Software Quality Assurance requirements (Contractor Requirements Document, Attachment 2, Paragraph 5):

(a) Personnel with software quality assurance (SQA) responsibilities must have technical competency to carry out their duties. Technical qualification requirements will be specified in technical qualification standards. This process is coordinated with Federal Technical Capability Panel (FTCP) in accordance with the requirements of DOE M 426.1-1A, *Federal Technical Capability Manual*, and DOE-STD-1172-2003, *Safety Software Quality Assurance Functional Area Qualification Standard*.

(b) Work processes involving safety software must be developed and implemented using national or international consensus standards and must include the following elements.

(1) Facility design authority involvement in the identification of software requirements specification, acquisition, design, development, verification and validation (including inspection and testing), configuration management, maintenance, and retirement.
(2) Identify, document, and maintain safety software inventory.
(3) Establish grading levels for safety software. Document those grading levels in the QAP [QIP].
(4) Using the grading levels established and approved above, select and implement applicable SQA work activities from the following list to ensure that safety software performs its intended functions. ASME NQA-1-2004, *Quality Assurance Requirements for Nuclear Facility Applications*, or other national or international consensus standards that provide an equivalent level of quality assurance requirements as NQA-1-2004, must be used to implement these work activities. The standards used must be specified by the user and approved by DOE. DOE G 414.1-4 provides acceptable implementation strategies and appropriate standards for these work activities.

- Software project management and quality planning.
- Software risk management.
- Software configuration management.
- Procurement and supplier management.
- Software requirements identification and management.
- Software design and implementation.
- Software safety.
- Verification and validation.
- Problem reporting and corrective action.
- Training of personnel in the design, development, use, and evaluation of safety software.

Implementation of these requirements supports ISMS Core Functions 3 and 4.

GENERAL INFORMATION

Management Expectations:

- Safety SQA processes should be consistent with guidance provided in DOE G 414.1-4, *Safety Software Guide*.

IMPLEMENTATION

EM typically delegates implementation authority for safety SQA through contracts and/or technical direction. EM monitors SQA practices through oversight activities.

Implementation documents are identified in the applicable QIP.

ATTACHMENT D – GRADED APPROACH

Note: EM is developing a model approach to grading as Project Area 4 of the QA Improvement Project. This section will be modified to reflect the results of this effort when complete.

The following are **DOE O 414.1C Graded Approach** requirements:

Implement the DOE O 414.1C 10 QA criteria using a graded approach and describe how the criteria and graded approach are applied.

GENERAL INFORMATION

DOE O 414.1C defines the **Graded Approach** as:

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

The graded approach is used to determine the applicability of the QAP and QIP requirements to any activity and the extent of rigor in applying them. The graded approach is the application of controls commensurate with the complexity of the activity, the potential consequences of a failure, and the probability of failure. The level of control and verification appropriate for a task is dependent upon the consequences of the task not being performed properly. This is defined as applying QA using a graded approach. The basis for the graded approach and process used to implement shall be documented in the respective QIPs and submitted for EM approval.

IMPLEMENTATION

Each QA criterion is stated as an expectation for management of work, performance of work, and assessment of work. As such, rigorous QA controls for any high-risk activity at EM and EM projects might include: identifying required and/or appropriate standards; establishing a work plan to prescribe work; assigning responsibilities; specifying personnel qualification and training provisions; developing and implementing work control processes and procedures including configuration control; implementing procurement process control; instituting verification and validation of items or services performed or procured; and/or performing assessments to verify adequacy of performance and to identify and implement improvement opportunities when performance is unsatisfactory.

Rigorous QA controls should be considered for activities that: (1) involve compliance with laws, regulations, agreements, or directives; (2) could result in failure to achieve enforceable milestones; (3) could have a significant adverse impact on the safety and health of the public, the workers, or the environment; (4) could result in incorrect data or information being released externally; or (5) could result in significant financial loss because of failure to perform an activity correctly or in a timely manner.

Less rigorous or routine QA controls may be considered, when appropriate levels of analysis, documentation, and planned actions allow, for activities such as: (1) application of EM policies procedures related to safety and regulatory issues; (2) providing program and acquisition direction; (3) review of contractor prepared documents such as those related to safety, regulatory, design, etc.; (4) evaluation of contractor performance; (5) investigation of employee concerns; (6) interfacing where commitments or agreements are established with DOE HQ or regulating agencies; (7) definition, preparation, and control of records; (8) review or conduct of evaluations or investigations of safety-related events; (9) implementation and evaluation of corrective actions; (10) obtaining safety and environmental related services or activities; and (11) conduct of management assessments. Minimal QA controls may be considered for activities such as the procurement of office supplies or internal correspondence that does not impact any of the above. This attachment does not relax any of the requirements or management expectations contained in this QAP.

Organizational QIPs will address the application of a graded approach to the applicable organizations activities and will identify the processes and procedures utilized to control the application of the graded approach, including quality level determination process and quality program application process used.

ATTACHMENT E – APPLICATION OF ASME NQA-1

The following are DOE O 414.1C National or International Consensus Standards Applications requirements:

DOE O 414.1C requires –

(a) The use of national or international consensus standards where practicable and consistent with contractual or regulatory requirements (e.g., 10 CFR 830) and identify the standards used. Appropriate standards include the following:

- ASME NQA-1-2000, *Quality Assurance Requirements for Nuclear Facility Applications* (for nuclear-related activities);
- ANSI/ISO/ASQ Q 9001-2000, *Quality Management System Requirements* (for nonnuclear activities); and
- ANSI/ASQ Z 1.13, *Quality Guidelines for Research*, 1999 (for nonnuclear research activities).

(b) The application of additional standards where practicable and consistent with contractual or regulatory requirements and as necessary to address unique/specific work activities (e.g., development and use of safety software or establishing the competence of a testing and calibration laboratory).

GENERAL INFORMATION

Management Expectations:

- EM HQ, EM Field/Project Offices and EM contractors shall apply ASME NQA-1-2004 consistent with guidance provided in DOE G 414.1-2A, *Quality Assurance Management System Guide*.

IMPLEMENTATION

Organizational QIPs will include a matrix showing the implementation relationship between the ASME NQA-1 program requirements, the DOE O 414.1C criteria, and the organization's implementing procedures.

EM adopts ASME NQA-1-2004 Part I and the noted requirements of Part II as its national consensus standard. Other subparts may be selected as appropriate for the work scope being performed.

APPLICATION OF ASME NQA-1
TO THE DEPARTMENT OF ENERGY
QUALITY ASSURANCE PROGRAM (QAP)
EM Federal Programs

DOE O 414.1C Criteria ***(See Note A)***	**QA Requirements**	Program	Personnel Training and Qualification	Quality Improvement	Documents and Records	Work Processes	Design	Procurement	Inspection and Acceptance Testing	Management Assessment	Independent Assessment	Safety Software Quality Requirements	Suspect/Counterfeit Items	Corrective Action Management Program	**Implementing Documents**
ASME NQA-1 Requirements ***(See Note B)***															
1. Organization		●									●				
2. Quality Assurance Program		●	●	●						●	●				
4. Procurement Document Control								●							
5. Instructions, Procedures, & Drawings					●	●									
6. Document Control					●										
7. Control of Purchased Items & Services								●				●			
16. Corrective Action				●							●			●	
17. Quality Assurance Records					●										
18. Audits										●	●				

Notes:

A. The 10 Criteria from DOE O 414.1C are listed followed by requirements from DOE O 414.1C, Attachments 3, 4, and 5.

B. ASME NQA-1 Requirements 3, 8, 9, 10, 11, 12, 13, 14 and 15, are not directly applicable to DOE EM activities. Where site-specific project applications vary from this base determination, a revised matrix is needed as part of the approved site QIP.

APPLICATION OF ASME NQA-1
TO THE DEPARTMENT OF ENERGY
QUALITY ASSURANCE PROGRAM (QAP)
EM Contractor Programs

DOE O 414.1C Criteria	**QA Requirements**	Program	Personnel Training and Qualification	Quality Improvement	Documents and Records	Work Processes	Design	Procurement	Inspection and Acceptance Testing	Management Assessment	Independent Assessment	Safety Software Quality Requirements	Suspect/Counterfeit Items	Corrective Action Management Program	**Implementation Documents**
ASME NQA-1 Requirements															
1. Organization		●									●				
2. Quality Assurance Program		●	●	●						●	●				
3. Design							●					●			
4. Procurement Document Control								●							
5. Instructions, Procedures, & Drawings					●	●									
6. Document Control					●										
7. Control of Purchased Items & Services								●				●	●		
8. Identification & Control of Items						●			●				●		
9. Control of Special Processes						●									
10. Inspection									●		●		●		
11. Test Control									●		●	●			
12. Control of Measuring & Test Equipment						●			●						
13. Handling, Storage, & Shipping						●									
14. Inspection, Test & Operating Status						●			●						
15. Control of Nonconforming Items				●							●		●		
16. Corrective Action				●							●				
17. Quality Assurance Records					●										
18. Audits										●	●				

Note: Where site-specific EM project contractual, local, state, or federal applications is needed as part of the QA Management System the applicable requirements must be included and approved in site/contractor(s) QIP.

ATTACHMENT F – INTEGRATED MANAGEMENT SYSTEM

The following are DOE O 414.1C Integrated Management System requirements:

DOE O 414.1C requires –

The integration, where practicable and consistent with contract or regulatory requirements, quality management system requirements as defined in DOE O 414.1C, the S/CI Prevention process (Attachment 3), the Corrective Action Management Program (Attachment 4), and Safety Software Quality Requirements (Attachment 5) with other quality or management system requirements in DOE directives and external requirements, including as applicable:

- DOE P 450.4, *Safety Management System Policy*;
- DOE P 226.1A, *Department of Energy Oversight Policy*;
- NNSA, *Quality Management Policy*, QC-1 (quality management system for the nuclear weapons complex and weapons-related activities);
- DOE/RW-0333P DOE Office of Civilian Radioactive Waste Management, *Quality Assurance Requirements and Description*; and
- DOE/CBFO-94-1012, DOE Carlsbad Field Office, *Quality Assurance Program Description*, (for the Waste Isolation Pilot Plant and related activities).

GENERAL INFORMATION

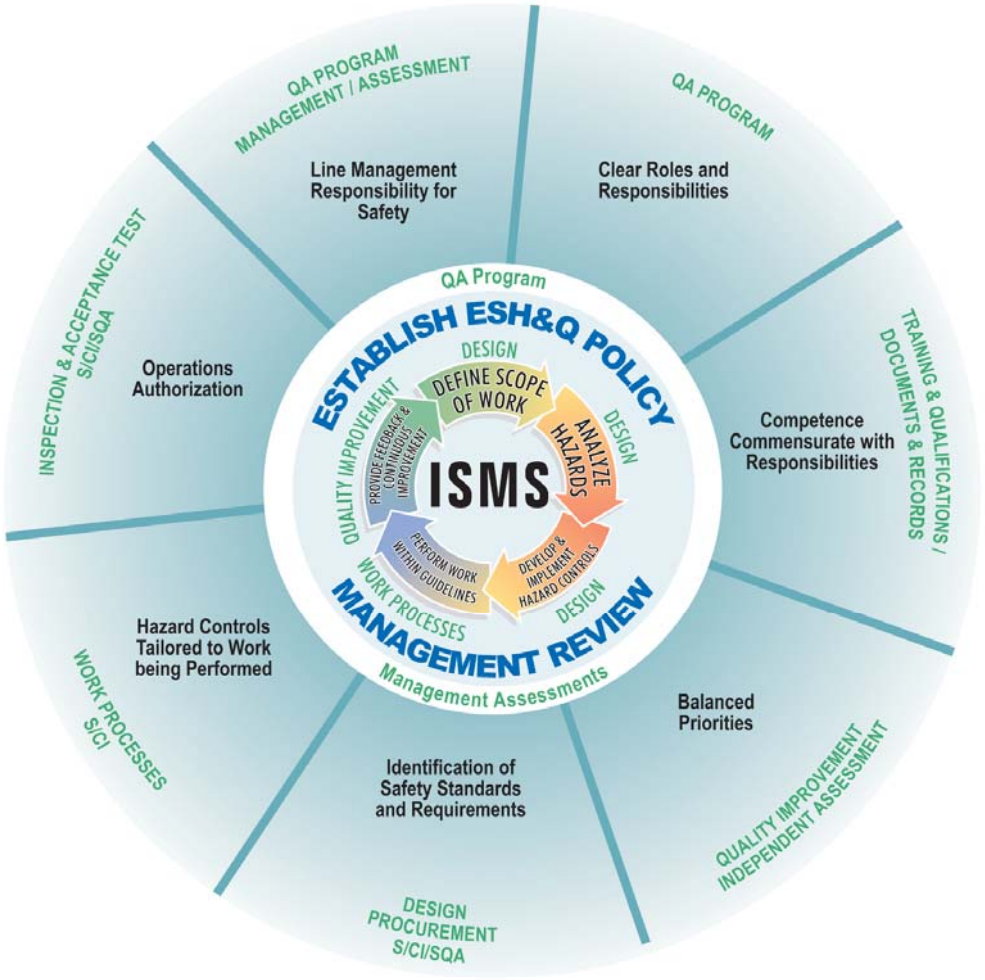
Management Expectations:

- Integration of EM HQ, EM Field/Project Offices, and EM contractor QIPs with other quality or management system requirements should be consistent with guidance provided in DOE G 414.1-2A, *Quality Assurance Management System Guide*.

IMPLEMENTATION

Where specific additional quality or management system requirements are needed, integration is implemented and documented in the applicable QIP. A sample QA/ISM alignment "wheel" is provided below for consideration as an example of documenting system integration.

QA Alignment with ISMS



QA Rule/DOE Order 414.1C/10 CFR 830, Subpart A & NQA-1 Alignment with ISMS

Competence Commensurate with Responsibilities
RULE-II,IV,IX,X
NQA-BR-1,2,3,4,6,10,11,15,16,17,18

Define Scope of Work
RULE-IV,V,VI,VII,VIII,IX,X
NQA BR-1,2,3,4,5,6,7,8,10,11,12,14,17,18

Analyze Hazards
RULE-IV,V,VI,VII,VIII,IX,X
NQA BR-1,2,3,4,5,6,7,8,9,10,11,12,14,15,16,17,18

Develop & Implement Hazard Controls
RULE-IV,V,VI,VII,VIII,IX,X
NQA-BR-1,2,3,4,5,6,7,8,9,10,11,12,14,15,16,17,18

Perform Work with Controls
RULE-II,V,VI,VIII
NQA-BR-2,3,6,8,9,10,11,12,13,14,18

Provide Feedback & Continuous Improvement
RULE-III,IV,V,VIII,IX,X
NQA-BR-3,4,6,8,9,12,13,14,17,18

Establish ES&H Policy
RULE-I,IV,V,VIII,IX
NQA-BR-1,2,3,4,6,8,9,12,13,14,17

Management Review
RULE-I,III,IV,IX
NQA-BR-1,2,3,4,6,15,16,17

Line Mgmt Responsible for Safety
RULE-I,IV,IX
NQA-BR-1,2,3,4,6,17

Clear Roles & Responsibilities
RULE-I,IV,IX,X
NQA-BR-1,2,3,4,6,10,11,15,16,17,18

Balanced Priorities
RULE-II,IV,IX,X
NQA-BR-2,3,4,6,10,11,12,15,16,18

Identification of Safety Standards & Requirements
RULE-IV,V,VI,VII,VIII,IX,X
NQA-BR-1,2,3,4,5,6,7,8,9,10,11,12,14,15,16,17,18

Hazard Controls Tailored to Work being Performed
RULE-IV,V,VI,VII,VIII,IX,X
NQA-BR-1,2,3,4,5,6,7,8,9,10,11,12,14,15,16,17,18

Suspect/Counterfeit Items (S/CI) QA Order - CRD 4

Safety Software Quality Assurance (SQA) - CRD 5

ASME NQA-1-2004 Part I

BR-1	Organization	BR-10	Inspection
BR-2	QA Program	BR-11	Test control
BR-3	Design Control	BR-12	Control of M&TE
BR-4	Procurement Document Control	BR-13	Handling, storage & shipping
BR-5	Instructions, Procedures & drawings	BR-14	Inspection test & operating status
BR-6	Document Control	BR-15	Control of nonconforming material
BR-7	Control of purchased items & services	BR-16	Corrective Action
BR-8	ID & Control of items	BR-17	QA Records
BR-9	Control of special processes	BR-18	Audits
		Part II - Subpart 2.7 - SQA	

BR = Basic Requirement & Supplemental Requirements as applicable

DOE 414.1C/10 CFR 830 Criteria

I. Program
II. Personnel Training & Qualification
III. Quality Improvement
IV. Documents & Records
V. Work Process
VI. Design
VII. Procurement
VIII. Inspection & Acceptance Testing
IX. Management Assessment
X. Independent Assessment
CRD - S/CI/SQA

Author: R.A. Carter, WCH E0807023_1

ATTACHMENT G – QUALITY ASSURANCE IMPLEMENTATION PLAN (QIP)

INTRODUCTION

QIPs will identify applicable procedures and documents for implementation of the applicable requirements of this QAP. A QIP may be developed using the sample QIP below as a template. The specific organization performs a gap analysis to determine the necessary procedures and documents for their specific needs. This is included within their QIP with reference to EM procedures as required.

SAMPLE – QA IMPLEMENTATION PLAN

DOE O 414.1C Criteria	Processes	Procedures and Documents
Management/Criterion 1—Program		
1. Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing work. 2. Establish management processes, including planning, scheduling, and providing resources for work.	Planning Scheduling Resource Allocation Graded Approach NQA-1 Application	EM Organization Chart EM Strategic Plan EM Mission and Function Statement for the EMCBC EM FRAM Definitions & Acronyms EM Quality Assurance Program
Management/Criterion 2—Personnel Training and Qualification		
1. Train and qualify personnel to be capable of performing assigned work. 2. Provide continuing training to personnel to maintain job proficiency.	Training Technical Qualification Professional Qualification	Training and Qualification for Federal Employees Technical Qualification Program
Management/Criterion 3—Quality Improvement		
1. Establish and implement processes to detect and prevent quality problems. 2. Identify, control, and correct items, services, and processes that do not meet established requirements. 3. Identify the causes of problems, and include prevention of recurrence as a part of corrective action planning. 4. Review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement.	Oversight Facility Tours Walkthroughs Work Observation Document Reviews Meeting Attendance & Participation Ongoing Interaction w/Contractor w/Workers, Support w/Staff, & Mgt Site Visits Facility Assessments Operations Assessments Program Assessments Contractor Assurance Systems Worker & Customer Feedback Causal & Root Cause Analysis Corrective Actions Improvement Actions Performance Evals Trending Analysis Verifications & Validations Self-Assessments	EM Oversight and Assessment Program EM Issues/Action Management System Operating Experience/Lessons Learned

DOE O 414.1C Criteria	Processes	Procedures and Documents
Management/Criterion 4—Documents and Records		
1. Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design. 2. Specify, prepare, review, approve, and maintain records.	Document Control Records Management	Preparation, Review, Approval, Revision, and Distribution of EM Implementing Procedures Records Management Policy Vital Records Identification and Protection Identifying, Filing & Maintaining Records File Plan Creation and Maintenance EM Records Disaster, Prevention, Mitigation, and Recovery Plan Electronic Records Management Disposition of Records
Performance/Criterion 5—Work Processes		
1. Perform work consistent with technical standards, administrative controls, and hazard controls adopted to meet regulatory or contract requirements using approved instructions, procedures, etc. 2. Identify and control items to ensure their proper use. 3. Maintain items to prevent their damage, loss, or deterioration. 4. Calibrate and maintain equipment used for process monitoring or data collection.	Quality Assurance Integrated Safety Mgt ISSM Cyber Security Emergency Mgt Business Operations	Preparation, Review, Approval, Revision, and Distribution of EM Implementing Procedures EM Quality Assurance Program EM Oversight and Assessment Program Regulatory Compliance documents (list) ISMS documents (list) Cyber Security documents (list) Emergency Management documents (list)
Performance/Criterion 6—Design		
1. Design items and processes using sound engineering/scientific principles and appropriate standards. 2. Incorporate applicable requirements and design bases in design work and design changes. 3. Identify and control design interfaces. 4. Verify/validate the adequacy of design products using individuals or groups other than those who performed the work. 5. Verify/validate work before approval and implementation of the design.		
Performance/Criterion 7—Procurement		
1. Procure items and services that meet established requirements and perform as specified. 2. Evaluate and select prospective suppliers on the basis of specified criteria. 3. Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.	Acquisition Planning Vendor Surveys Bid Evaluations Contractor Oversight Contract Admin Source Evaluation	Procurement Authorities, Delegations, and Responsibilities

DOE O 414.1C Criteria	Processes	Procedures and Documents
Performance/Criterion 8—Inspection and Acceptance Testing		
1. Inspect and test specified items, services, and processes using established acceptance and performance criteria.		
2. Calibrate and maintain equipment used for inspections and tests.		
Assessment/Criterion 9—Management Assessment		
1. Ensure that managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.	Assessment	EM Oversight and Assessment Program EM Issues/Action Management System Operating Experience/Lessons Learned
Assessment/Criterion 10—Independent Assessment		
1. Plan and conduct independent assessments to measure item and service quality and the adequacy of work performance and to promote improvement.	Assessment	EM Oversight and Assessment Program EM Issues/Action Management System Operating Experience/Lessons Learned
2. Establish sufficient authority and freedom from line management for independent assessment teams.		
3. Ensure that persons conducting independent assessments are technically qualified and knowledgeable in the areas to be assessed.		
Appendix A – Suspect/Counterfeit Items Prevention		
Appendix B – Corrective Action Management Program		
	Reporting Findings Corrective Action Plan Tracking/Reporting Effectiveness Review Lessons Learned	EM Oversight and Assessment Program EM Issues/Action Management System Operating Experience/Lessons Learned
Appendix C – Safety Software Quality Requirements		

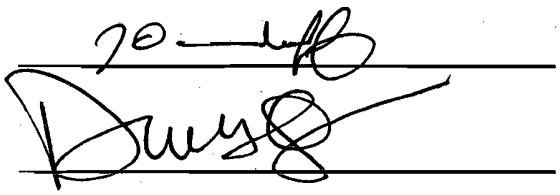
Legend:
Blue – DOE and Contractor Implementation
Yellow – DOE Oversight and Contractor Implementation

Department of Energy/Office of Environmental Management
And
Energy Facility Contractors Group

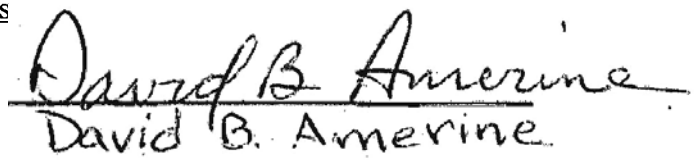
Quality Assurance Improvement Project Plan Rev. 1

Approved by:

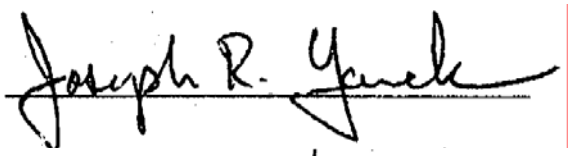
James Owendoff, DOE/EM
Chief Operations Officer



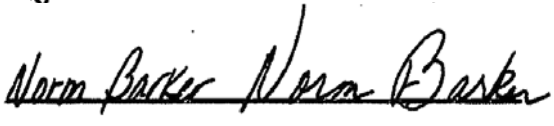
Dae Chung, DOE/EM
Deputy Assistant Secretary
Office of Safety Management and Operations



Dave Amerine, Parsons
EFCOG Board of Directors



Joe Yanek, Fluor
EFCOG Board of Directors



Norm Barker, Energy Solutions
Chair, EFCOG ISM/QA Working Group

EM Quality Assurance Corporate Board (7/29/2008)

OFFICE OF ENVIRONMENTAL MANAGEMENT
And
ENERGY FACILITY CONTRACTORS GROUP
QUALITY ASSURANCE IMPROVEMENT PROJECT PLAN

1.0 INTRODUCTION

This Project Plan was developed in response to the Department of Energy (DOE) Environmental Management's (EM's) challenge to improve quality assurance performance across its operations. This project will also provide execution support to the EM Quality Assurance (QA) Corporate Board. Further, it reflects a significant commitment by EM contractors, through the Energy Facility Contractors Group (EFCOG), to take an active role in improving quality assurance implementation throughout its operations.

This Project Plan was developed jointly with EM senior management to provide an over-arching strategy for achieving continuous improvement in quality assurance within the EM complex. The Project Plan documents a formal approach for managing the scope of the EM/EFCOG Quality Assurance Improvement Project. The Project Plan builds on the successful quality assurance programs already in place at various EM Sites and will be updated as needed to reflect ongoing progress.

2.0 SCOPE

The scope of this Project Plan is to address the priority QA focus areas identified by the EM QA Corporate Board. The Project Plan's initial scope includes the five (5) project focus areas (Attachment 1) identified during the initial EM QA Corporate Board meeting held in Las Vegas, Nevada on March 13, 2008. Any additional project focus areas, sub-project areas or related initiatives may also be added to the scope of this Project Plan upon approval by the EM QA Corporate Board.

3.0 PROJECT ORGANIZATION

The overall Project Managers for this initiative are: Ms. Sandra Waisley, Director, EM Office of Standards and Quality Assurance, and, representing EFCOG, Mr. Dave Tuttel, Site QA Manager, Savannah River Nuclear Solutions. The project's Executive Committee includes:

- James Owendoff, Chief Operations Officer (EM/HQ);
- Mr. Dae Chung, Deputy Assistant Secretary of the Office of Safety Management and Operations (EM/HQ);
- Mr. Dave Amerine, Senior Vice President, Parsons, EFCOG Board of Directors;
- Mr. Joe Yanek, Executive Director Environmental Safety, Health, & Quality, Fluor, representing the EFCOG Board of Directors; and

- Mr. Norm Barker, Energy Solutions, Chair of EFCOG's Integrated Safety Management/QA Working Group.

Additional leadership may be added to the Project Executive Committee, as needed, to further execute the Project Plan.

Each project area will have designated EM and EFCOG Leads. These individuals are expected to interface and coordinate completion of the project area milestones. As this Project Plan is carried forward, EFCOG representatives will work in partnership with EM representatives to maintain alignment with EM's performance objectives regarding quality assurance.

Figure 1 identifies the project organization and identifies the EM and EFCOG leads for each of the five project's focus areas. Attachment 1 provides a description of the initial Project Focus Areas and agreed upon actions and milestones. Additional line participants from both EM operations and contractors will be added to the project teams as needed to ensure accomplishment of the specific objectives.

4.0 KEY PROJECT PERSONNEL ROLES AND RESPONSIBILITIES

The Project Executive Committee is responsible to:

- Provide advice and counsel to the Project Managers as needed. Ensure barriers identified by the Project Managers are successfully eliminated or mitigated. Quarterly, monitor progress of the agreed upon project focus area milestones, and, provide their expertise to the project as needed to ensure its successful completion.
- Provide periodic status updates to EM senior management, EM Vice President's Forum and, the EFCOG Board of Directors

The Project Managers are responsible to:

- Lead the overall project coordination effort and maintain the Project Plan and associated schedules.
- Work with EM staff and EFCOG's ISM/QA Working Group Chair to identify Project Focus Area Leads and participants.
- Regularly monitor project area milestone completion progress and provide guidance and direction to Project Area Focus Leads as needed.
- On a quarterly basis, report Project progress to the Project Executive Committee and the EM QA Corporate Board.

The Project Focus Area Leads are responsible to:

- Identify and obtain EM and EFCOG participants to support completion of project focus area milestones.
- Define and implement the strategy for accomplishing the project focus area milestones.
- Lead efforts to successfully complete assigned milestones.

- Coordinate project focus area activities with his/her designated co-lead (contractor or federal).
- Define project focus area completion approach and coordinate activities of project area teams.
- Participate in project status meetings and teleconferences.
- On a monthly basis, report progress to the designated EM and EFCOG Project Managers.

5.0 PROJECT EXECUTION AND PERFORMANCE MANAGEMENT

This project will be executed using project management techniques. All key decisions will be coordinated with the Project Managers and, as appropriate, with the respective Project Focus Area Leads. Formal project status reviews of the Project Focus Areas will be held with the Project Executive Committee on a quarterly basis during the duration of the project.

Management of specific project milestones, task activity scheduling, and task completions is the direct responsibility of the Project Focus Area Leads. In order to declare a milestone complete, the Project Focus Area Leads must issue the necessary supporting documentation to the Project Managers for acceptance. Any changes to a designated project area scope, milestones, or overall target completion dates must be approved by the Project Managers. The Project Managers will review all such changes with the Project Executive Committee.

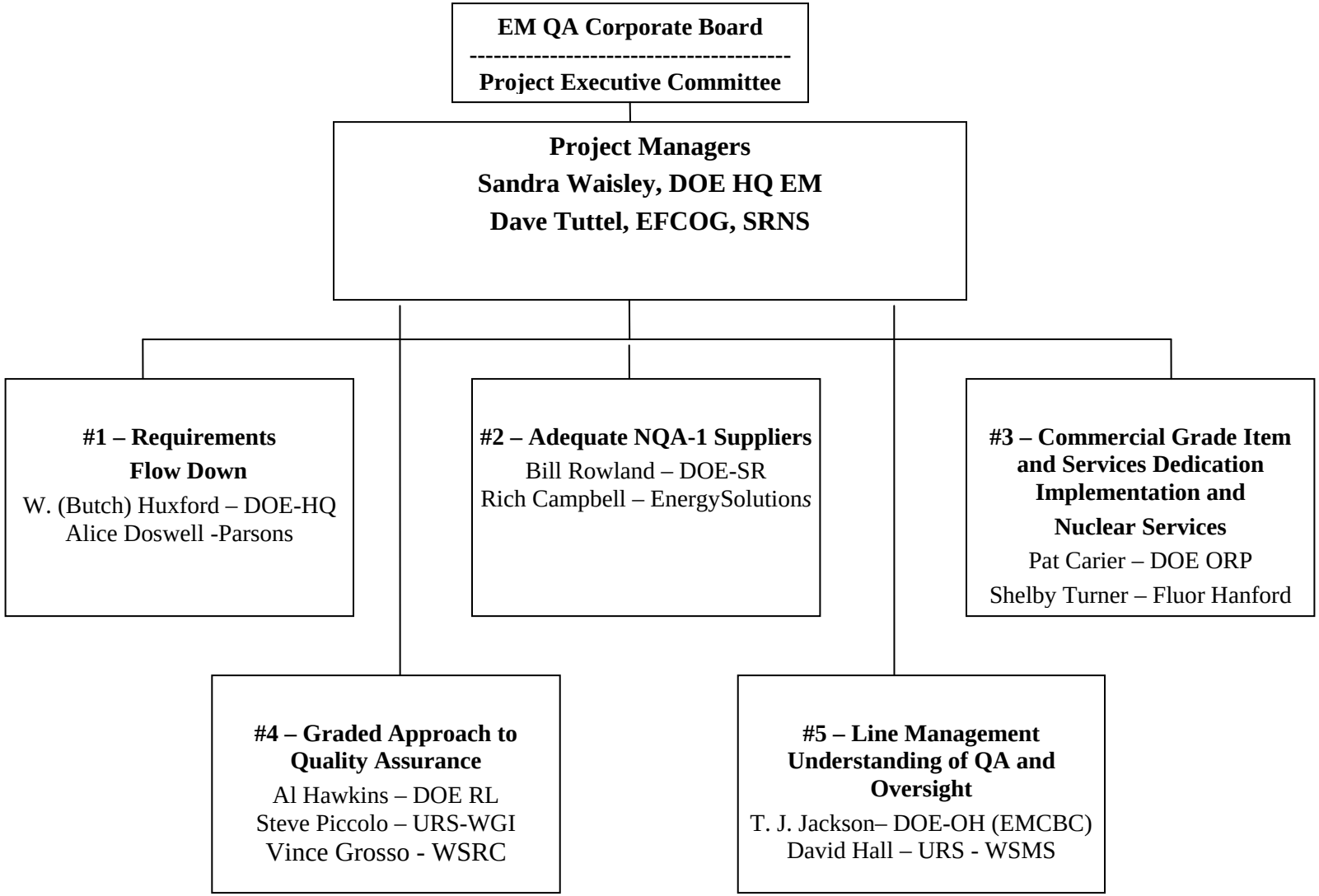
6.0 COMMUNICATIONS

The Project Managers will conduct monthly teleconferences to status project area progress with the Project Focus Area Leads. Additional conference calls or meetings will be scheduled if needed. Email and video-conferencing will be used, to the maximum extent possible, to communicate status among Project Focus Area teams and the Project Managers. Individual Project Focus Area teams will determine the communication needs and methods for their specific teams.

7.0 PROJECT TERMINATION

The Quality Assurance Improvement Project Plan will be maintained in an active state until all actions are completed, or, the EM QA Corporate Board (by vote) terminates the Project.

Figure 1. Quality Assurance Program Improvement Project



Quality Assurance Project Focus Areas

Project Area 1 – Requirements Flow Down
Target Completion Date: September 5, 2008

Background

When deficiencies are observed in DOE's Quality Assurance (QA) programs as implemented by major contractors, they are not usually due to a lack of prime contractors' program descriptions or procedural guidance, but, rather the result of a failure to implement the procurement requirements and inadequate oversight by the Prime Contractor of its supply chains. It is the responsibility of line management to ensure that:

- Appropriate technical and quality-related requirements are specified for products (i.e. System Structures and Components {SSC's}). Additionally, the appropriate technical resources (e.g., Engineering, QA, and Operations) are involved in the procurement process to define and appropriately tailor QA requirements into procurement documents.
- The Quality Assurance organization is included in the decision-making process when establishing the QA requirements or when assessing the supplier's QA program and procedures. As an example, quality engineers are supporting design reviews, risk determinations, procurement document development, vendor selection activities, source inspections, receipt inspections, on-site fabrication inspections and record reviews.
- Requirements are clear with Acceptance/Inspection Criteria identified.
- Requirements are flowed down through to suppliers, and, suppliers understand the requirements.
- Procurement processes are flexible enough to specify the applicable QA requirements, and Contractor supplier evaluation processes are adequate allow the Vendor to satisfy its NQA-1/10 CFR 830-based QA program requirements.
- Requirements are evidenced in the products delivered for use.
- There are adequate oversight functions to ensure completion of all of the above.

Scope

Provide EM with the following recommendations: 1) Identify the process for ensuring appropriate technical Quality Assurance program requirements are flowed down to suppliers and subcontractors, and, 2) Develop approaches to provide increased assurance of the effectiveness of requirement flow-down processes.

DOE Lead: Wm. (Butch) Huxford, EM-HQ **EFCOG Lead: Alice Doswell, Parsons**

Support Team: Don Paine, SRNS
Amy Ecclesine, LANL

Project Milestones:

Task #	Estimated Due Date	Task Description	Deliverable
1.1	6/16/08	Develop a brief questionnaire to send out to both commercial and EM contractors to describe their current approach for identifying the applicable QA requirements for subcontractors, tailoring the requirements based upon risk, process for working with procurement to ensure QA requirements are incorporated into subcontracts, and implementing verification of requirement flow-down by their suppliers, subcontractors, and sub-tiers.	Questionnaire
1.2	7/7/08	Request targeted EM contractors to respond to questionnaire	Completed Questionnaires
1.3	8/1/08	Solicit similar input from a few commercial nuclear contractors to compare with the DOE processes.	Completed Questionnaires
1.4	8/15/08	Select contractors will be asked to provide a briefing of their approach for flow-down of QA program requirements and quality-related requirements (i.e., NQA-1, ISO, etc.) to their suppliers, subcontractors, and sub-tiers. Briefing should address the basis for flow-down and extent of requirements addressed	Briefing from Select Contractors
1.5	8/15/08	Complete an analysis of the DOE and commercial processes used.	Summary of Completed Analysis of Commercial & DOE Contractor Processes
1.6	8/30/08	Develop a composite flow-down process including best practices from both DOE and the commercial sector and provide recommendations to EM for its action.	Decision Tree Flow Diagram
1.7	9/15/08	Work closely with Project Focus Area 4 – Graded Approach to Quality Assurance Implementation to amend the Decision Tree Flow Diagram with implementation guidance notes. This will ensure that the Decision Tree has considerations for contractor oversight, and vendor submittals to ensure that requirements are evidenced in the products delivered for use and there are adequate oversight functions to ensure all of the above issues are addressed.	Amended Decision Tree Flow Diagram Incorporating Implementation Guidance Notes

Project Area 2 – Adequate NQA-1 Suppliers
Target Completion Date: December 12, 2008

Background:
The issue is three-fold: 1) difficulty of contractors finding adequate NQA-1 suppliers; 2) contractors duplicating supplier audits adding to overall project costs for vendor/supplier shops; and 3) suppliers not trained and qualified to common criteria based on national standards. An additional issue that needs consideration is the expansive DOE mandated selection process that must be followed to select a supplier of items or services. Working with the DOE process is viewed by many vendors as not being worth the time and expense. Non-DOE procurements are such that DOE business is not a necessity for success. Qualified suppliers are decreasing for various reasons such as retirement and working overseas. DOE policy and nuclear safety regulation require procured items and services to meet established requirements and perform as specified. To meet this expectation, DOE also requires prospective suppliers to be evaluated and selected on the basis of specified criteria. Finally, DOE requires processes to be established and implemented to ensure that approved suppliers continue to provide acceptable items and services. Past and continuing weaknesses in supplier evaluations conducted by DOE contractors have resulted in: project cost overages; schedule delays; decrease in safety margins; and regulatory enforcement civil penalties. Contractor supplier evaluation issues include: an absence of or poorly performed supplier evaluations; redundant supplier evaluations by multiple DOE contractors which has resulted in multiple reviews of the same supplier by each contracting organization instead of a coordinated review; inconsistent training and qualification of assessors; and assessments conducted without rigorous criteria based on national standards. The EM-Complex should leverage resources by developing and maintaining a list of approved/qualified suppliers of commodities common to DOE contractors (need to address liability issues); developing a procedure to address the performance of joint supplier audits; and developing checklists using the requirements matrices developed for identifying common commodities which could subsequently be used for evaluating suppliers to provide consistency across the complex for sharing supplier evaluation information.

Scope:
Perform research and evaluation to identify methods for expanding the number of willing and qualified suppliers for nuclear grade items and services within EM. Provide recommendations for promoting information sharing, resource sharing and standardization of efforts within EM to improve quality, safety and cost associated with identifying, qualifying and maintaining suppliers.

DOE Lead: Bill Rowland, EM - SR EFCOG Lead: Rich Campbell, Energy*Solutions*

Support Team: Lynne Drake, SRNS
Cathy Nesser, WIPP
Steven Stein, BNL
Robert Thompson, ICP
Paula Richards, Isotek Systems

Project Milestones:

Task #	Estimated Due Date	Task Description	Deliverable
2.1	6/9/2008	Request a current list of commodities/ items/ services from major EM contractors	List from Contractors
2.2	6/9/2008	Request a list of the current points of contact for Supplier Quality Assurance from each of the major EM contractors	List of Points of Contacts
2.3	6/13/2008	Attend the NEI Manufacturing Outreach Workshop to gain insight into NEI efforts to attract nuclear suppliers	Trip Report
2.4	6/23/2008	Request the names of current suppliers that are providing nuclear grade (Safety Class, Safety Significant, and Important to Safety) materials, equipment, items and services from each major EM contractor	List of Suppliers
2.5	6/23/2008	Request the procedures used for qualifying nuclear grade suppliers from each major EM contractor	Procedures
2.6	7/18/2008	Evaluate procedures being used by major EM contractors for consistency	Evaluation Report
2.7	7/31/2008	Hold a one day Nuclear Vendor Day, possibly in conjunction with other groups, EFCOG, NEI, etc.	Complete Vendor Day
2.8	7/25/2008	Evaluate impact of “Buy American” clause on efforts to expand the supplier base within EM.	Evaluation Report
2.9	8/29/2008	Evaluate the applicability and completeness of the listing of common commodities/items/ services provided by the major EM contractors.	Final Complete List
2.10	9/12/2008	Determine the feasibility of EM contractors performing joint audits of common suppliers. If feasible, recommend procedure and checklist requirements that would be needed to implement.	Evaluation Report
2.11	9/12/2008	Evaluate inputs to determine if there are common suppliers being used for nuclear grade procurements within EM. Identify redundant supplier audits being performed by major EM contractors	Evaluation Report
2.12	11/28/2008	Determine the feasibility of issuing a consolidated nuclear grade approved/qualified supplier list for EM. Evaluation should include legal and liability issues as well as any restrictions that would be needed on use of list by EM contractors	Evaluation Report
2.13	10/31/2008	Evaluate the possibility of integrating EM procurement activities with other supplier initiatives such as NEI, NIAC, NASA, etc.	Evaluation Report

2.14	11/14/2008	At the site level, conduct a small business nuclear QA reach out symposium similar to the EM nuclear protégé program.	Develop Recom-mendations and Draft Plans for Symposium
2.15	11/14/2008	Develop a formal process or "alert" system for documenting and notifying the EM-complex and other DOE offices of nuclear suppliers not meeting QA requirements.	Draft Process Description
2.16	12/12/2008	Provide final draft deliverable and/or recommendations to EM-60 for review and approval.	Draft Report

Project Area 3 – Commercial Grade Item and Services Dedication Implementation and Nuclear Services
Target Completion Date: November 21, 2008

Background

The issue is using Commercial Grade Dedication (CGD) versus the use of a qualified supplier based on economic considerations for the procurement of safety-related items and other items. In the past, (commercial nuclear power) industry typically procured equipment for safety related systems from approved nuclear vendors. Many of these vendors have now eliminated their nuclear QA programs, resulting in equipment that cannot be used for safety related systems. Because of a decrease in the number of qualified nuclear-grade vendors, there has been a change in the industry's (DOE's contractors) procurement practices. Currently, due to the reduction in the number of qualified nuclear-grade vendors, industry (some DOE contractors are) is increasing the numbers of commercial-grade replacement parts that they procure and dedicate for use in safety-related applications in a manner that is not consistent with DOE Order, NQA-1, and 10 CFR 21 requirements. This is a substantial change from the environment in which 10 CFR Part 50, Appendix B was promulgated and DOE Order 414.1C issued. Therefore, dedication processes for commercial-grade parts have increased in importance. EM should evaluate the adequacy of this approach and, if deemed adequate, seek to have complex-wide consistency and standardization in the application of the CGD process (downgrading from Procurement Level (PL) 1 to PL 2 and PL 3, and using the graded approach to determine whether additional quality is required)

Scope

Provide EM with a recommended baseline scope and approach for the application of Commercial Grade Item (CGI) Dedication and acceptance of nuclear services within EM consistent with code requirements (NQA-1, 2000).

DOE Lead: **Pat Carier, EM-ORP** **EFCOG Lead: Shelby Turner, FH**

Support Team:
Jim Davis, EM/HQ
Michael McElroy, CH2M Hill
Scott Spencer, FH
Tony Hawkins, WSRC
Herb Berman, CH2M Hill
Tony Hawkins, SRNS
Jerry Southard, BEA
Steven Foelber, BNI
Gary Helton, Isotek Systems

Project Milestones

Task#	ECD	Task	Deliverable
3.1	8/31/08	Complete a survey of selected EM contractors requesting them to identify the process and basis for their CGI dedication program including safety classification of items being dedicated for nuclear applications within their facilities.	Survey
3.2	8/31/08	Complete a survey of selected EM contractors requesting them to identify the process and basis for the process used to accept nuclear services.	Survey
3.3	9/30/08	Conduct benchmarking activities of operating reactor plants to review CGI dedication and acceptance of nuclear services processes.	Benchmarking Report
3.4	10/30/08	Provide EM with recommended baseline requirements/guidance actions considered necessary for implementation of an effective CGI dedication process within EM nuclear facilities.	Recommendation to EM
3.5	10/30/08	Provide EM with recommended baseline requirements/guidance actions necessary for implementation of an effective acceptance of nuclear services process within EM nuclear facilities.	Recommendation to EM
3.6	11/21/08	EFCOG QA Working Group prepare a tutorial on what is/is not allowed by the ASME NQA-1 code (NQA-1, 2000) relative to dedication of commercial grade items and acceptance of services for nuclear applications (i.e., SC, SS, ITS, etc).	Tutorial

Project Area 4 – Graded Approach to Quality Assurance
Target Completion Date: March 31, 2009

Background:
The graded approach to Quality Assurance can be applied consistently in EM complex facilities by establishing a common understanding of why DOE policy allows grading and how grading may be accomplished. In general, grading is based on the relative importance of an item or activity to the success of the mission. 10 CFR 830.3 defines graded approach as "…the process of ensuring that the level of analysis, documentation, and actions used to comply with a requirement in this part are commensurate with:

a. The relative importance to safety, safeguards, and security;
b. The magnitude of any hazard involved
c. The life cycle stage of a facility;
d. The programmatic mission of a facility;
e. The particular characteristics of a facility;
f. The relative importance of radiological and non-radiological hazards

10 CFR 830.7, requires that "Where appropriate, a contractor must use a graded approach to implement the requirements of this part, document the basis of the graded approach used, and submit that documentation to DOE."

DOE guidance advocates applying grading to the application of quality assurance controls in the design and construction of systems, structures and components (SSCs) based on their importance to nuclear safety. Some EM elements limit their application of the graded approach to this area, while others use the graded approach to determine whether additional quality assurance is required when procuring commercial items and materials that are not Safety Class. Still others consider programmatic risk in assigning quality controls (although not always under the title of "graded approach").

EM users generally recognize that graded approach must be implemented without compromising the safety of the public and workers, adversely impacting the environment, or failing to comply with DOE requirements, rules, and regulations. They also recognize grading cannot be used to "grade to zero" (i.e., eliminate requirements) and that even in the least stringent application of the graded approach process, compliance with the applicable requirements is mandatory.

The grading of QA requirements is applicable to nuclear and non-nuclear services, processes, activities, and programs, as well as to nuclear and non-nuclear systems, structures, and components. A single QA program can be used in a graded manner for both nuclear and non-nuclear items and activities.

Mission-critical and programmatically significant risks are among the fundamental factors (in addition to government-regulated safety and environmental factors) to be considered in analyzing and determining the extent to which QA requirements and associated management controls and verification functions are to be applied to items and

activities in nuclear and non-nuclear facilities. The relative size and complexity of a project or activity is not necessarily an effective indicator of its risks. Mission-critical and programmatically significant risks must be analyzed in order to determine the degree of formality, level of effort, and specificity of the QA requirements applied to an item and activity.

Scope:
The Project Focus Area #4 team will provide EM with a model process for application of a graded approach for QA in both contractor and federal QA programs. This includes framing the graded approach process, considering its multiple uses and interfaces, and providing examples of successful application from across the complex.

DOE Lead: Al Hawkins, EM -RL
EFCOG Lead: Steve Piccolo – URS/WGI
Vince Grosso - WSRC

Support Team:
Phyllis Bruce, ATL
Dale Cottingham, Isotek Systems
Dave Faulkner, EM/HQ
Vince Grosso, WSRC
Mike Hassell, WCH
Clif Hoover, FH
Dave Jantosik, BNI
Charlie Kronvall, FH/CHPRC
Cathy Nesser, Washington TRU Solutions
Dave Shugars, CH2M – WG Idaho (CWI)
Sam Vega, EM - ORP

Project Milestones:

Task #	Estimated Due Date	Task Description	Deliverable
4.1	06/27/08	With input from EM contractors, develop a listing of the processes (i.e., Engineering, Procurement, Inspection, etc.) warranting application of a formal graded approach to QA.	Listing of Areas Warranting Application of a Graded Approach to QA.
4.2	09/26/08	Draft an EM Position Paper describing the application of the graded approach in federal QA programs.	Memorandum to EM-60 Forwarding Draft EM Position Paper on Application of Graded Approach to EM Federal QA Activities for Review and Approval.
4.3	03/31/09	Provide draft DOE Standard on the graded approach to QA, based upon the EM Position Paper, to EM-60 for review and approval.	Memorandum to EM-60 Forwarding Draft DOE Standard on Graded Approach to QA for Review and Approval.

Project Area #5 - Line Management Understanding of QA and Oversight
Target Completion Date: January 31, 2009

Background:
To understand quality and to instill a quality culture in the EM-complex, participating organizations and its personnel must:

1. Understand the EM mission and its strategic goals and objectives as stipulated in the EM Corporate Board By-Laws;
2. Define the importance of Quality as it pertains to each organization in achieving its mission, goals, and objectives;
3. Exhibit the EM values (for example --- Safety, Integrity, Quality, Teamwork, Accountability, and Continuous Improvement) needed to establish a quality culture and quality program throughout the EM complex;
4. Have management commitment and support to develop and implement a standardized EM QA Program; and
5. Emphasize line ownership and accountability in implementing a quality program.

Furthermore, the Federal Project Directors (FPDs) need to proactively manage oversight reviews and interactions at the sites. Most importantly, performance expectations need to be established for FPDs to coordinate site reviews and to understand NQA-1 requirements and issues. The Integrated Project Teams (IPTs) should be expected to access QA resources at the site and/or have a QA subject matter expert on the team. The IPT, organized and led by the FPD, should consist of federal and support contractor professionals representing diverse disciplines with the specific knowledge, skills, and abilities to support the FPD in successfully executing a project. However, the QA aspect has been missing from many of the IPTs.

QA capabilities are needed particularly during the CD-1 to CD-2 (design), CD-3 (construction), and post CD-3 to CD-4 (commissioning) phases, but these capabilities are not always available or sought after at the site. There should be a common and systematic process to evaluate, monitor, and continuously improve QA performance in the EM-Complex. This should include “how” and “what” the FPDs are doing to ensure that quality requirements and objectives are being met, using a periodic evaluation for review.

In addition, a site-wide programmatic flow down and implementation verification should be performed by the site QA manager on an annual basis, similar to the ISM annual declaration process. However, to ensure success with our quality efforts in the field the Headquarters’ quality program needs to be a leading advocate for the understanding and implementation of quality within DOE programs and projects.

Scope:
Provide a QA management system, training, and assessment expectations for line management to instill “consistency” in application, awareness, and performance of QA principles for both federal workers and contractor staff.

DOE Lead: T. J. Jackson, DOE EMCBC **EFCOG Lead: Dave Hall, URS-WGI**

Support Team: Brain Anderson, DOE-ID
Tom Fallon, Bechtel BWXT Idaho
Kriss Grisman, EM/HQ
Bob Torro, EM/HQ
Clark Vanderneit, Isotek Systems
Jack Zimmerman, PPPO

Project Milestones:

Task #	Estimated Due Date	Task Description	Deliverable
5.1	07/15/08	Add interim QAP Performance/Risk data to the agenda of every Quarterly Performance Review (QPR). Develop final QPR Quad Chart by 9/30/08.	Revised QPR Template ("Quad Chart")
5.2	07/30/08	Obtain commitment of all EM site managers on QA qualifications/training for assigned project QA staff and development of a schedule to achieve qualifications for any areas that are incomplete. Analyze EM sites responses to EM-2 memorandum (issued May 13, 2008), and identify gaps in implementation in qualifying and training staff.	List of QA Points of Contact for All Organizations, Commitment, and Schedule for Development of Qualifications
5.3	9/30/08	Develop an EM QA Program (QAP) that will be applicable to all EM sites (contractor and federal staff) to ensure consistency and to instill a strong QA culture (training specific to this document will follow its issuance). Draft QAP will be discussed at 2nd EM QA Corporate Board meeting- 7/29/08.	Final Draft QAP to EM-64 for Issuance
5.4	10/31/08	EM-1, 2 provides direction and guidance to EM field sites to promulgate EM Corporate QAP.	EM-1,2 Memorandum
5.5	10/31/08	Develop Indoctrination/Training modules on the value of a strong QA Program • Establish 1st EM Centralized Training Platform or Academy: 40-hour training course for federal staff • Develop a module that will describe integration of NQA-1 criteria at each stage of the project (all CD Phases) based on the new EM Standard Review Plan module format (Lines of Inquiries). • Focus on line management (contractor and federal), FPDs, and the IPTs: develop a half-day training program using Training Platform and SRP modules.	EM Training Academy Modules (23); Hold 1st Course in 10/08. Standard Review Plan QA module. Develop ½ day training program for IPTs and FPDs.
5.6	3/31/09	Complete QA training for all FPDs and IPT participants to reinforce consistent performance expectations	Training Records to EM-64 or Approval Authority
5.7	3/31/09	Establish assessment expectations for FPDs and IPTs (e.g., Phase I, Phase II, annual reviews, performance measures, lessons learned). Include QA capabilities at all CD phases of a project. Complete IPT/FPD assessments before Annual Declarations are submitted to HQ end fiscal year.	Draft Assessment Expectations Document with Common Checklists (for consistency)
5.8	6/30/09	Following EM QA Program promulgation, associated Project Execution Plans, procedures, implementation plans, and charters will be developed to ensure adequate and consistent implementation of the QAP.	Sites to Deliver Procedure/Plan Set to Their Approval Authority

Glossary

ATL	Advanced Technologies and Laboratories International
BNI	Bechtel National, Incorporated
DOE EM	Department of Energy Office of Environmental Management
DOEEM/HQ	Department of Energy Office of Environmental Management/Headquarters
DOE-ORP	Department of Energy - Office of River Protection
DOE-RL	Department of Energy - Richland
DOE SR	Department of Energy Savannah River
DOE EM-64	Department of Energy - Office of Environmental Management - Standards and Quality Assurance
EFCOG	Energy Facility Contractors Group
FH	Fluor Hanford Inc.
FPD	Federal Project Directors
IPT	Integrated Project Team
ISM	Integrated Safety Management
LANL	Lawrence Livermore National Laboratory
PPPO	Portsmouth and Paducah Project Office
QAP	Quality Assurance Program
QPR	Quarterly Performance Review
SRNS	Savannah River Nuclear Solutions
WCH	Washington Closure Hanford
WGI	Washington Group International
WIPP	Waste Isolation Pilot Plant
WSRC	Westinghouse Savannah River Company
WTS	Washington TRU Solutions
WVDP	West Valley Demonstration Project