EM QUALITY ASSURANCE CORPORATE BOARD MEETING
Augusta, Georgia
March 19, 2009

Key Workshop Objectives:

1. Provide Board Members a Summary of Actions Accomplished since the last Corporate Board Meeting in November 2008.

2. Review and Discuss the EM/EFCOG Project Action Plan Working Groups' Progress and Completed Deliverables.

3. Provide Briefings on Quality Assurance Lessons Learned for Discussion.

Desired Outcomes:

1. Board Members Vote on EM/EFCOG Quality Assurance Improvement Initiative Project Plan Deliverables.

2. Board Members Vote on Proposed EM Standard QA Contract Language.

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

EM QUALITY ASSURANCE CORPORATE BOARD MEETING

Meeting Location: Augusta Marriott Hotel & Suites Two Tenth Street, Augusta, Georgia 30901 Main Number: 1-706-722-8900		
Room: Lamar Ballroom A		
DRAFT AGENDA for March 19, 2009		
8:00	**COFFEE (Plaza Lobby)**	**ALL**
8:30	Welcome and Opening Remarks	Dae Chung (EM/HQ)
8:45	Introduction of Board Members and Other Participants; Agenda; and Logistics	Sandra Waisley (EM/HQ)
9:00	Lessons Learned: Executing With Quality on Energy & Environment Projects	David Pethick (URS Washington Division)
9:40	Lessons Learned: Fabrication of 9975 Type B Shipping Packages	Kyle Rankin (EM/RL)
10:00	**Break**	**ALL**
10:15	Progress Report on Actions from 2nd Corporate Board Meeting: • Federal & Contractor QA Resources Surveys	Sandra Waisley (EM/HQ) Dave Tuttel (EFCOG/SRNS)
10:30	EM/EFCOG Quality Assurance Improvement Project Review and Discussion of Completed Deliverables/Products: • #2: Adequate NQA-1 Suppliers • #3: Commercial Grade Item and Services Dedication Implementation and Nuclear Services	 Bill Rowland (EM/SRS) Rich Campbell (Energy*Solutions*) Pat Carier (EM/ORP) Shelby Turner (CH2M HILL)
12:00	**LUNCH**	**ALL**
1:15	EM/EFCOG Quality Assurance Improvement Project Review and Discussion of Completed Deliverables/Products: • #4: Graded Approach to Quality Assurance #1: Requirements Flow Down • #5: Line Management Understanding of QA and Oversight Project Action Plan	 Al Hawkins (EM/RL) Vince Grosso (WSRC/SRS) Mike Hassell (WCH) Butch Huxford(EM/HQ) Alice Doswell (Parsons) TJ Jackson (EM/CBC) Dave Hall (URS-WGH)
3:15	**Break**	**ALL**
3:30	Lessons Learned: LES Perspectives on Importance of Quality Assurance with Design-Build Construction	Reinhard Hinterreither (LES)
4:30	Proposed EM Standard Quality Assurance Contract Language	Jack Craig (EM/CBC) Joe Yanek (FLUOR)
5:00	**Adjourn: End Full Board Session**	**Dae Chung**

URS
Washington Division

Executing with Quality on Energy & Environment Projects

David Pethick

President, URS Corporation
E&E Group

DOE EM QA Board Meeting

March 19, 2009

2008 - A Year of Change for URS-E&E

URS Washington Division

- 2008 Brought Both Success and Changes to the E&E business unit
  - Contract awards in the UK (LLWR and Sellafield)
  - Contract awards in the US for Hanford Tank Farms, Yucca Mountain and SRS Liquid Waste (pending)
  - Transition out of the SRS M&O contract
  - Expansion of our Consulting, Engineering and Projects business line to over 1000 staff
  - Integration of our business unit with URS Corporation
- Management initiatives undertaken to ensure performance results
  - Safety-Increased emphasis on Personnel and Nuclear Safety
  - QA-Established Corporate QA Mgr-.Increased emphasis on QA
  - Corporate oversight/coordination of technical performance across projects
  - Integrated site management model
  - Review teams

Improvements in Quality Assurance

URS Washington Division

- To promote quality assurance in DOE's EM projects,

  (1) We appointed one person, Dave Hall, to serve as our corporate QA point of contact, with responsibility for coordinating policy, supporting individual projects, and guiding corrective actions where improvements needed.

  (2) We strengthened our focus on quality assurance project-by-project across the EM complex in several key areas:

  - Issue Identification and Corrective Action Process
  - Error Reduction in Project Execution
  - Improvements in Engineering Design
  - Sharing of Improvement Initiatives

Improvements in Quality Execution

URS Washington Division

- Issue Identification and Corrective Action Process
  - Our WIPP team established a single point-of-contact for tracking and monitoring Corrective Action Reports with senior management team weekly status reviews.
  - Our River Corridor Cleanup team at Hanford has implemented new QA performance metrics as part of the Contractor Assurance System. The new metrics identified a potential problem with waste shipper knowledge levels. Training was performed to correct the weakness.
  - River Corridor also implemented a new user friendly web-based corrective action management system. Since rolling it out they have seen a 250% increase in use of the system by employees to identify and solve problems.

Improvements in Quality Execution

URS Washington Division

- Error Reduction in Project Execution
  - WSRC at Savannah River has instituted a Conduct of Operations Improvement Plan which has strengthened the process for communicating lessons learned and reinforced the workers rights and obligation to call a “time out” if any part of the work does not meet expectations. This improvement is reflected by a reduction in human performance related errors in the last six months.
  - WTS has implemented an upgraded causal analysis process and is training the WIPP Cause Analysis Team Leaders. The breadth, depth, and rigor of investigations has improved noticeably since the training.

Improvements in Quality Execution

URS Washington Division

- Improvements in Engineering Design
  - The Projects group redesigned truck beds to reduce the potential for release of free liquids and avoid the puncture of containers when loading waste at K-25. The Projects group has 3 million miles and over 40,000 shipments of hazardous waste over public roads with ZERO incidents of leaking radioactive material over the last five years.
  - WTS is employing benchmarking at commercial and DOE facilities for the Equipment Life Extension Process in progress at WIPP, resulting in a 5 step path forward which will culminate in a fully implemented Equipment Reliability Program.

Improvements in Quality Execution

URS Washington Division

- Sharing of Improvement Initiatives
  - The Hanford River Corridor Cleanup team prepared a set of "how to" tools for ISMS Phase II verification. The tools include planning documents, schedules, training modules, employee communications, assessment plans, and other preparations needed to prepare for ISMS verification. URS is using this tool for the TOC ISM preparations.
  - A similar roadmap for VPP STAR certification was developed by URS, piloted at WTS to prepare for VPP recertification at WIPP, and will be used across all our projects.

A Need for Continuous Improvement

URS Washington Division

- The increased QA focus in 2008 showed a need for continued improvement in key areas of project execution
  - Repetitive, long-term operations
  - Procurement issues identified with sub-tier suppliers
  - Hiring/training of quality assurance personnel to match resource requirements in projects undergoing transition and in startup of new projects
- URS also wanted stronger alignment with DOE-EM QA initiatives throughout all of our projects

2008 Initiatives to Improve Quality in Project Execution

URS Washington Division

- Based on lessons learned, URS took a more aggressive approach in 2008 to identify project execution problems early and take aggressive actions to identify and correct the problems
  - Established a process for identification of problems early at the project director level and the leveraging of resources across all URS-E&E projects for rapid response and corrective action
  - Established Expert Review Teams, with independent advisors, to perform in-depth evaluations of project execution
    - The Expert Review Team initiative in 2008 focused on WIPP, West Valley, and SPRU
    - Initiative will give a good baseline across E&E projects

2008 Initiatives to Improve Quality in Project Execution

URS Washington Division

- Actively supported DOE EM QA Board Initiatives
  - Senior QA staff support for the development of the EM Quality Assurance Plan
  - Executive support for EM QA Board
  - E&E QA staff support for EM QA Board Improvement Teams
- Continued support for EFCOG Working Groups
- Development of QA managers for new projects – succession planning, rotational assignments, transfers from other URS business units
  - Staff rotation and use of succession plans for meeting QA management needs of new projects (e.g., Tank Operations Contract at Hanford and Yucca)
  - Internal candidate development for QA managers of Projects and Consulting work
  - Rotation assignments to fill time-critical needs within existing projects
- Expanded use of our URS-E&E QA support group
  - Resource sharing for audits and assessments
  - Expanded support to include major URS subprojects (IWTU and Eng. Products Division)

Where Are We Headed In 2009?

URS Washington Division

- Continuous Improvement
  - The key to this is the early identification of problems by project directors and the leveraging of resources across URS-E&E to find and execute the corrective action.
  - To promote success, we will:
    - Continue with the Expert Team Reviews
    - Continue support for the EM-60 rollout of the EM QAP
    - Continue support for EM's QA Board and improvement initiatives
    - Continue support for EFCOG
    - Continue development of Quality Assurance managers
    - Update URS-E&E Quality Policy and the Quality Management System

Long-Term Goals

URS Washington Division

- To establish a lasting culture of quality that is designed into our projects – and establish a new generation of workers that understands the long-standing lessons on the critical need for quality:
  - "Good ideas are not adopted automatically. They must be driven into practice with courageous impatience. Once implemented they can be easily overturned or subverted through apathy or lack of follow-up, so a continuous effort is required." (Admiral Hyman G. Rickover)
  - "If we deliver on time, but the product has defects, we have not delivered on time." (P. Crosby, 1989)
  - "I have made this letter longer than usual, only because I have not had the time to make it shorter." (B. Pascal, 1600's)

Lessons Learned from Fabrication of 9975 Type B Shipping Packages

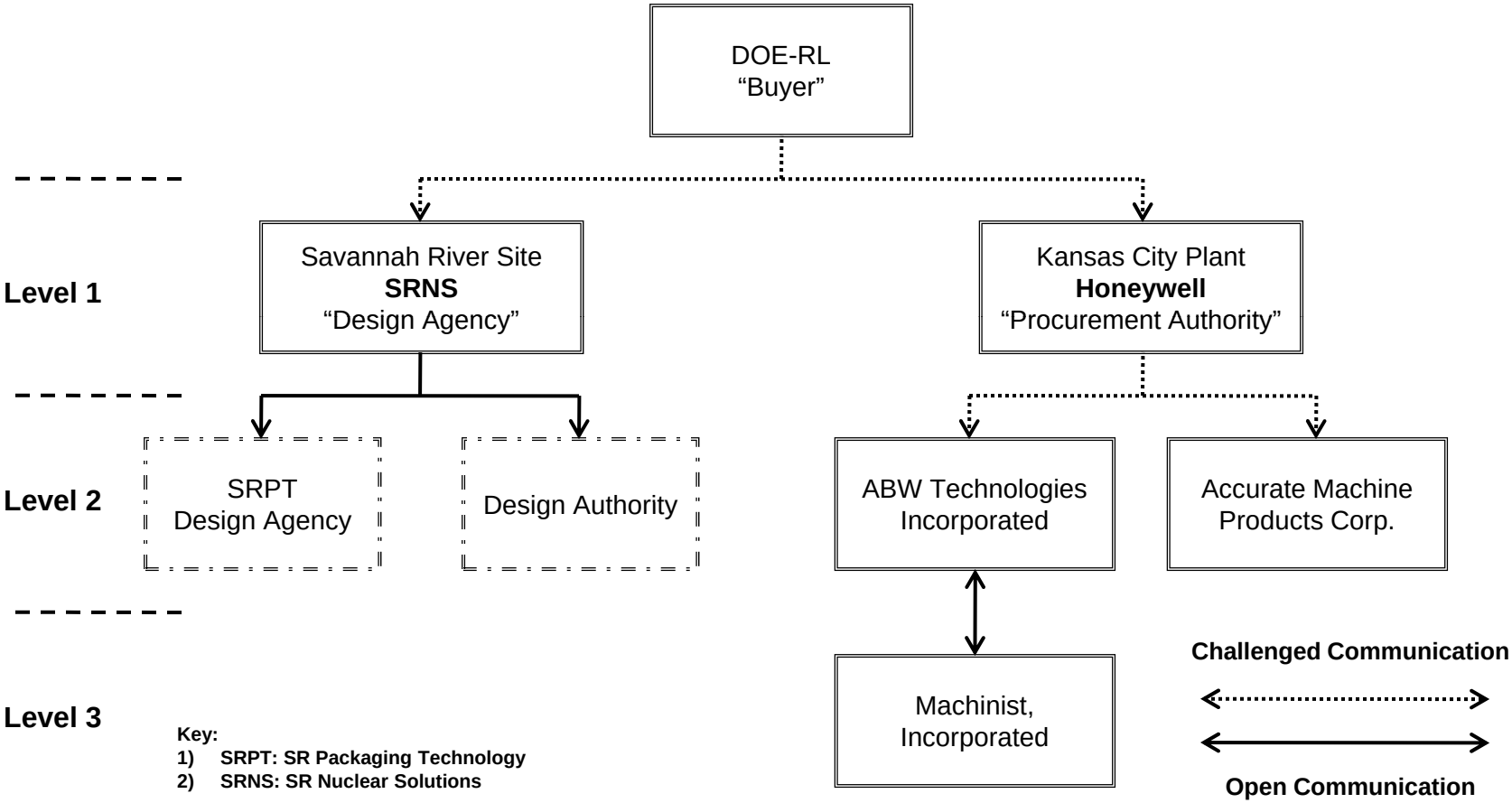
Kyle M. Rankin
Quality Assurance Subject Matter Expert
Richland Operations Office

March 19, 2009

HISTORY

- In September 2007 DOE announced its decision to consolidate surplus plutonium at the Savannah River Site (SRS) in South Carolina
- To meet the requirements of the shipping campaign of plutonium from DOE-RL to SRS additional 9975 Type B shipping containers were required
- DOE-RL contracted the services of NNSA Kansas City Plant (KCP) to procure 1100 units of the 9975 shipping containers and SRS as the Design Agency/Design Authority. LANL and LLNL entered into similar arrangements
- Due to a number of QA issues with the fabricators it was decided that EM-60 would lead a QA audit of ABW Technologies
- DOE-RL Senior Management requested a review of the EM-60 audit for Lessons Learned that focused on management issues that affected the outcome of the 9975 procurement

ISSUES


DOE-RL
"Buyer"
Level 1
Savannah River Site
SRNS
"Design Agency"
Kansas City Plant
Honeywell
"Procurement Authority"
Level 2
SRPT
Design Agency
Design Authority
ABW Technologies
Incorporated
Accurate Machine
Products Corp.
Level 3
Machinist,
Incorporated
Challenged Communication
Open Communication
Key:
1) SRPT: SR Packaging Technology
2) SRNS: SR Nuclear Solutions

ISSUES

- Roles and Responsibilities were inadequately defined:
  - DOE-RL incorrectly attempted to pass both authority and responsibility to KCP and SRNL through language in the IEWOs.
  - DOE-RL was responsible for establishing the contractual relationship between KCP and SRNL and therefore was ultimately responsible for the success of the project
- Communication was less than adequate:
  - Limited sharing of information between fabricators
  - Previous fabrication issues were not shared from Design Authority to Procurement Authority
  - Issues found during audits were not shared with impacted fabricators
  - Required communication with the Design Authority was not permitted by the Procurement Authority

LESSONS LEARNED

- Communication
  - Effective communication between all parties involved must be established and maintained
- Design Authority / Procurement Authority Relationship
  - When possible the Design Authority and Procurement Authority should be the same entity to help facilitate communication throughout the life of the project
- Understanding of Roles / Responsibilities
  - The roles and responsibilities of all parties involved in the procurement should be documented
  - Interfaces between organizations and the internal interfaces between organizational units, and changes to those interfaces, should be documented
  - Federal Project Directors have a significant challenge in balancing cost, schedule, production, environmental, safety, and QA responsibilities

QUESTIONS

???

Quality Assurance Improvement Project Plan

Graded Approach

Task Team #4

Graded Approach to Procurement

- Current product combines Task Team #1 and #4 deliverables
  - Quality Assurance Requirements Flow Down and Graded Approach Application (procurement specific)
- Primary assumptions
  - Risk assessment process
  - Baseline premise used in development
  - Graded application table:
    - Suppler evaluation/selection
    - Supplier monitoring
    - Inspection and acceptance

Graded Approach Risk Assessment Process

- Software system to evaluate/document the risk associated with the activity
- Product from the system:
  - Quality Level determination
  - Development of “in-house” database for future procurements of the same item/service
- Supporting procedure applies exclusions for categories of low risk items/services and uses “grandfather” approach (i.e. no need to back-fit to pre-existing facilities)

Grade Approach Risk Assessment Process

- System asks a series of questions to determine overall risk

•Credited in DSA?

- Failure consequence
  - o Safety
  - o Mission interruption
  - o Environmental damage
  - o Public perception
  - o Cost

- Mission critical?
- Failure potential
  - o Permanent?
  - o Complex?
  - o Standardization mature?
  - o Failure detection easy?
  - o History of failure?

Graded Approach Baseline Assumptions

- EM would be the owner/provider of the risk assessment software system
- Quality Assurance program applies to all activities performed by the contractor for the Department of Energy
- Procurement requirements of the QA program apply to all procurements made by the contractors
- While Quality Levels (QL) are used, projects may use terms with same meaning – i.e. Procurement Levels (PL), Quality Control Levels (QCL)

Quality Assurance Criteria	QL-1	QL-2	QL-3	QL-4
Review and approval	Requisitioner Project Controls Cost Account Manager QA Engineering Safety (1) Environmental (1) IH (1) RadCon (1)	Requisitioner Project Controls Cost Account Manager QA Engineering Safety (1) Environmental (1) IH (1) RadCon (1)	Requisitioner Project Controls Cost Account Manager QA (1) Engineering (1) Safety (1) Environmental (1) IH (1) RadCon (1)	Requisitioner Project Controls Cost Account Manager Engineering (1) Safety (1) Environmental (1) IH (1) RadCon (1)
Supplier Evaluation	Evaluation of supplier's implementation of their QA program if not procured as commercial grade item. Must be a site visit	Evaluation of supplier's implementation of their QA program if not procured as commercial grade item. Site visit expected unless basis for not doing is justified and documented	Identified components of the supplier QA program, supporting procedures, and processes submitted for review and acceptance. Review and acceptance is documented.	Supplier selection and approval based on commercial standard.
Acceptance	• QA Receipt Inspection • Source Inspection/verification for Fabrications required • Surveillances for Services • Submittals formally reviewed by designated SMEs	• QA Receipt Inspection • Source Inspection/verification for Fabrications required • Surveillances for Services optional • Submittals formally reviewed by designated SMEs or designated representative	• QA Receipt Inspection (1) • Source Inspection/verification for Fabrications considered. • Surveillances for Services optional • Submittals formally reviewed by designated representative.	• Receipt Inspection (non-QA) • Submittals reviewed by designated representative
Monitoring	• Development of Subcontractor Oversight Plans (2) • Receipt Inspection • Acceptance Testing • Submittal Review	• Basis for not developing a Subcontractor Oversight Plan needs to be documented (2) • Receipt Inspection • Submittal Review • Acceptance testing optional	• Receipt Inspection • Submittal Review	• Receipt Inspection • Submittal Review

(1) Scope Dependent
(2) Due to higher risk, intentional oversight activities are planned out – could range from periodic surveillance to in-process inspections/witness or hold points.

Environmental Management
safety ❖ performance ❖ cleanup ❖ closure

www.em.doe.gov

FCOG

Energy Facility Contractors Group

Project Focus Area #5

Line Management Understanding of QA and Oversight

EM QA Corporate Board Meeting
Augusta, GA
March 19, 2009

Team Members

- **DOE Lead: T. J. Jackson, DOE EMCBC**
- **EFCOG Lead: Dave Hall – URS-Washington Div.**
- Jack Zimmerman, PPPO
- Bob Toro, DOE EM-HQ
- Kriss Grisham, DOE EM-HQ
- Al Hawkins, DOE EM-RL
- Brian Anderson, DOE EM-ID

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 Quarterly Performance Review (QPR) briefing packages.	Working. Draft QPR Quad Chart was distributed to the Exec. Committee on 10/23/08 for review and comment. The new QPR Quad Chart guidance has not been distributed to the FPDs for use.
Task 5.2: Obtain commitment from all EM site managers on QA qualifications and training for assigned project QA staff.	Complete. Training for the Federal QA Staff is ongoing.
Task 5.3: Develop an EM QA Program (QAP) that will be applicable to all EM sites.	Complete. QAP was approved by EM-2 in November 2008.

Actions / Status

Task 5.4: EM-1 provides direction and guidance to EM field sites to promulgate EM Corporate QAP.	Complete. Memorandum issued in November 2008 to HQ and Sites.
Task 5.5: Develop detailed QAP implementation guidance for EM-3.	Complete. Memorandum issued in December 2008 to HQ and Sites.
Task 5.6:Develop Training modules on the value of a strong QA Program	Complete. Training Academy course was given in October 2008 at CBFO. Training to be provided twice yearly at different locations.
Task 5.7: Complete QA training for all FPDs and IPT participants to reinforce consistent performance expectations. Focus will be on ensuring IPTs understand the importance of a rigorous QAP	Working. 4 hour course has been developed and reviewed by the Team as well as 3 FPDs. Board should discuss whether training should be mandatory and what constitutes completion for this Task.

Actions / Status

Task 5.8: Establish assessment expectations for FPDs and IPTs (e.g., Phase I, Phase II, annual reviews, performance measures, lessons learned). Draft assessment expectations document with common checklists.	Working. Assessment expectations have been developed and reviewed internally. Copies will be distributed and discussed at this meeting. Board to discuss distribution and what constitutes completion of this Task.
Task 5.9: 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.	Due 6/30/09. Guidance on the implementation process is a deliverable for Task 5.5.

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 culture takes high level management commitment and time

“Lessons Learned - Construction of the National Enrichment Facility”

Reinhard Hinterreither
President & CEO
Louisiana Energy Services (LES)

Augusta, March 19, 2009

Overview

- Who is LES and what do we stand for?
- Why and where are we constructing the National Enrichment Facility?
- What is it like to construct under a Construction Operating License?
- What are key lessons learned?
- Where do we go from here?

Treaty of Washington

The Agreement was previously published as United States No. 2 (1994) Cm 2456

ATOMIC ENERGY

Treaty Series No. 133 (2000)

Agreement

between the Three Governments of the
United Kingdom of Great Britain and Northern Ireland,
the Federal Republic of Germany and the
Kingdom of the Netherlands
and the Government of the United States of America

regarding the Establishment, Construction and
Operation of a
Uranium Enrichment Installation in the
United States

Washington, 24 July 1992

- Louisiana Energy Services LLP (LES) formed in 1990
- The name LES is memorialized in the Treaty of Washington
- LES is 100% owned subsidiary of Urenco Limited

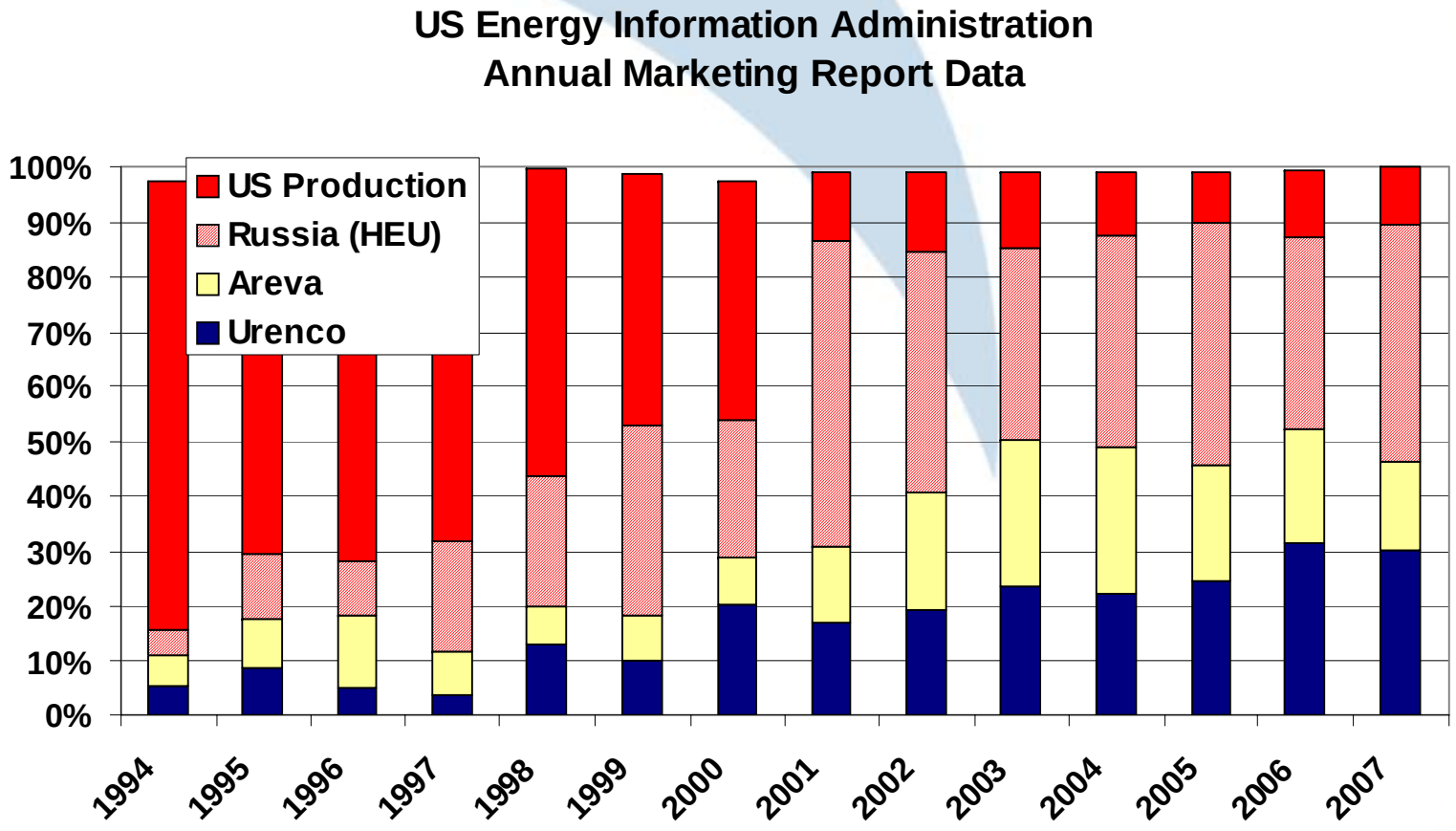
Americanization of European Technology

- Proven to be the world's most advanced, energy efficient, and cost effective technology for enriching uranium
- Successfully operated in Europe for over 30 years
- Technology implemented in three enrichment plants in Europe

Security of Supply to Customers

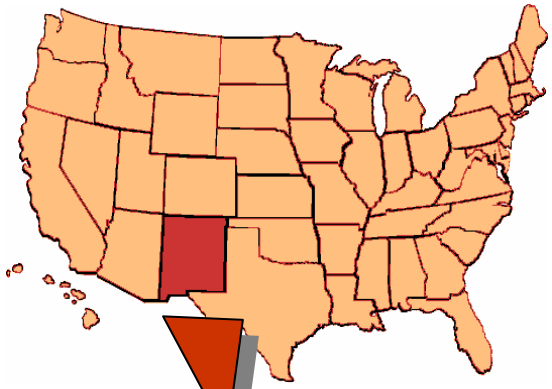
- Transfer and exchange of knowledge and resources with existing European facilities
- Hired staff with extensive, safe and reliable US nuclear operating experience
- LES has contracting portfolio for its services in place stretching through 2026

Only approx. 10% of US Enrichment Services provided by Domestic Supply



Source: Uranium Industry Annual Reports, Energy Information Administration, Office of Coal, Nuclear, Electric and Alternate Fuels, U.S. Department of Energy

National Enrichment Facility near Eunice, New Mexico



"Energy Independence for America"

Construction Operating License Received in June of 2006

- Received first COL in the United States
- Chose Greenfield site near Eunice, NM
- Built from scratch: organization, programs and procedures to function under a COL
- Addressed housing challenges

Extensive Preparation of Greenfield Site during late 2006 and early 2007

“Where No One Has Gone Before” August 2007

First NQA1 concrete placement at the National Enrichment Facility

- COL - constructing under an operating license – no re-do’s – real time evaluation between drawings and as built
- Any deviations from the design require a prompt operability assessment against your design basis
- No one in the world has experience in this way (not like 10CFR50)

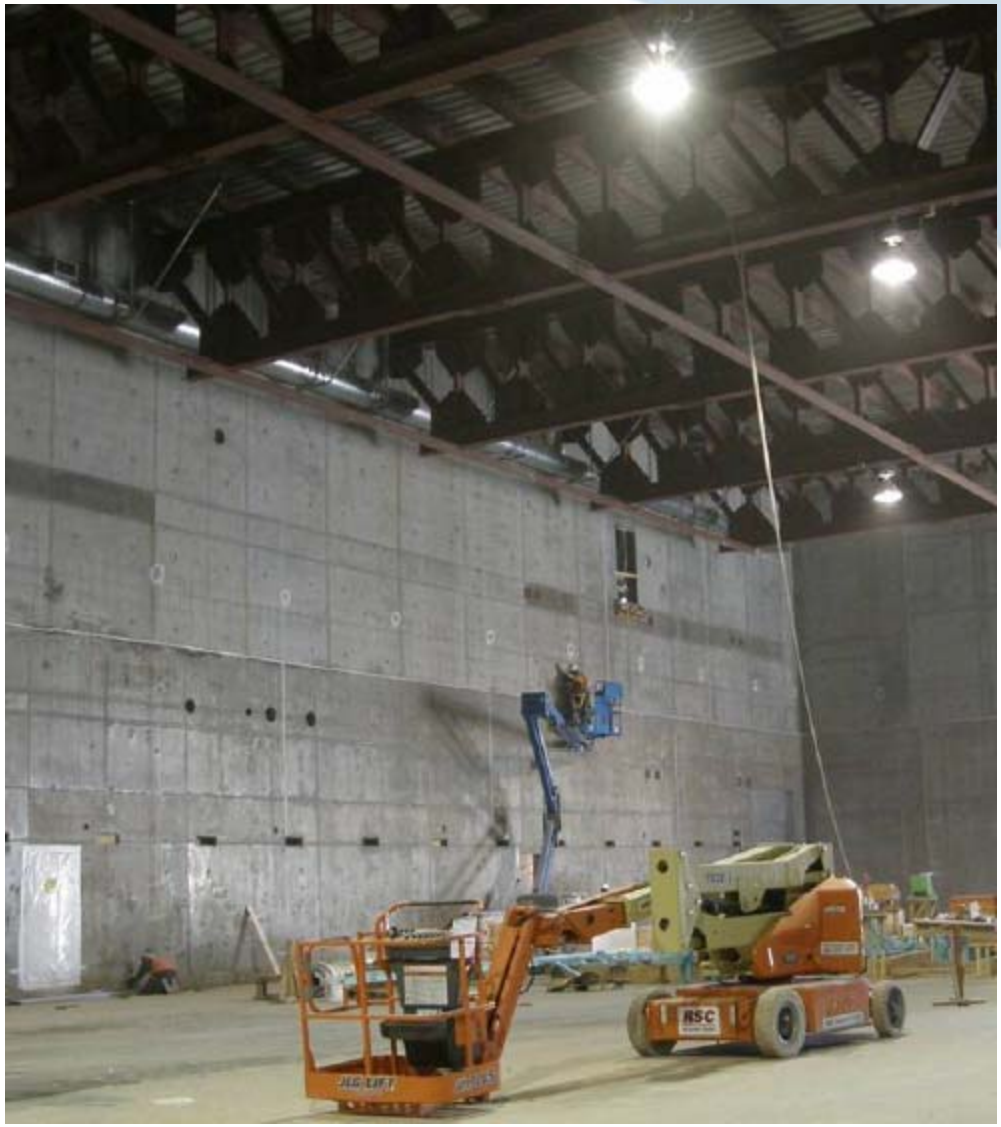
Aerial View of National Enrichment Facility

- Safety and quality are our overriding priorities
- More than 3.5 million construction man hours worked without a single lost time accident
- Construction rework rate at 0.188 per 10,000 man-hours
- Site self ID rate is greater than 80% for all groups

Key Lessons Learned

- Management, programs and procedures in place before you start designing
- Design oversight and reviews at various stages of completion
- Understand your engineering specs
- Design complete before start of construction

Key Lessons Learned (continued)

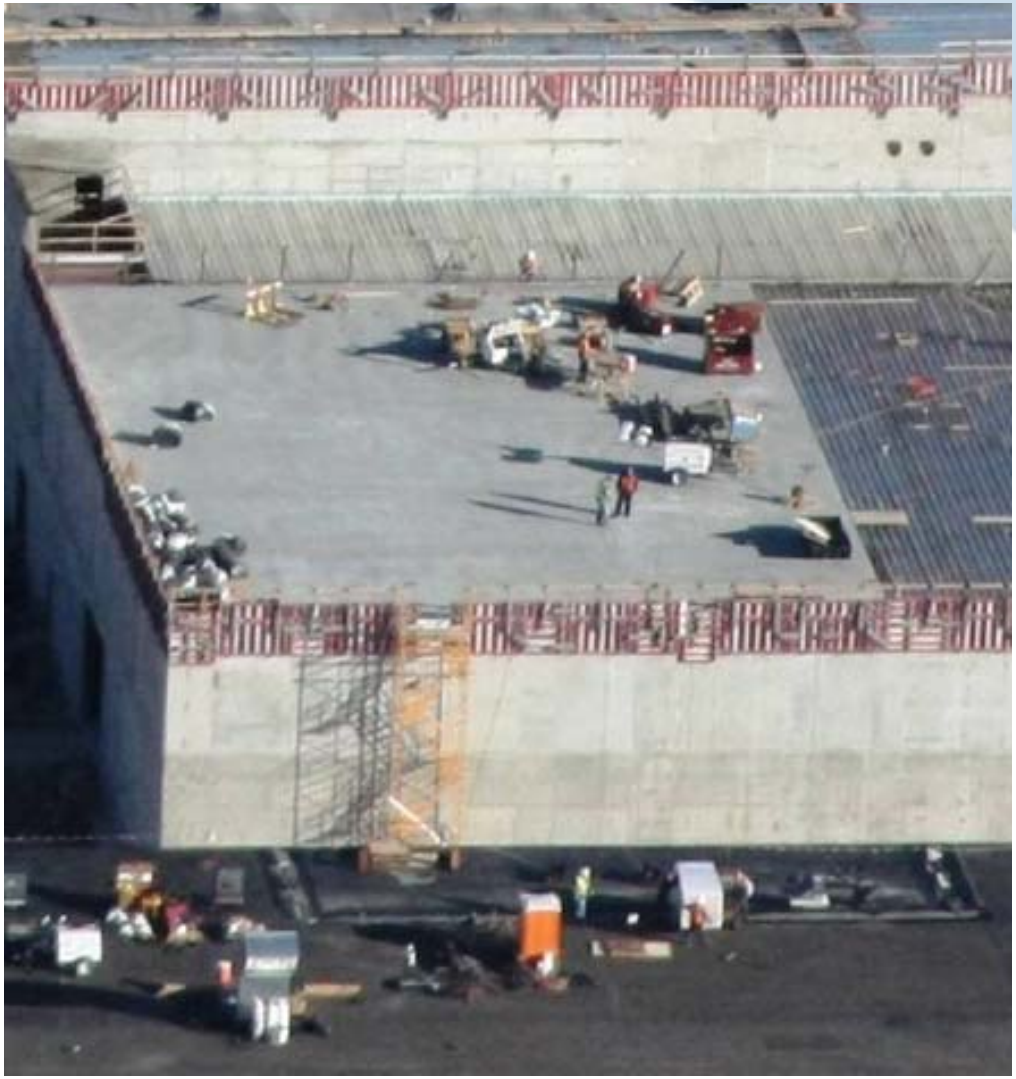


- Detailed constructability reviews
- Engineering, Procurement and Construction (EPC) contracting
- Procurement requires commercial grade dedication of NQA-1 equipment (organizational readiness)
- Recognize the need for a strong nuclear culture in the work force (e.g. greenfield, soil, rebar, concrete)

Key Lessons Learned (continued)

- Extensive training on mock ups
- Planning, planning, planning & planning to keep construction on critical path
- Review and adjust your engineering specs
- QC involved from the beginning in each and every work evolution

Key Lessons Learned (continued)



- Heavy “owner” observation in the field – keep expensive mistakes from happening
- Get as many “silverbacks” as possible
- Repeatedly streamline procedure and document revision process

Key Lessons Learned (continued)

- Implementation of effective operational corrective action program
- One NCR program for all contractors and departments for the entire site
- One CR program for all contractors and departments for the entire site

Next Steps for the Project

- Begin centrifuge testing under UF6 in March
- Start installation of centrifuges in the halls in summer
- Plant testing and commissioning followed by NRC ORR
- Ready for operations in the fall

Conclusions

- The COL process has clear advantages, but constructing under a COL brings new and complex challenges
- Key lessons learned to successfully constructing under a COL revolve around
  - Completeness and flexibility of design
  - Presence of a strong nuclear culture
  - Planning, planning & planning to keep construction on critical path
  - Extensive owner involvement in the field
  - Implementation of an effective operational corrective action program
- It can be done safely and to highest quality standards, while maintaining schedule and cost targets

EM QUALITY ASSURANCE CORPORATE BOARD MEETING
Augusta Marriott Hotel & Suites, Augusta, GA
MARCH 19, 2009

Project Focus Area Group	Deliverables	Board Vote (Y/N)
#1 Flow Down of Requirements	Task #1.9: White Paper (EM Standard) and Flow Diagram	Y
#2 Adequate Nuclear Suppliers	Task #2.11: Evaluation Results of EM Common Suppliers	N
	Tasks #2.10/2.12: Joint Supplier Audits Evaluation Summary and Recommendations	Y
	Task #2.13: Joint Supplier Qualification Process (w/ NEI, NUPIC, NIAC) Evaluation and Recommendation	Y
	Task #2.14: EM QA ALERT System Process (Flow Diagram, ALERT Template) and Recommendation	Y
#3 Commercial Grade Item/Services Dedication Implementation	Tasks #3.4/3.6: - Recommendations for Baseline Requirements and Path Forward - CGD Training Module Course Content	 Y N
#4 Graded Approach Implementation	Task #4.4: - EM Graded Approach Procedure for Procurements - Standardized Risk Assessment Process	 Y N
#5 Line Management Understanding of QA and Oversight	Task #5.6: QA Training Course for Integrated Project Teams and Federal Project Directors	Y
	Task #5.8: Assessment Expectations Document w/ Common Checklists	**N**

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

Quality Assurance Improvement Project Plan
Rev. 4

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

David B. Amerine

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 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. This Project Plan 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 Plan 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 REVIEW AND COMMENT PROCESS FOR PROJECT FOCUS AREAS

The Project Focus Area Leads (Working Groups) will follow a three tier process for review and comments of deliverables or products (in sequence):

- First Level of Review (2 weeks review/2 weeks comment resolution): Project Managers (Sandra Waisley and Dave Tuttel)

- Second Level of Review (1 week review/1 week comment resolution): Executive Committee (Dae Chung, David Amerine, Joe Yanek, and Norm Barker)

- Third Level of Review: EM QA Corporate Board Members (voting and non-voting Full Members)

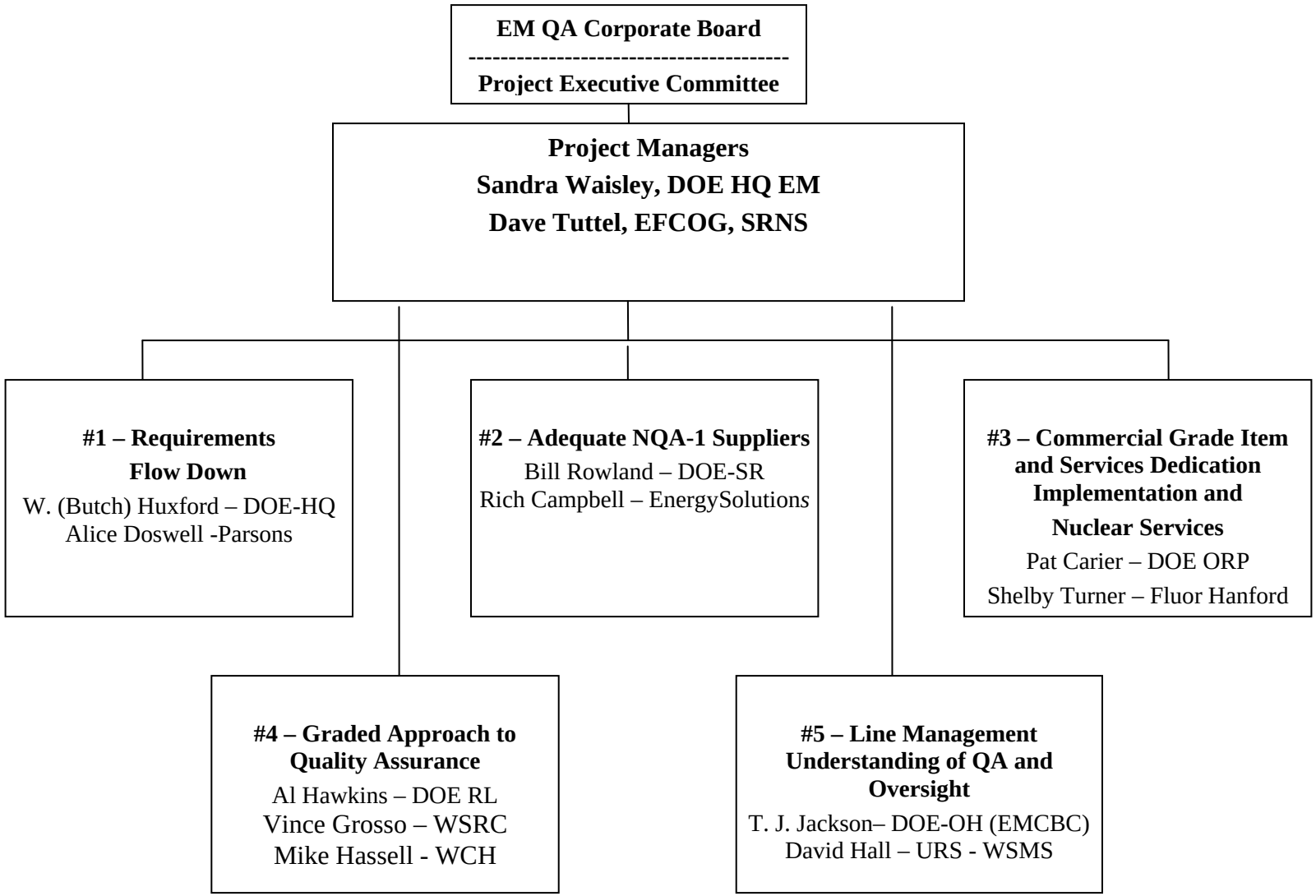
7.0 COMMUNICATIONS

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.

8.0 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: February 28, 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 QA 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 that contractor supplier evaluation processes are adequate, allowing 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 QA 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: Telak Verma, Juan Hernandez

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.	Completed Questionnaire
1.2	7/07/08	Request targeted EM contractors to respond to questionnaire	Completed Questionnaires
1.3	8/01/08	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	Completed 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, ensuring requirements are evidenced in the products delivered for use, and that there are adequate oversight functions to address all of the above issues.	Amended Decision Tree Flow Diagram
1.8	12/20/08	Resolve path forward with Projected Focus Area #4. White Paper will include section consistent with Project Focus Area #4	Clarify Roles and Responsibilities between Project Focus Areas #1 and #4 Following Re-direction from 3rd Corporate Board Meeting (11/08)
1.9	2/20/09	Complete White Paper covering procurement QA process flow diagram (will combine eventually with Project Focus Area #4 Task #4.2.	Draft white paper and Amended Flow Diagram
1.10	3/09/09	Incorporate comments from EFCOG QA Committee	Final Project Focus Area #1 Deliverables- Flow Diagram and White Paper

Project Area 2 – Adequate NQA-1 Suppliers
Target Completion Date: February 28, 2009

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
Robert Thompson, ICP
Paula Richards, Isotek Systems

Project Milestones

Task #	Estimated Due Date	Task Description	Deliverable	Deliverable To Be Submitted to Project Managers
2.1	6/9/2008	Request a current list of commodities/ items/ services from major EM contractors	Commodity List for Use in Task 2.9	No Informational
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 Contacts	No Informational
2.3	6/13/2008	Attend the NEI Manufacturing Outreach Workshop to gain insight into NEI efforts to attract nuclear suppliers	Trip Report	No Informational
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 for Use in Tasks 2.10 and 2.11	No Informational
2.5	6/23/2008	Request the procedures used for qualifying nuclear grade suppliers from each major EM contractor	Procedures for Use in Task 2.6	No Informational
2.6	7/18/2008	Evaluate procedures being used by major EM contractors for consistency	Evaluation Report	Yes
2.7	7/31/2008	Hold a one day Nuclear Vendor Day, possibly in conjunction with other groups, EFCOG, NEI, etc.	Complete Vendor Day	No
2.8	11/3/2008	Evaluate impact of “Buy American” clause on efforts to expand the supplier base within EM.	Evaluation Report	Yes
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 List	Yes
2.10	12/31/2008	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.	Report of Recommendations	Yes
2.11	10/31/2008	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	Yes
2.12	12/31/2008	Determine the feasibility of issuing a consolidated nuclear grade approved/qualified supplier list for EM. Evaluation should include legal	Report of Recommendations	Yes

		and liability issues as well as any restrictions that would be needed on use of list by EM contractors		
2.13	12/31/2008	Evaluate the possibility of integrating EM procurement activities with other supplier initiatives such as NEI, NIAC, NASA, etc.	Evaluation Report	Yes
2.14	1/16/2009	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 Document	Yes
2.15	1/23/2009	Provide deliverables and recommendations to Project Managers and Project Focus Area Leads for review and comment.	Draft Report (incorporates tasks #2.6 – 2.13)	Yes
2.16	1/30/2009	Receive comments from Project Managers and Project Focus Area Leads.	Written Comments	No
2.17	2/6/2009	Resolve comments from Project Managers and Project Focus Area Leads	Revised Draft Report	No
2.18	2/11/2009	Provide revised draft report to Project Executive Committee for review and comment	Revised Draft Report	Yes
2.19	2/19/2009	Receive comments from Project Executive Committee	Written Comments	No
2.20	2/25/2009	Resolve comments from Project Executive Committee	Revised Report	No
2.21	2/27/2009	Submit Final Report to Project Managers	Final Report	Yes

Project Area 3 – Commercial Grade Item and Services Dedication Implementation and Nuclear Services
Target Completion Date: March 27, 2009

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, 2004).

DOE Lead: Pat Carier, EM-ORP **EFCOG Lead: Shelby Turner, CH2M Hill**

Support Team:
Jim Davis, EM/HQ
Michael McElroy, WRPS
Scott Spencer, CH2M Hill
Tony Hawkins, SRNS
Herb Berman, WRPS
Jerry Southard, BEA
Dominic Canazaro, BNI
Pat Hooks, Isotek Systems
Gary Grant, CH2M Hill

Project Milestones

Task#	Estimated Due Date	Task Description	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.	Completed 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.	Completed Survey
3.3	12/15/08	Conduct benchmarking activities of operating reactor plants to review CGI dedication and acceptance of nuclear services processes.	Completed Benchmarking Report
3.4	01/15/09	Provide EM for review and concurrence recommended baseline requirements/guidance actions considered necessary for implementation of an effective CGI/Services dedication process within EM nuclear facilities.	Recommendation to EM
3.5	01/15/09	Combined w/ #3.4	
3.6	2/20/09	Issue final baseline requirements/guidance actions considered necessary for implementation of an effective CGI/Services dedication process within EM nuclear facilities.	Baseline Requirements Issued to EM Complex
3.7	2/20/09	Combined w/ #3.6	
3.8	3/15/09	Establish training for EM Projects on CGI/Services dedication process based on requirements/guidance baseline approved by EM.	Training Subcontract Issued
3.9	3/27/09	Provide CGI/Services dedication training to site personnel (i.e., “Train the Trainer”)	DOE/Contractor Training Schedule Issued

Project Area 4 – Graded Approach to Quality Assurance
Target Completion Date: June 1, 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**
Contractor Leads: **Vince Grosso – WSRC**
Mike Hassell - WCH

Support Team:
Phyllis Bruce, ATL
Dale Cottingham, Isotek Systems
Dave Faulkner, EM/HQ
Clif Hoover, FH
Dave Jantosik, BNI
Charlie Kronvall, FH/CHPRC
Cathy Nesser, Washington TRU Solutions
Kyle Rankin, RL
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.	Completed 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.	Completed Submission of Draft EM Position Paper to Reviewers on Application of Graded Approach to EM Federal QA Activities
4.3	11/13/08	Present draft EM Position Paper to the EM QA Corporate Board for review and discussion.	Completed EM Position Paper on Graded Approach Issued to Corporate Board Members
4.4	02/20/09	In coordination with Project Focus Area #1, provide an EM Standard for application of the graded approach to procurement. The standard will include: • A consistent process for assessing risk and assigning Quality Levels (QLs) • Standard QLs and terminology • Description of procurement variables as function of QL • Expectations for implementation and approval • Training proposal Ensure consistency with Project Focus Area #5. Transmit to EM HQ for EM QA Corporate Board review in a format suitable for addition to the EM QA Program.	EM Graded Approach Procedure for Procurements
4.5	06/01/09	Provide team consensus recommendation to EM HQ on extending the procurement Graded Approach to items, services, and activities affecting quality.	Position Paper in EFCOG Format to EM HQ Forwarding Team Recommendation on Extending the Procurement Graded Approach Process to Items, Services, and Activities Affecting Quality.

Project Area #5 - Line Management Understanding of QA and Oversight
Target Completion Date: June 30, 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
Al Hawkins, RL
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 Quarterly Performance Review (QPR) briefing packages. Develop final QPR Quad by 11/15/08.	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.	Completed List of QA Points of Contact for All Organizations, Commitment, and Schedule for Development of Qualifications
5.3	9/30/08	Develop EM QA Program (QAP) applicable to all EM sites (contractor/federal staff) to ensure consistency and to instill a strong QA culture. Draft QAP discussed at 2nd Corporate Board Mtg.	Completed Final Draft QAP
5.4	10/31/08	EM-1 provides direction and guidance to EM field sites to promulgate EM Corporate QAP.	Completed EM-1 Memorandum (11/5/08)
5.5	11/30/08	More detailed QAP implementation (QIP) - next steps and guidance - will be issued by Office of Safety Management and Operations (EM-60 Deputy Assistant Secretary) following the EM-1 Memorandum. Draft presented to Corporate Board for review and discussion.	Completed EM-60 Memo to Field Sites on Path Forward (12/2/08)
5.6	10/31/08	Develop Indoctrination/Training modules on the value of a strong QA Program: 1) Establish 1st EM Centralized Training Platform or Academy: 40-hour training course for federal staff; and 2) Focus on line management (contractor and federal), FPDs, and the IPTs: develop a half-day training program using Training Platform and SRP modules. FPF Workshop scheduled for March 30 – April 1, 2009 (obtain slot on agenda).	Training Academy Modules & Course Held in 10/08. Develop ½ day training program for IPTs and FPDs.
5.7	3/31/09	Complete QA training for FPDs/IPT participants to reinforce consistent performance expectations	Training Records to EM HQ or Approval Authority
5.8	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)
5.9	6/30/09 – 9/30/09	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	Washington Savannah River Company
WTS	Washington TRU Solutions
WVDP	West Valley Demonstration Project

Energy Facility Contractors Group

Office of Environmental Management And Energy Facility Contractors Group

Quality Assurance Improvement Project Plan

Project Focus Area	Task # and Description	Deliverable
Project Area 1: Requirements Flow Down	Task #1.9 - Complete White Paper covering procurement QA process flow diagram	Draft White Paper and Amended Flow Diagram
Project Area 4: Graded Approach Implementation	Task #4.4 - In coordination with Project Focus Area #1, provide an EM expectation for application of the graded approach to procurement.	EM Graded Approach Procedure for Procurements

Approvals:	Yes/No/NA
Project Managers: S. Waisley, D. Tuttel (3/12/09)	Y
Executive Committee: D. Chung, J. Yanek, N. Barker, D. Amerine	Y
EM QA Corporate Board:	Y

Forward

The Department of Energy (DOE) Environmental Management (EM) prepared a Quality Assurance (QA) Improvement Project Plan (Project Plan) to improve QA performance across EM operations. The plan is supported by EM and Energy Facility Contractors Group (EFCOG) representatives. The initial plan addresses five high priority QA issues which resulted in the establishment of five Project Focus Area teams:

1. *Requirements Flow Down*
2. *Adequate NQA-1 Suppliers*
3. *Commercial Grade Item and Services Dedication Implementation and Nuclear Services*
4. *Graded Approach to Quality Assurance*
5. *Line Management Understanding of QA and Oversight*

This model and expectation respond to issues 1 and 4, Requirements Flow Down and Graded Approach to Quality Assurance.

Project Focus Area Team #1 was asked by the EM QA Corporate Board to develop a model that would provide some consistency to the approach for flow down of requirements to subtier suppliers/subcontractors performing work under prime contractors to EM. Project Focus Area Team #1 developed a draft model and presented it to the Corporate Board in November 2008. Following that meeting, the Team was requested to develop an expectation for graded approach to quality assurance. Recognizing the overlap between the model developed by Project Focus Area #1 and the revised charter of Project Focus Area #4, the two groups' efforts were combined. The deliverables include a model which diagrams the overall procurement process, and an expectation for applying the graded approach to procurement of items and services. The model is shown as Attachment 1.

The Project Plan states, "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 of quality assurance is based on the relative importance of an item or activity to the success of the mission."

Further, the Project Plan states "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")."

How EM Headquarters (HQ), EM Field/Project Offices, and EM contractors implement the graded approach has been inconsistent. Surveys of various contractor organizations throughout the EM complex completed during the summer of 2008 provided insight into

the degree of inconsistency across the complex. The inconsistencies begin as the Department prepares its Requests for Proposal (RFPs) and carry through the various contractor organizations as they prepare service and commodity oriented procurements to meet the needs of operating facilities and construction projects. In addition, with no common expectation graded approach assessments may be influenced by the individual assessor's perspective, leading to further inconsistency.

This model and expectation provide EM with a defined process for application of a graded approach for QA in both contractor and federal QA programs for procurement. By applying this model and expectation across EM, consistency in the application of the graded approach is established. Application of this model and expectation ensures contractors meet the expectations and requirements of DOE Order 414.1C, 10 CFR 830, 10 CFR 835 and NQA-1-2004 with addenda through 2007.

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Graded Approach for Procurement

1.0 Purpose

This model and expectation provide the method for applying a graded approach to procurement activities across EM. The model and expectation are to be used by EM HQ, EM Field/Project Offices and EM Contractors to develop procurement processes associated with all work performed for the EM Program.

2.0 Background

A model (Attachment 1) was developed to describe the overall process for providing consistency in the procurement of items and services across EM. Driving consistency in the procurement process begins with four principal areas:

- EM serving in the capacity of owner and regulator
- Prime contractors (Managing and Operating/Integrating Contractors, Engineering, Procuring and Construction Contractors, etc.)
- Subcontractors performing work directly for EM prime contractors
- Subtier suppliers/subcontractors performing work

EM performs its owner/regulator duties while developing (modifying) its contracts. The EM Corporate Quality Assurance Program promulgated by the Principal Assistant Secretary for EM during October 2008 invoked the national consensus quality standard used by the American Society of Mechanical Engineers' (ASME) Quality Assurance Requirements for Nuclear Facility Applications (NQA-1) version 2004 and addenda through 2007. As EM forms Integrated Project Teams to develop acquisition strategies for new procurements, it is incumbent upon EM to fully and completely address the quality assurance requirements associated with that acquisition. In addition, EM Field and Project Offices should consider modifying existing contracts considering the following:

- Contract language shall be tailored to meet the needs of the specific project/program.
- Tailoring will manifest itself in the form of a review of the various NQA-1 parts and subparts to ascertain their applicability to procurement's specific scope. As expressed in the Introductions to Parts I and II, Requirement 300 of NQA-1 requires the "organization invoking this Part shall be responsible for specifying which requirements, or portions thereof, apply, and appropriately relating them to specific items and services".
- The development of the QA requirements may also consider Parts III and IV of NQA-1 and provide specific contractual expectations regarding the Parts III and IV (nonmandatory) portions of NQA-1 within the contract's quality related clauses.

EM has the duty to ensure that contractors develop and operate an effective QA program. This duty is evidenced by Departmental representatives' presence in prime contractor and subcontractor work places:

- Evaluating the effectiveness of the prime contractor's oversight of its and subcontractors' conduct of work.
- Evaluating actual work being performed against various engineering documents and assessing the effectiveness of QA Program at the point where work is being performed within the entire supply chain.
- Communicating observed conditions to the prime contractor.

Through the Inspection Clause found in DOE Contracts, EM representatives have the right to access prime and subcontractor work places, particularly those away from DOE Sites, for the purposes of inspecting DOE-related work as it is performed. The clause reads:

> *The Government, through any authorized representatives, has the right at all reasonable times, to inspect, or otherwise evaluate the work performed or being performed hereunder and the premises in which it is being performed. If any inspection, or evaluation is made by the Government on the premises of the Contractor or a subcontractor, the Contractor shall provide and shall require his subcontractors to provide all reasonable facilities and assistance for the safety and convenience of the Government representatives in the performance of their duties. All inspections and evaluations shall be performed in such a manner as will not unduly delay the work.* (DEAR 952.236-71)

As communicated in the model, EM has specific expectations of its prime contractors. EM expects its prime contractors to assure the integrity of safe operations, design, and construction of its facilities/projects:

- The responsibility encompassed within the "safe operations" expectation requires intimate understanding of a wide variety of topical areas engaging multiple technical and engineering disciplines. Their critical importance to safe operations makes many of these responsibilities difficult to delegate through subcontracts to subordinate entities. The body of expertise must reside in the contractor's house to assure safe facility operations.
- Analyzing the safety significance of the various SSCs is not generally subcontracted to outside entities. Therefore, the expectation is that the design authority will perform this function for the operating facility or project under design or being constructed.
- Identifying critical attributes to safe performance of SSCs is essential. Often these attributes are determined acceptable when measured as prescribed in various national consensus codes and standards that address the particular commodity. For example, in terms of concrete, critical attributes will likely be measured against the various consensus standards promulgated by the American Society of Testing Materials (ASTM) and American Concrete Institute (ACI). Quality may not be completely achieved without a thorough identification of the particular critical attribute (e.g., slump, air content, etc.).

- Develop procurement documents that:
  - Communicate with the subcontractors the key engineering/performance attributes necessary to successfully achieve safe SSC operations and how they will be measured at delivery.
  - Establish contractual expectations regarding which quality requirements must be provided to subordinate subcontractors or material suppliers. Taking appropriate care in describing precisely those requirements of NQA-1 applicable to the item or service to be delivered under the procurement is essential in formulating a sound quality approach.
  - Ensure subcontractor and subtier subcontractor performance through surveillance, assessments, audits (capability and compliance) and receipt inspection activities.
  - Measure delivered work by established engineering/performance criteria and accept completed work products.

Suppliers/Subcontractors to Suppliers have the responsibility to develop quality programs that assure engineering requirements are adequately performed throughout the various procurements performed by the supplier/subcontractor, including:

- material receipt;
- storage and segregation of materials;
- fabrication (including assuring adequate measurement and test equipment (M&TE);
- inspection, testing; and,
- delivery of commodity to the prime contractor.

Subtier Suppliers/Subcontractors to Suppliers must also:

- Ensure the adequacy of subtier subcontractor performance through surveillance, assessments, audits (capability and compliance) and receipt inspection;
- Accept completed work products from subtier subcontractors, raw material, commodity, and subcomponent suppliers; and
- Develop quality programs that assure engineering requirements associated with the subcontracted scope of work are adequately performed throughout the various procurements exercised by the supplier/subcontractor.

3.0 Application

EM Field/Project Offices and EM Contractors are required to establish and implement a QA Program (QAP) and to maintain a QA Implementation Plan (QIP) that meet the requirements of the EM QAP, DOE O 414.1C (Order) and, for activities governed under 10 CFR 830 (Rule), 10 CFR 830.121. Criterion 7 of both the Order and the Rule requires:

- Procure items and services that meet established requirements and perform as specified;
- Evaluate and select prospective suppliers on the basis of specified criteria; and

- Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.

The Order and the Rule further require the use of a national consensus standard in the development of the QA program. EM Headquarters (HQ), EM Field/Project Offices and EM Contractors are required by the EM Corporate QA program to use NQA-1 2004 and addenda through 2007. DOE Guide 414.1-2A, *Quality Assurance Management System Guide*, section 4.7 and NQA-1 Part 1, requirements 4 & 7 identify the following areas associated with procurement and procurement documentation:

- Content of Procurement Documents
- Procurement Document Review
- Procurement Document Changes
- Supplier Evaluation and Selections
- Bid Evaluation
- Control of Supplier Generated Documents
- Supplier Performance Monitoring
- Acceptance of Item or Service
- Control of Supplier Non-conformances
- Commercial Grade Items and Services

Along with the Order and Rule, NQA-1 allows implementing these requirements through a graded approach. Subpart 4.2 of NQA-1, paragraph 300 provides a definition of the graded approach: *The graded approach is the application process for administrative controls. It is a process by which the level of analysis, extent of documentation, and degree of rigor of process control are applied commensurate with their significance, importance to safety, life cycle state of a facility or work, or programmatic mission.*

The graded approach does not allow for a requirement to be waived. As such, for all procurement activities, the above areas shall be addressed. However, the methods used to implement the requirements can vary commensurate with the risk of the activity. The graded approach, when implemented, is applied to the following key activities associated with procurement:

- Review and approval of the procurement activity
- The methods used to evaluate the supplier's capability
- The methods used to monitor supplier's performance
- The methods used to accept the deliverable

This expectation describes the framework to be used by EM Field/Project Offices and EM Contractors. In addition to allowing for a cost beneficial approach, the framework minimizes the subjective nature of the graded approach by specifying "how" requirements are implemented. This expectation does not address attributes associated with the procurement process in such areas as:

- Sole Source Justifications
- Funding approval requirements

- Classification/Declassification
- Offer Solicitations
- Contract Award
- Payment for items/services
- Contract closeout
- Claims

4.0 Implementation

Each EM Field/Project Office and EM Contractor shall demonstrate how its procurement process incorporates the following:

- Use of the standard EM risk assessment process to quantify the risk [Note: EM Office of Standards and Quality Assurance will provide the standard risk assessment process to be used by EM HQ, EM Field/Project Offices, and EM Contractors];
- Establishment of Quality Levels (QLs) as defined in this expectation based on the quantified risk (to establish the rigor to be applied); and
- Identification of how each requirement is implemented consistent with the QL of the procurement and compliant with this expectation.

The documented approach of each EM Field/Project Office and EM Contractor is submitted for approval as part of the site's QAP/QIP submittal.

5.0 Procurement Process Attributes

In general, the following procurement process attributes vary according to QL:

- Review and approval of procurement activity
- Evaluation of supplier capability
- Supplier monitoring
- Acceptance of items and services

To assure consistency in how these attributes are implemented, EM Field/Project Offices and EM Contractors must:

- Determine risk/consequence of failure of the item/service
- Identify requirements applicable to the item/service
- Establish the QL

Performing these three activities diminishes the subjective nature of applying the graded approach.

5.1 Determine Risk of Failure

This is the critical step in applying a graded approach to procurement. The rigor must be commensurate with the risk of failure. DOE O 414.1C provides a list of attributes to be

evaluated when determining the risk of failure. Through this expectation EM provides a common, computer-based, process for evaluating risk. The risk evaluation looks at risk of failure from two perspectives: 1) Safety and 2) Mission Criticality.

Risks associated with failure for structures, systems, or components that are specifically credited within a facility's associated documented safety analysis or hazard evaluation are generally well captured. Risks associated with improper performance of a service or delay in delivery that could have an impact on safe operations or critical timelines and milestones are not as well captured and require evaluation to ensure the appropriate rigor is applied to the procurement activity. For example, a pump used for environmental ground water cleanup may not have nuclear safety implications, yet its failure or late delivery could have significant implications for meeting customer time lines or could degrade stakeholder perception of the organization's ability to meet expectations. Or, its failure could result in unnecessary exposure of personnel to hazards due to the need to remove/repair/replace the pump. These issues warrant elevated QA rigor to ensure successful completion of the procurement. The common computer-based risk assessment process will provide consistency in evaluating the risk to appropriately apply to correct QA rigor.

5.2 Identify Requirements Applicable to Item/Service

Identification of requirements is a design input, and is tightly connected to the risk assessment. The graded approach is generally not used in flow down of requirements unless the requirements are associated with inspections and acceptance. Generally requirements either are or are not applicable to the item or service. The requirements associated with the item or service to be procured are defined by the customer organization and usually involve the technical authority or subject matter expert to ensure that appropriate national standards, codes, quality requirements, state requirements, laws, regulations, etc. are appropriately applied to the procured item.

Identification of requirements applicable to the item or service not only involve technically oriented codes and standards, but also include a well described expectation for implementation of QA standards with particular emphasis regarding the flow down of QA requirements to subcontractors and suppliers, for example. Prime contractors have the duty to describe how Part I and Part II of NQA-1 will be implemented within the subordinate contractor's QA program with special care taken to identify those sections of NQA-1 applicable to the scope of work being contracted.

Based on risk, a purchaser should consider identifying a Technical Representative (TR) for highly critical procurements to ensure the appropriate technical requirements are included in the procurement documents and understood by the supplier. The TR should also participate in the supplier evaluation process.

The purchaser shall develop a standard methodology to flow down QA requirements to Suppliers, e.g. using QA Specifications (CSI* Section 1400[1]).

[1] **C**onstruction Specification Institute

The QA specifications shall be included with the procurement document and contain a statement to indicate applicability of NQA-1 requirements to the supplier's QA Program. The specification shall identify any other project-specific QA requirements, e.g., driven by the customer such as SCI controls and laboratory certifications that are not covered by NQA-1. The need to submit QA program documents with bids and whether acceptance of the Supplier's QA Program is a condition of procurement shall be identified.

Selection of the NQA-1 requirements that apply to the specific procurement scope shall be documented. An Applicability Matrix or equivalent tool, attached to the QA specification or the procurement documents, should be used to document such selection and to communicate QA requirements to the supplier.

Requirements for the supplier to flow down to a sub-tier supplier shall be identified in the QA specification. The requirements shall be commensurate with the scope of the sub-tier procurement. The supplier shall ensure the sub-tier supplier's QA Program is acceptable for the assigned task prior to procurement, and implement oversight functions as needed to ensure the supplied item or service is compliant.

In addition to identifying the requirements for the supplier's QA program, the QA specification shall be used to communicate the purchaser's expectations for implementation of the supplier's QA program, and to establish communication protocols for oversight functions. The QA specification shall be clear regarding the right of access by project and customer representatives to perform oversight functions such as audits and surveillances. The purchaser's right to stop work at a supplier due to non-compliances with the QA program shall be stated in the QA specification. Other considerations include:

- Identify the conditions that need to be satisfied in order for the fabrication or activity to commence.

- Protocols and communications required for witness and hold points shall be identified. Witness and hold points shall be defined and communicated to the supplier for planning and inclusion in its fabrication control documents. Advance notification requirements to the purchaser prior to performing the activity affected by these witness and hold points shall be defined. The purchaser shall ensure sufficient witness and hold points are included to provide confidence that the item is acceptable. Points may include initial or first article monitoring or inspection, in-process inspections, and final inspections.

- Inspection requirements shall include preparation and submittal of supplier's QC procedures and inspection personnel qualifications to the purchaser for review and acceptance prior to performing inspection activities.

- Disposition of nonconforming items that involve repair or use-as-is shall be made and documented. Nonconformances to design requirements shall be subject to design control measures commensurate with those applied to the original design.

- Requirements for the compliance documentation package to be supplied with the item to evidence the item's quality, e.g., completed Travelers, Inspection and Test reports, etc. shall be identified. The QA specification or the procurement documents shall include a listing of such documents.

- When a shipping release is used, how the release will be granted shall be identified (e.g., include or make reference to the shipping release form and identify the purchaser's organization authorized to approve the release).

5.3 Establish the Quality Level

Based on the risk determination, a QL is established for the procurement activity. The QL defines:

- The level of review and approval of the procurement activity
- The method used to evaluate the supplier's capability
- The method used to monitor supplier's performance
- The method used to accept the deliverable

This expectation establishes four QLs as described in the following section.

6.0 Quality Levels

QLs are established based on risk such that higher risk activities result in higher rigor associated with the supplier evaluation and acceptance activities. Risk is defined by a cumulative evaluation using the standard EM process against variables such as Nuclear Safety, Personnel Safety, Environmental Impacts, Mission Impacts, Cost, and Stakeholder perception. Based on cumulative risk, the QLs are:

- QL-1 – High risk
- QL-2 – Medium to high risk
- QL-3 – Low to medium risk
- QL-4 – Commercial quality and low risk

QL-1: Important to safety or mission, high risk procurement where additional quality controls are needed to verify critical attributes **and** a high level of assurance is needed to ensure expectations associated with additional quality controls are being met.

QL-2: Important to safety or mission, medium to high risk procurement where quality controls are needed to verify critical attributes **and** a moderate level of assurance is needed to ensure expectations associated with additional quality controls are being met.

QL-3: Important to safety or mission, low to medium risk procurement where quality controls are needed to verify critical attributes.

QL-4: No safety or mission impact - level of controls for those items, services, or processes where, based on an evaluation of risk, no additional quality controls beyond the providers published or stated attributes of the item, service, activity, or process are required. General receipt inspection processes to ensure item, quantity, and other characteristics are met.

6.1 Review and Approval

In all cases, procurement activities are approved by an organizational representative who has authority to expend funds and authority to acquire items or services. Who or how many personnel this takes will vary depending on the item/service being procured. It may be limited to a single individual for low risk items such as office supplies or other items purchased directly in support of administrative activities, or may require multiple approvals such as the requisitioner, a project controls specialist, and the cost account manager for items with higher risk or funding requirements.

In addition to those reviews, technical and support personnel reviews may be warranted to include Engineering, Safety, Industrial Hygiene, Quality, Environmental, and Radiological Controls or others depending on the requisitioned item or service.

Table 6-1 provides EM's minimum expectations for review and approval based on QL.

6.2 Supplier Evaluation

NQA-1 requires, prior to award, that the purchaser shall evaluate the supplier's capability to provide items or services in accordance with the requirements of the procurement documents. This must be done for all procurements. NQA-1 provides options for performing this evaluation. The specific methods addressed are:

- Supplier's history of providing an identical or similar product that performs satisfactorily in actual use. The Supplier's history shall reflect current capability;
- Supplier's current quality records supported by documented qualitative and quantitative information that can be objectively evaluated; and
- Supplier's technical and quality capability as determined by a direct evaluation of the facilities, personnel, and the implementation of the Supplier's QA program.

The rigor behind the selected approach takes into account the risk determined QL.

Which approach to take is generally determined based on current supplier knowledge, the item or service being procured, and the QL. For low risk activities, such as office supplies, purchasing from a reputable vendor based solely on commercial industry presence can be sufficient to meet this requirement, as long as the decision to use the vendor for this service is documented (i.e., a material request form identifying the supplier). As the risk escalates additional evaluations may be warranted, but can be met by reviewing requested documents that support the objective evaluation of the supplier's

capabilities during the bid proposal. For higher risk activities, an onsite evaluation of the implementation of the suppliers program becomes the most prominent method to ensure the supplier is capable of meeting the needs. Table 6-1 provides EM's minimum expectations for supplier evaluation based on QL.

6.3 Supplier Monitoring

Periodic monitoring of a suppliers performance is an area where implementation may vary. Although risk plays a role in determining the monitoring methods and frequency, scope of the activity also influences supplier evaluation. For low risk activities, monitoring can be performed simply through receipt inspection of deliverables. As risk escalates, the monitoring strategy should address:

- Source inspections
- Witness points, hold points
- On-Site surveillances/assessments
- Submittal reviews

See Table 6-1 for EM's minimum expectations for supplier monitoring.

6.4 Acceptance of Items

NQA-1 provides the following methods for use for acceptance of an item or service:

- Supplier Certificate of Conformance (COC)[2]
- Source Verification
- Receiving Inspection
- Post installation test
- Combination of the above
- For services only, any or all of the following may be used:
    - Technical verification of data produced
    - Surveillance and/or audit of the activity
    - Review of objective evidence for conformance to the procurement document requirements

The procurement shall specify which of these are to be used. With the exception of the supplier certificate of conformance, the methods used have latitude with regard to "who" performs the activity. For example, some receipt inspections will require inspection by someone that has non-destructive examination qualifications, while others may be performed by a material coordinator/warehouseman with training in suspect/counterfeit item control, and others can be performed by other support personnel. See Table 6-1 for EM's minimum expectations regarding acceptance of items.

[2] Reliance on Supplier COCs as a principal component of receipt inspection and acceptance processes should be considered a weak practice. See NQA-1, Requirement 7, paragraph 503 for minimum criteria for use of COCs.

Attachment 1

FLOW DOWN OF QUALITY ASSURANCE SPECIFICATIONS AND PROCUREMENT OF ITEMS AND SERVICES - GRADED APPROACH APPLICATION

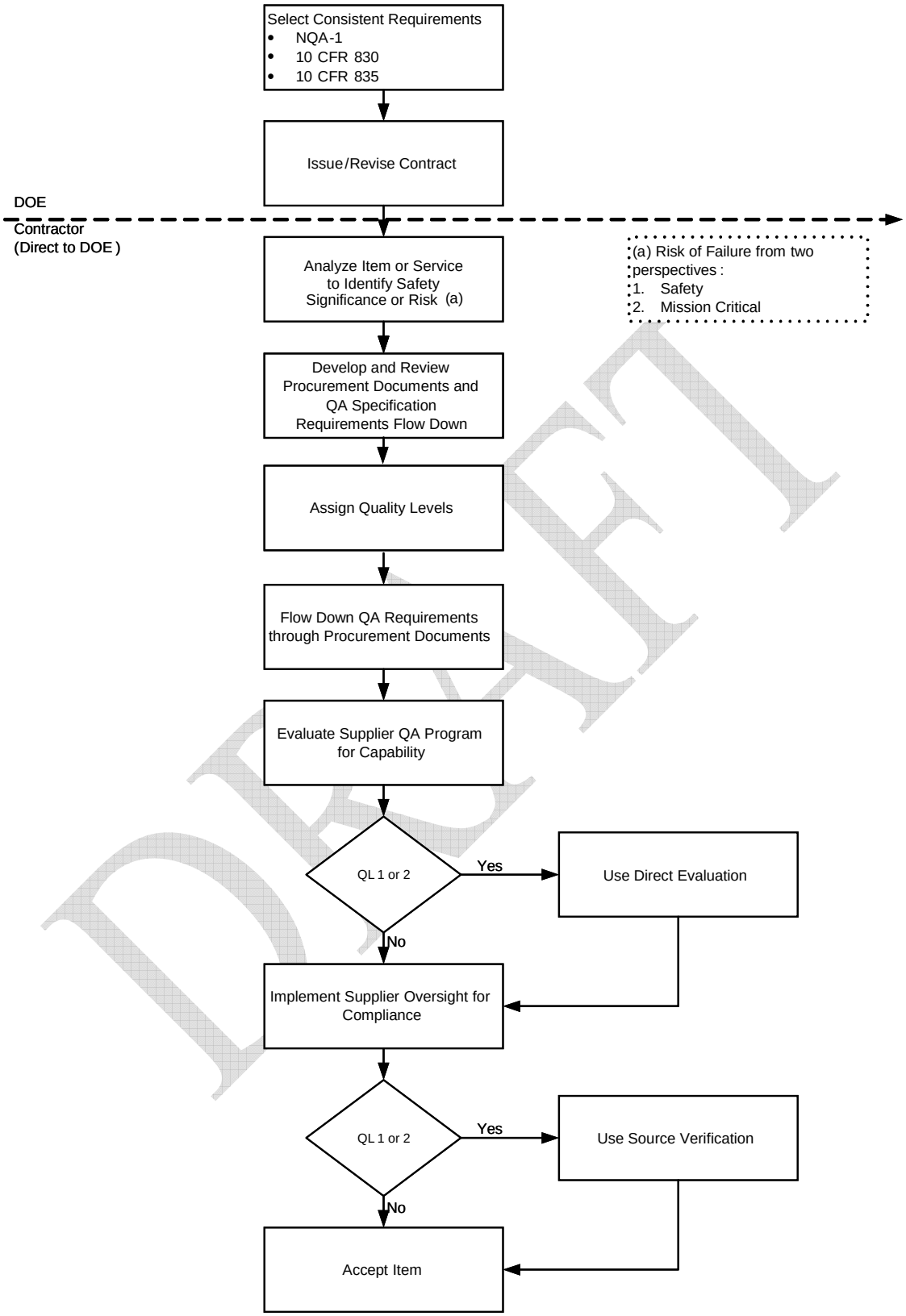


Table 6-1 – EM Graded Approach QL Level and Activity Matrix Minimum Expectations

Quality Assurance Criteria	QL-1	QL-2	QL-3	QL-4
Review and approval	Requisitioner Project Controls Cost Account Manager QA Engineering Safety (1) Environmental (1) IH (1) RadCon (1)	Requisitioner Project Controls Cost Account Manager QA Engineering Safety (1) Environmental (1) IH (1) RadCon (1)	Requisitioner Project Controls Cost Account Manager QA (1) Engineering (1) Safety (1) Environmental (1) IH (1) RadCon (1)	Requisitioner Project Controls Cost Account Manager Engineering (1) Safety (1) Environmental (1) IH (1) RadCon (1)
Supplier Evaluation	Evaluation of supplier's implementation of its QA program if not procured as commercial grade item. Must be a site visit	Evaluation of supplier's implementation of its QA program if not procured as commercial grade item. Site visit expected unless basis for not doing is justified and documented	Identified components of the supplier QA program, supporting procedures, and processes submitted for review and acceptance. Review and acceptance is documented.	Supplier selection and approval based on commercial standard.
Acceptance	• QA Receipt Inspection • Source Inspection/verification for Fabrications required • Surveillances for Services • Submittals formally reviewed by designated SMEs	• QA Receipt Inspection • Source Inspection/verification for Fabrications required • Surveillances for Services optional • Submittals formally reviewed by designated SMEs or designated representative	• QA Receipt Inspection (1) • Source Inspection/verification for Fabrications considered. • Surveillances for Services optional • Submittals formally reviewed by designated representative.	• Receipt Inspection (non-QA) • Submittals reviewed by designated representative
Monitoring	• Development of Subcontractor Oversight Plans (2) • Receipt Inspection • Acceptance Testing • Submittal Review	• Basis for not developing a Subcontractor Oversight Plan needs to be documented (2) • Receipt Inspection • Submittal Review • Acceptance testing optional	• Receipt Inspection • Submittal Review	• Receipt Inspection • Submittal Review

(1) Scope Dependent
(2) Due to higher risk, intentional oversight activities are planned out – could range from periodic surveillance to in-process inspections/witness or hold points.

EM Project Area 2 – Adequate NQA-1 Suppliers
Project Milestone Tasks 2.10 and 2.12

Scope of Project Milestone 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.

Scope of Project Milestone 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.

Evaluation Summary:

Due to the close nature and inter-relationship of Task 2.10 and 2.12 the team elected to combine the results and recommendations for both tasks into this one document. This evaluation included:

- Procedures being used by EM contractors for qualifying nuclear grade suppliers (Task 2.6)
- Common commodities and services being used by the EM sites (Task 2.9)
- Determination on whether there are common suppliers and redundant audits being performed by EM contractors (Task 2.11)
- Review of existing industry organizations' approach to joint audits or shared audits (Task 2.13)
- Evaluation of recent or current EFCOG activities in the supplier arena.

Our evaluation determined that a consolidated nuclear grade supplier list and contractors performing joint supplier audits is not only feasible, but highly recommended. First, a distinction should be made between an EM consolidated nuclear grade supplier list and an EM Approved Supplier List. A consolidated supplier list is a list of those suppliers that have been audited under the applicable joint audit program, but does not contain endorsements or approvals by EM for contractors to use these suppliers. This list is also used for the purpose of scheduling and tracking joint supplier audits within the complex. An EM Approved Supplier List would be an approval of the supplier for use on any EM site without requiring any additional action by the sites or contractors using a supplier on the list. This approach will create liability issues and possibly legal issues for EM and will not comply with the current QA Program requirements. Our research into existing programs and methods within EFCOG and DOE led us to the Energy Facility Contractors Group (EFCOG) Supply Chain Quality Task Team (SCQTT). The SCQTT has been working on a similar task as the EM NQA-1 Supplier Team and has put in place programs and systems that address joint audits and sharing of audit results. This team is comprised of representatives from DOE, NNSA and contractor organizations. The SCQTT has developed a Supplier Evaluation Program (SEP) which adopted a standard audit protocol that includes audit scheduling, planning, performance, reporting, follow up

and verification and closure of the audit process. Implementation of this methodology ensures that audits are documented and performed in a consistent manner by trained and qualified professionals. Additionally, the program has established methods to input joint supplier information into the Integrated Supplier Information System (ISIS) to enable contractors to view and evaluate audit reports and associated documents prior to using the supplier. The SCQTT Supplier Evaluation Program has been reviewed and accepted by representatives from the following organizations/sites:

- Pacific Northwest National Laboratory
- Parsons
- Fluor Hanford
- WIPP
- Oak Ridge National Laboratory
- Lawrence Livermore National Laboratory
- Savannah River Nuclear Solutions
- National Security Technologies
- Los Alamos National Laboratory
- Argonne National Laboratory
- Brookhaven National Laboratory
- BWXT Pantex
- Idaho National Laboratory

This approach is consistent with elements of both the NUPIC joint audit program and the NIAC shared audit program. This approach eliminates the legal and liability issues for EM and fully complies with NQA-1. This program has already been implemented by the EFCOG Supply Chain Working Group in other parts of the DOE Complex.

Recommendations:

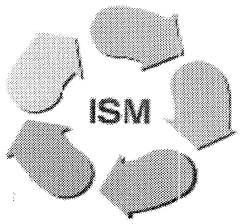
- EM endorse the EFCOG Supply Chain Working Group procedure for performing joint audits, *Energy Facility Contractors Group (EFCOG) Supply Chain Quality Task Team Supplier Evaluation Program*, approved August 2008 (Attached)
- EM endorse the posting of supplier audit information for use under the above Program
- EM input to the EFCOG audit schedule to ensure cost effective and efficient use of limited resources (Attached)
- EM ensure that contractors understand their responsibility to evaluate the audit reports and make their own determination as to the adequacy for specific suppliers meeting the quality and technical requirements on a case-by-case basis
- EM should issue a contract clause requiring the use of SCQTT SEP.
- EM should conduct audits of the SCQTT SEP to determine compliance with 10CFR830 and NQA-1. Address any gaps identified during audits.

Benefits to EM:

1. Eliminate redundant supplier audits
2. Provide consistent process for performing audits
3. Compliance with 10CFR830 and NQA-1
4. Sharing of audit resources with other DOE organizations and contractors.
5. Allows for simplified EM and Field oversight by conducting joint audits of the SCQTT SEP.
6. Achieves the mission of Project Area 2 by "promoting information sharing, resource sharing and standardization of efforts within EM to improve quality, safety and cost associated with identifying, qualifying and maintaining suppliers".

Energy Facility Contractors Group (EFCOG)
Supply Chain Quality Task Team
Supplier Evaluation Program

August 2008



Energy Facility Contractors Group (EFCOG)
Supply Chain Quality Task Team
Supplier Evaluation Program

August 2008

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Paul Bills, Supply Chain Quality Task Team Lead — Date: 8-22-08

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INTRODUCTION

EFCOG ISM Working Group QA Subgroup Supply Chain Quality Task Team (SCQTT) is comprised of representatives from Department of Energy (DOE) and National Nuclear Security Administration (NNSA) contractors' organizations. Each of these organizations procures various commodities that are used in both nuclear facilities and non-nuclear facilities. The SCQTT meets semiannually to network with other contractors, to share supplier information, and to address supplier and other supply chain quality issues that face the complex.

The SCQTT has noted that a number of DOE contractors continually evaluate the same suppliers, usually on a triennial basis. In order to reduce the duplication of effort by contractors and to free suppliers from continual evaluations that audit to the same or similar criteria, the SCQTT has established its own Supplier Evaluation Program (SEP). SCQTT has developed a standardized assessment program to evaluate suppliers of common commodities that have the potential to be used in both nuclear and non-nuclear facilities. The SCQTT has developed requirements matrices for the common commodities (available from the SCQTT Lead).

This SEP program adopts a typical standard audit protocol that includes audit scheduling, planning, performance, reporting, follow up and verification, and closure of the audit process. It also identifies lines of communication to ensure the proper reporting of audit/evaluation information. Implementation of this standardized methodology ensures that audits are documented and performed in a consistent manner by trained and qualified professionals. A trained and qualified Lead Auditor will lead these audits. The audit report is the product of this program. The audit report will be based on the applicable requirements identified in the audit plan. Where applicable the audit team will include Subject Matter Experts (SMEs) trained and qualified in areas applicable to the commodity being audited. Findings identified during the audit will be corrected and verified by an audit team member and accepted by the Lead Auditor. When completed, the audit report will be made available to DOE and NNSA contractors through the SCQTT. Each site that uses the results of a SCQTT audit will be responsible for reviewing and evaluating the evaluation results to ensure that the information meets their site specific quality and regulatory requirements and to make a determination regarding the extent to which the supplier evaluation information is relied upon.

1. PURPOSE

The SCQTT SEP is designed to ensure consistency when conducting evaluations of suppliers of commodities that have the potential to be used in both nuclear and non-nuclear facilities. Consistency is incorporated into this program by using requirements matrices that have been developed by SCQTT and by selecting joint audit teams that may include auditors and SMEs from multiple DOE and/or NNSA Contractors' organization. By using shared resources, this program will reduce the number of audits performed of common suppliers, provide the benefit of using multi-site expertise, and reduce costs to suppliers by eliminating multiple audits of the same suppliers.

2. SCOPE

The scope of this SEP covers commodities that have the potential to be used in both nuclear and non-nuclear applications. This program does not include site-specific requirements and/or specifications; however, these documents may be provided by the sites to the Lead Auditor and auditors to be used as part of the audit preparation. The SCQTT has developed requirements matrices based on a national consensus standard.

3. DEFINITIONS

Audit - A planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents, and the effectiveness of implementation. An audit should not be confused with surveillance or inspection activities performed for the sole purpose of process control or product acceptance.

Audit Checklist - A listing of documents or questions that identify each element or area the evaluation is intended to address.

Auditor - Any individual in the organization who performs any portion of an assessment includes Lead Auditors, technical specialists, and others, such as management representatives and auditors in training.

Audit Plan - The Lead Auditor develop and document an assessment/audit plan for each audit. This plan shall identify the audit scope, requirements, audit personnel, activities to be audited, organizations to be notified, applicable documents, schedule, and written procedures or checklists.

Corrective Action - Measures taken to rectify conditions adverse to quality and, where necessary, to preclude repetition.

Document - Any hard copy or electronic (text or graphic) information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results. A document is not considered to be a quality assurance record until it satisfies the definition of a quality assurance record as defined by NQA-1.

Finding - A direct departure from a procedural, regulatory, or contractual requirement.

Lead Auditor - A person certified as a Lead Auditor who is responsible for organizing, directing, and coordinating the conduct of an audit; reporting findings and observations; issuing the audit report; and evaluating the adequacy of responses.

Objective Evidence - Any documented statement of fact, other information, or record, either quantitative or qualitative, pertaining to the quality of an item or activity, based on observations, measurements, or tests which can be verified.

Observation - A weakness that, if not corrected, could yield a departure from a requirement.

Observer – An individual authorized by EFCOG SCQTT to observe an audit. An observer shall not actively participate in (i.e., perform auditor functions) or interfere with audit activities and shall be subject to the direction of the Lead Auditor while at the audited facility.

Quality Assurance - All the planned and systematic activities implemented within the quality system and demonstrated as needed, to provide adequate confidence that an entity will fulfill requirements for quality.

Supplier - Any individual or organization who furnishes items or services in accordance with a procurement document. An all-inclusive term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, consultant, and their subtier levels.

Subject Matter Expert (SMEs) - An individual who has demonstrated technical expertise and knowledge in a specific subject area. The technical expert provides technical, system, and process information as an audit team member.

4. ACRONYMS

DOE	Department of Energy
DOT	Department of Transportation
EFCOG	Energy Facility Contractors Group
ISIS	Integrated Supplier Information System
NNSA	National Nuclear Security Administration
POC	Point of Contact
QA	Quality Assurance
SCQTT	Supply Chain Quality Task Team
SEP	Supplier Evaluation Program
SME	Subject Matter Expert

5. RESPONSIBILITIES

Supply Chain Quality Group Task Team Lead

When an audit is requested, the SCQTT Lead acts as the single point of contact (POC) for the maintaining and updating of the Annual Audit Schedule. The SCQTT Lead maintains the EFCOG SCQTT Common Supplier Listing. This listing is used to identify potential SCQTT-sponsored joint audits that can be performed to reduce costs to both DOE/NNSA contractors and suppliers.

Lead Auditor and Audit Team Members (as appropriate)

1. The Lead Auditor has ultimate responsibility for all phases of the audit and has the authority to make final decisions regarding conduct of the audit and determination of whether objective evidence indicates a finding and represents the audit team with the Supplier's management.
2. During the course of an audit it will be the Lead Auditor's responsibility with input from the Audit Team Members to determine if the Supplier has met the requirements identified in the audit plan. This decision can be made after all corrective actions have been completed and verified. During any phase of the audit if it is determined the Supplier's program fails to meet the requirements identified in the audit plan, the Lead Auditor may terminate or postpone the audit after discussion with other team members.
3. Prepares the audit plan.
4. Schedules the audit in concert with the Supplier.
5. Issues the audit plan in a formal notification letter with a copy being sent to audit team members and the SCQTT Leader.
6. Requests the QA and applicable documentation along with and safety or security requirements from the Supplier.
7. Reviews the documents and distributes them to the appropriate team members. These documents will include any applicable SCQTT-approved requirements matrix.
8. Defines the requirements of each audit team assignment, i.e. QA, SMEs, briefs the team members on there respective assignments, and ensures team members have completed required reading of this document. When required reviews and approves additional checklist questions based on the audit team members' review of the Supplier's documentation.
9. During the audit conducts the entrance/exit meetings, daily caucus meeting with team members, and daily debrief meeting with Supplier's management.

10. When compiling the audit report works with the audit team members in assembling the audit report. Ensure all findings, if applicable, are supported by appropriate documentation, and acts as an independent reviewer to ensure consistency.
11. Prepares and signs the audit report and letter, which may include requests for corrective action for findings identified during the audit and formally transmits to Supplier and audit team members.
12. When corrective action is requested in the audit report the Supplier will send the objective evidence for closure to the Lead Auditor. The Lead Auditor will review the documents and send them to the appropriate team member for review, verification and acceptance. When clarification of corrective actions is needed from the Supplier by the audit team member they work through the Lead Auditor to resolve that issue. If an at-site verification audit is required the Lead Auditor will assign the appropriate audit team member. Once accepted by the audit team member the Lead Auditor will sign the corrective action form.

Audit Team Members

1. Complete required reading of this document and sign the required reading form. The Lead Auditor will include with the audit documentation.
2. Review all appropriate documentation provided by the Lead Auditor and when appropriate provide additional checklist questions for approval by the Lead Auditor.
3. Perform their assigned activities and appropriately document all answers identified in the checklist with the appropriate objective evidence.
4. All findings are to be supported by appropriate objective evidence and are to be reported to the Lead Auditor during the daily caucus meetings prior to the daily debrief meeting with the Supplier's management.
5. After the audit is completed the audit team members are to submit their checklist to the Lead Auditor within the time period defined by the Lead Auditor.
6. When corrective action is required as a result of the audit, the appropriate audit team member is to review and verify the documentation provided by the Supplier that would close the finding. When clarification of corrective actions or a verification audit is needed, the audit team member will work through the Lead Auditor to resolve.
7. Provide auditor qualifications and experience to the Lead Auditor for inclusion in the audit report.

Observer

An observer shall not interfere with the audit process and is to direct all questions and comments to the Lead Auditor.

6. WORK INSTRUCTIONS

Audit Preparation

The Lead Auditor is selected during scheduling process with input from participating Contractors and Supply Chain Quality Group members. The SCQTT Lead provides to the Lead Auditor the name, address, phone number and contact information of the supplier to be audited.

The SCQTT members and Lead Auditor review possible audit team members (i.e. SME in DOT, Welding, QA, etc., audit team members are selected based on their field of expertise and qualifications). The Lead Auditor contacts potential audit team members and obtains a commitment to participate on the audit (the SCQTT Lead may assist in this process). The Lead Auditor informs the SCQTT Lead once the team is assigned.

Audit Planning and Scheduling

The Lead Auditor prepares the audit plan (See appendix A for content); works with the supplier to determine a schedule for the audit and time of the entrance meeting and then confirms this with the audit team members; prepares the audit notification letter (See appendix B for content) that will be sent to the Supplier with the audit plan (see Appendix B) attached. When completed the audit notification letter and audit plan will be sent directly to the Supplier with copies going to the audit team members and the SCQTT Lead.

Audit Team Preparation

The Lead Auditor communicates with audit team members to ensure all questions are answered prior to the actual audit (this can be done by various conference calls); distributes applicable checklist to audit team members for review and audit preparation; receives the supplier documentation and ensures what has been received is what was requested; and distributed the supplier documentation to the appropriate audit team members.

Audit team members review documentation and determine if any new requirements are needed. If the checklist requires a revision audit team members will seek the approval of the Lead Auditor.

Conducting the Audit

Entrance Meeting

The Lead Auditor in coordination with the Supplier's management conducts this meeting (explains the purpose of the audit and reviews the audit plan and identifies the lines of communication for the audit team); provides an Entrance Meeting Form (see Appendix C) to document those in attendance; and introduces members of the audit team and if an observer is in attendance explains their role.

Audit Team Members and Observers complete required reading of this document and sign the required reading form (Appendix D) at the Entrance Meeting.

A tour or walk through of the facility is not required, but is highly recommended. The object of the walk-through is to give the audit team members an overview of the Supplier's operation and activities.

Performance of the Audit

During the daily caucus with the audit team, members provide objective evidence to support either a finding or observation during the day. The objective evidence will be discussed to ensure accuracy so they can be reported during the daily out briefing with the Supplier's management.

During the daily debrief meeting with the Supplier's management the Lead Auditor reports the day's activities. The Lead Auditor will facilitate any discussions.

When a finding or observation has been identified and the Supplier takes immediate corrective action, the audit team member that identified the finding or observation may accept the corrective action and close the finding or observation during the audit. Findings or observations closed during the audit will be documented in the audit report.

Exit Meeting

The Lead Auditor in coordination with the Supplier's management conducts this meeting (reviews the purpose of the audit); provides an Exit Meeting Form (see Appendix C) to document those in attendance; reviews with those in attendance all findings and/or observations identified during the

audit (all findings and/or observations should have already been identified to the Supplier so there are no "surprises" during the Exit Meeting); when possible provides the Supplier a draft copy of all findings and/or observations identified during the audit; identifies when the report will be issued to the Supplier, (e.g. 15-20 working days after the audit) or as deemed appropriate by the Lead Auditor; when applicable, and in agreement with the Supplier's management, will identify when the corrective action will be expected after receipt of audit report.

The Lead Auditor will determine on or before the exit meeting, based on daily caucus's and debrief meetings with the Supplier, if the findings and/or observations identified during the audit will meet the requirements identified in the audit plan. This is a crucial point in the audit because if the results of the audit show that the findings identified are of such an extent that they cannot be corrected in a reasonable amount of time the Lead Auditor must determine if the requirements identified in the audit plan are met.

Audit Report and Letter
The audit report (see Appendix E) and letter (see Appendix F) are prepared by the Lead Auditor with assistance from the audit team members. If there are questions concerning the audit they are to be directed to the Lead Auditor.

Completed Checklist - Checklists are to be completed and in an electronic form (i.e., pdf file). Each checklist used during the audit will be completed with the appropriate information answering the question using the objective evidence obtained during the audit. It should also include references to program documents in support of the requirements.

Any noteworthy practices may also be identified in the audit report.

Corrective Action
Each finding and observation identified during the audit will be documented on an audit finding/observation report form (see Appendix G). The supplier is to provide objective evidence that the finding has been corrected and implementation of that corrective action has been validated. When corrective action requires longer than the agreed upon time, the Supplier will provide a corrective action plan as to how and when the finding will be resolved.

Audit Follow-Up
The Lead Auditor receives the objective evidence from the Supplier for all findings identified during the audit. At this time the Lead Auditor will review objective evidence supplied for completeness and forward them to the appropriate audit team member for review.

The audit team member is to review the objective evidence submitted by the Supplier and determine if the corrective action taken effectively closes the finding. If more information is required to close the finding the audit team member works through the Lead Auditor to get this additional information from the Supplier.

When appropriate the audit team member may have to travel to the Supplier's facility and verify that the actions taken to close the finding have been properly implemented. This action is agreed upon between the Lead Auditor and the audit team member. When an on site verification is required the Lead Auditor works with the Supplier and audit team member to schedule site visit.

When the audit team member is satisfied with the information provided he or she signs the audit finding/observation report form (corrective action verified by) and informs the Lead Auditor.

When the Lead Auditor receives notification from the audit team members that all findings have been successfully addressed, the Lead Auditor signs the audit finding/observation report form accepting the corrective action taken and closes the finding.

Audit Closure

Audit closure is completed by the Lead Auditor. After the audit team has completed their review of all the corrective action and verified implementation and the audit finding/observation report forms have been signed the audit is ready to close.

The audit closure letter acknowledges the Supplier for allowing the audit to take place, it also states that the corrective actions taken and/or planned are acceptable and attaches the signed audit finding/observation report forms to the letter. The closure letter identifies the QA program elements the Supplier is approved for. The letter also states that the complete audit report will be shared with other DOE/NNSA contractors upon request.

The audit closure letter (see Appendix H) formally closes the audit and is sent directly to the Supplier by the Lead Auditor with copies going to the audit team members and the SCQTT Lead for distribution. The following documents are required for entering audit information in the Integrated Supplier Information System (ISIS):

- Notification Letter (unless justification is entered in the evaluation history field of the ISIS record – e.g., lack of lead time)
- List of Entrance and Exit meetings' attendees (separate attendance form or cited in the Audit Report and/or Audit Report Cover Letter)
- Audit Checklist (scan hand written documents)
- Audit Report Cover Letter and/or Audit Report
- Auditee's Response Letter *
- Response Evaluation Letter *
- Close-Out Letter

  * Not required if there are no Findings

Appendix A – Sample Audit Plan

Audit Number: [Lead Auditor assigns this number using contractor's site-specific number log if available; if not assign a number using the calendar year, site name, sequential number (e.g., 2008-ORNL-001)]
Contractor (include point of contact information):
Location of Audit:
Dates of Audit:
Audit Team Members:
Audit Scope: **Technical Requirements:**

Prepared By: _____ **Date:** _____

Approved By: _____ **Date:** _____

Appendix B – Sample Notification Letter

Date

Company's Representative
Company's Name
Address

Dear Mr/Ms./Dr.:

PLANNED QUALITY ASSURANCE AUDIT OF WIDGET EXPRESS CORPORATION ON SEPTEMBER 15-16, 2005

As agreed in an earlier discussion, an audit at your facility is scheduled for September 17, 2005. The purpose and scope of the audit is to determine if Widget Express Corporation has an implemented quality assurance/technical program to (specify requirement criteria). Lead Auditor (name, site represented) and IM Sidekick (Auditor, site represented) and UR Technical (Technical Auditor, site represented) will be the Representatives for this audit. The entrance meeting is scheduled for September 15, 2005, at 8:30 a.m., and the exit meeting is tentatively scheduled for September 16, 2005, at 2:00 p.m. See the attached audit plan for additional information.

Please ensure that adequate facilities are available both for conducting an entrance and exit meeting and for the audit team to caucus and review documents. Please ensure all appropriate documents are available for the auditor's use during the audit. Notify the appropriate cognizant management and other appropriate personnel of the proposed audit schedule.

Please provide an uncontrolled copy of your Quality Assurance Manual to (insert the name, address or email of the Lead Auditor where these documents are to be sent.)

The results of this audit may be shared within the DOE/NNSA complex.

If you have any questions, please call me at (xxx) XXX-XXXX.

Sincerely,

Lead Auditor

cc: Audit Team Member(s)
EFCOG SCQTT Lead

Appendix C – Entrance and Exit Meeting Form

Entrance/Exit Meeting	
Date:	**Supplier Name:** **Address:**
Audit #	

Name	Title/Position	Email address	Work Phone No.

Appendix D – Required Reading Completion Form

Note: This form is to be completed and signed by the Audit Team Member and/or Observer then presented to the Lead Auditor prior to conducting the audit.

Name:
Company:
Document: Energy Facility Contractors Group (EFCOG) Supply Chain Quality Task Team Supplier Evaluation Program, dated May 2008
I have read and understand my responsibilities per my assigned role (i.e., Team Member, Observer) as described in the above document.
Signature _____
Date:

Appendix E – Audit Title Page and Report

Department of Energy (DOE)
Energy Facility Contractor's Group (EFCOG)

Supply Chain Quality Task Team Audit

of

Supplier's Name
Address

Audit No. XXX-XXX-01

Audit Date: XX-XX, XXXX

This document is subject to being shared with other Department of Energy (DOE) Government Owned Contractor Operated facilities; however, it is not approved for release to the public. Therefore, the information contained in this document is not to be disclosed outside of the DOE complex.

[Add Lead Auditor's site-specific disclaimer information as appropriate.]

Appendix E – Audit Title Page and Report (continued)

Company:

Address: **Telephone No.:**

Evaluation Date(s): **Report Date:**

Team Members: **Contact:**

INTRODUCTION

Note the evaluation purpose and scope if it has not already been addressed in the notification letter.

Personnel present during the entrance and exit meeting are as follows:

Name Title Entrance Exit

SUMMARY OF RESULTS

Provide the number of findings and observations.

There were two findings and one observations noted during the course of the At-Site Evaluation.

FINDINGS

A finding is a direct departure from a procedures, regulatory, or contractual requirement. It should be understood that any lack of a finding in a specific area is not considered an indication that deficiencies do not exist. The company should continue its own evaluations to ensure compliance to the (add criteria) and internal QA program requirements.

REQUIREMENT:

FINDING 1:

OBSERVATION:

An observation is a weakness that, if not corrected, could yield a departure from a requirement.

OBSERVATION 1:

Appendix F – Audit Report Letter

Date

Company's Representative
Company Name
Address

Dear Mr./Ms./Dr.:

QA AUDIT OF WIDGET EXPRESS CORPORATION PREFORMED ON SEPTEMBER 15-16, 2005

Thank you for the cooperation extended to the audit team during the subject audit. The management system was documented and effectively implemented to most of (insert evaluation criteria) requirements; exceptions are noted in the attached audit report.

The audit team requests that a written response to each (finding or observation) be made within 20 working days after receipt of this report. The response must include identification of the root cause for each deficiency/finding as well as a description of the corrective action taken (or being taken) to correct immediate problems and to prevent future occurrences, and the date completed or scheduled to be completed. In addition, please identify any lessons learned as a result of this evaluation.

Resolution of the identified findings and objective evidence of implementation will give the audit team the right to enter Widget Express Corporation in into the Integrated Supplier Information Systems (ISIS) as having an implemented QA program to (***National/International QA Program***).

If you have any questions, please contact me at (XXX) XXX-XXXX.

Sincerely,

Lead Auditor

IMC/ATL/xxx

Attachment

cc: Audit Team Members
EFCOG SCQTT Lead

Appendix G – Sample Finding and Observation Report Form

Audit Finding/Observation Report Form

Audit No.	Finding No.	Observation No.	Date
Audited Organization		Lead Auditor	
Person(s) Contacted		Auditor(s)	
Requirement			
Finding/Observation (as Indicated Above)			
Response Required ☐ Yes ☐ No	Acknowledged By	Date	
Corrective Action			
Scheduled Completion Date	Signature/Date		
Corrective Action to Preclude Recurrence			
Scheduled Completion Date	Signature/Date		
Lead Auditor Concurrence With Proposed Corrective Actions		Date	
Corrective Action Verified By		Date	
Lead Auditor		Date	

Audit Finding/Observation Report
Continuation Page

Audit No.	Finding No.	Observation No.

Appendix H – Closure Letter

Date

Company's Representative
Company Name
Address

Dear Mr./Ms./Dr.:

CLOSE-OUT OF QA AUDIT OF WIDGET EXPRESS CORPORATION PERFORMED ON SEPTEMBER 15-16, 2005

Thank you for the final corrective action response to the subject at-site evaluation. Your response has been deemed acceptable and this at-site evaluation is considered closed.

The audit team will be entering Widget Express Corporation in to the Integrated Supplier Information System (ISIS) as having an implemented Quality management system to **(National/International QA program)**.

If you have any questions, please contact me at (XXX) XXX-XXXX,

Sincerely,

Lead Auditor

IMC/ATL/xxx

cc: Audit Team Member(s)
EFCOG SCQTT Lead

Supply Chain Quality Task Team
Joint Audit Schedule
January 20, 2009

Audit Information		Audit Schedule			Audit Team Members		
Supplier & Location	**Audit Scope**	**Audit Planned**	**Audit Performed**	**Audit Closed**	**Audit Team Lead**	**Audit Team Members/Commitments**	**Users**
Flanders Filters Washington, NC	HEPA Filter and Housing Matrix	Jan/Mar 2009 (SRS) May 2009 (WIPP)? 6/2009 (INL) 12/2009 (LANL) 5/2010 (ANL) 5/2010 (PNNL)				**SRS** **INL** **ORNL**	ANL INL LANL PNNL SRS WIPP
Nuclear Filter Technology Golden, CO		Find audit support **Jan 2009 (LANL & SRS)**				**WIPP** **LANL**	INL LANL LLL NSTec Oak Ridge Pentex SRS WIPP
American Air Filter Columbia MO	HEPA Filter and Housing Matrix	Not at this time					BNL LANL LLL NTS ORNL
~~**Camfil Farr Washington, NC**~~	~~HEPA Filter and Housing Matrix~~	~~2/14/09 (?LANL)~~					~~LANL~~
Nova Machining Middleburg Heights, OH		11/2009 (LANL) 11/2010 (ANL)				**SRS** **INL** **ANL**	ANL INL LANL ORNL SRS Pentex WIPP

Audit Information		Audit Schedule			Audit Team Members		
Supplier & Location	**Audit Scope**	**Audit Planned**	**Audit Performed**	**Audit Closed**	**Audit Team Lead**	**Audit Team Members/Commitments**	**Users**
Swagelok **Solon, OH**		1/2009 (LANL) 2/2009 (INL) ANL				**INL** **ORNL?** **ANL**	ANL INL LANL LLL Y12
Energy & Process Corp. **Tucker, GA**	Nuclear Raw Material Matrix	Jan/Mar 2009 (SRS) 3/2009 (LANL) 9/2009 (INL)				**SRS** **INL** **ORNL**	ANL INL LANL LLL SRS
Canberra Industries **Oak Ridge, TN**	Radiation Detection and Analysis Matrix	**TBD**				**ORNL** **SRS**	LLL SRS
Fluke **Everett, WA**		4/2010 (LANL)					BNL LANL LLL WIPP
Canberra Industries **Meriden**	Radiation Detection and Analysis Matrix	8/2009 (LANL) 9/2009 (INL)				**BNL** **INL**	INL LANL WIPP
Petersen Inc **Ogden, UT**	Machine/Fabrication without Design Responsibility Matrix Other?	1/2009 (LANL) 4/2009 (SRS)				**SRS** **INL**	INL LANL LLL SRS WIPP
Matheson Tri-Gas Inc **Neward, CA**						**ORNL ?** **WIPP ?**	LLL ORNL WIPP
Scott Specialty Gases **Longmont, CO**		8/2009 (LANL) 7/2010 (PNNL) WIPP				**LANL?** **WIPP?**	ANL BNL LANL LLL ORNL PNNL PX WIPP
Praxair, Inc						**?**	BNL INL LLL

Audit Information		Audit Schedule			Audit Team Members		
Supplier & Location	**Audit Scope**	**Audit Planned**	**Audit Performed**	**Audit Closed**	**Audit Team Lead**	**Audit Team Members/Commitments**	**Users**
Air Liquide						**?**	ANL LLL PNNL WIPP
Central Research Lab **Red Wing, MN**		6/2010 (LANL) 7/2010 (INL)				**?**	INL LANL LLL
Skolnik Industries **Chicago, IL**		Target March 2009 (LANL) Schedule with PMC				**SRS** **WIPP** **ANL**	LANL **SRS** **WIPP** **ANL**
Myers **(define location)** **Grief** **(define location)** **Ionex** **Lafayette, CO**		Myers - 8/2009 (LANL) Grief - 1/2010 (LANL)- Ionex - 9/2009 (LANL)				**Not at this time**	INL LANL
Ludlum **Sweetwater, TX**		6/2009 (LANL) WIPP				**LANL?** **WIPP ?**	LANL WIPP

EM Project Area 2 – Adequate NQA-1 Suppliers
Project Milestone Task 2.13

Scope of Project Milestone Task 2.13:
Evaluate the possibility of integrating EM procurement activities with other supplier initiatives such as Nuclear Energy Institute (NEI), Nuclear Utilities Procurement Issues Committee (NUPIC), Nuclear Industry Audit Committee (NIAC), etc.

Evaluation Summary:

An evaluation of the supplier qualification activities associated with NEI, NUPIC and NIAC were evaluated with the following results:

- NEI is the policy organization of the nuclear energy and technologies industry. NEI does not participate in the qualification of nuclear suppliers nor do they maintain any type of approved suppliers listing for the industry.

- NUPIC was founded in 1989 by the nuclear utility industry for the purpose of performing joint supplier audits and sharing procurement issues. NUPIC membership is restricted to USNRC 10CFR50 licensees and international nuclear utilities. NUPIC performs joint supplier audits and shares the results with members. NUPIC does not maintain an "Approved Supplier List". Each member utility is responsible for evaluation the NUPIC audits prior to their use of the suppliers.

- NIAC is an organization whose membership consists of nuclear suppliers, both commercial and government companies. NIAC's purpose is to share audit results among its membership. NIAC does not perform joint audits nor do they maintain an "Approved Supplier List". Audits are performed by Certified Lead Auditors under the auditing company's QA Program and procedures. Audit reports may be shared by members if the audited supplier approves a request for the audit to be shared. Many DOE EM contractors are members of NIAC.

Recommendation:

Implement a joint supplier audit process, including the sharing of audit results, as recommended in Task 2.10 and 2.12. Further recommend that EM encourage their contractors to participate in NIAC. Typically, a company can obtain 4 audit reports through NIAC for every 1 supplier audit they perform. A reduction in the number of supplier audits by a ratio of 4 to 1 when using NIAC can create considerable cost savings.

EM Project Area 2 – Adequate NQA-1 Suppliers
Project Milestone Task 2.14

Scope of Project Milestone Task 2.14:
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.

Evaluation Summary:

In response to a Department of Energy (DOE) Environmental Management (EM) challenge to improve quality assurance performance across its operations, the EM/Energy Facility Contractors Group (EFCOG), in cooperation with EM senior leaders, developed a Quality Assurance Improvement Project Plan. During the evolution of the Project Plan, one of the tasks assigned to EM Project Area 2 – NQA-1 Suppliers was the development of a formal process for an "Alert" system for documenting and notifying the EM-complex and other DOE offices of nuclear suppliers who fail to meet the QA requirements defined in 10CFR830, DOE Order 414.1.c or NQA-1. The Alert system is intended for findings or nonconformances that are determined to be significant as defined by NQA-1 and that could have a wide-ranging impact throughout EM, throughout DOE or even throughout the industry. Examples of findings that should be considered for an Alert include, but are not limited to: failure to implement major portions of the supplier's QA program; delivery of defective safety class or safety significant structures, systems or components; and, delivery of suspect/counterfeit items. The intended scope of the Alert system includes both nuclear grade equipment and service suppliers.

The Alert system does not relieve the contractor(s) of the responsibility to assess their quality suppliers regularly in accordance with their established supplier qualification program.

Contractors should protect the information under consideration for an Alert during the entire process.

Recommendation:

It is recommended that EM adopt the process described below as their Supplier Alert System and convert this information into a formal EM procedure for implementation across the EM-complex. The process should undergo DOE legal review to ensure that there will be no legal/liability issues arising from the issuance of the Alerts.

The following defines the Alert process. These steps follow the process flow as illustrated in Figure 1.

Step 1

Contractor identifies supplier's failure to meet QA requirements. Methods whereby a supplier's failure to meet QA requirements might be identified are audits, surveillances, inspections, or supplier submittals of Nonconformance Reports (NCR). However, in some cases other events, such as a whistleblower activities followed by a formal investigation, may initiate this process.

An audit or surveillance performed for the initial qualification of a supplier would typically not trigger this process, unless that supplier has already delivered items or services to other EM contractors. In those cases an Alert may be warranted. NCRs that are repetitive or critical in nature may prompt an Alert.

Step 2

The contractor is responsible for initially determining the significance of an identified issue/finding based on the criteria and requirements of their corrective action program. Contractors' are also responsible for initially determining if an "alert" should be issued based on the guidance given in this process plan. Examples of significant issues are vendor removed from ASL (Approved Supplier List), falsified documents, SCAQ (Significant Condition Adverse to Quality), repetitive quality issues, etc.

If the contractor determines that the issue does not warrant an alert, the issue is processed through the organization's established corrective action process.

Step 3

If the contractor determines that the issue does warrant an alert, the contractor shall immediately draft Alert per this procedure. The draft Alert should only contain the facts of the case without speculation as to causes, impacts, etc. The contractor should notify the supplier that their quality issues are under consideration for a possible Alert within EM. (A suggested Alert Form is attached)

Step 4

The contractor submits the draft Alert to the site's DOE EM QA Representative for review and concurrence. The submittal of the draft Alert shall occur within five (5) days of the contractor determining that an Alert is warranted.

Step 5

The site's DOE EM QA Representative reviews the draft Alert and discusses the information with the contractor as necessary. If the local EM QA representative concurs that the Alert is necessary and the documentation is complete, the Alert is forwarded to EM HQ. If the local EM QA representative determines that the issue is not significant or has comments, the Alert is returned to the contractor for disposition or revision as necessary.

Step 6

The site's DOE EM QA Representative promptly forwards the draft Alert to DOE EM Headquarters for review and concurrence.

Step 7

DOE HQ EM QA Representative reviews the draft Alert and discusses the information with the site's DOE EM QA Representative and contractor, as necessary. If the HQ EM QA representative concurs that the Alert is necessary and the documentation is complete, the process continues. If the HQ EM QA representative determines that the issue is not significant or has comments, the Alert is returned to the originating site for disposition or revision as necessary.

Step 8

DOE HQ EM finalizes the Alert and distributes the Alert within five (5) days of receipt of the draft Alert. DOE HQ EM ensures the Alert Notice receives legal review by the Office of Chief Council prior to issuance.

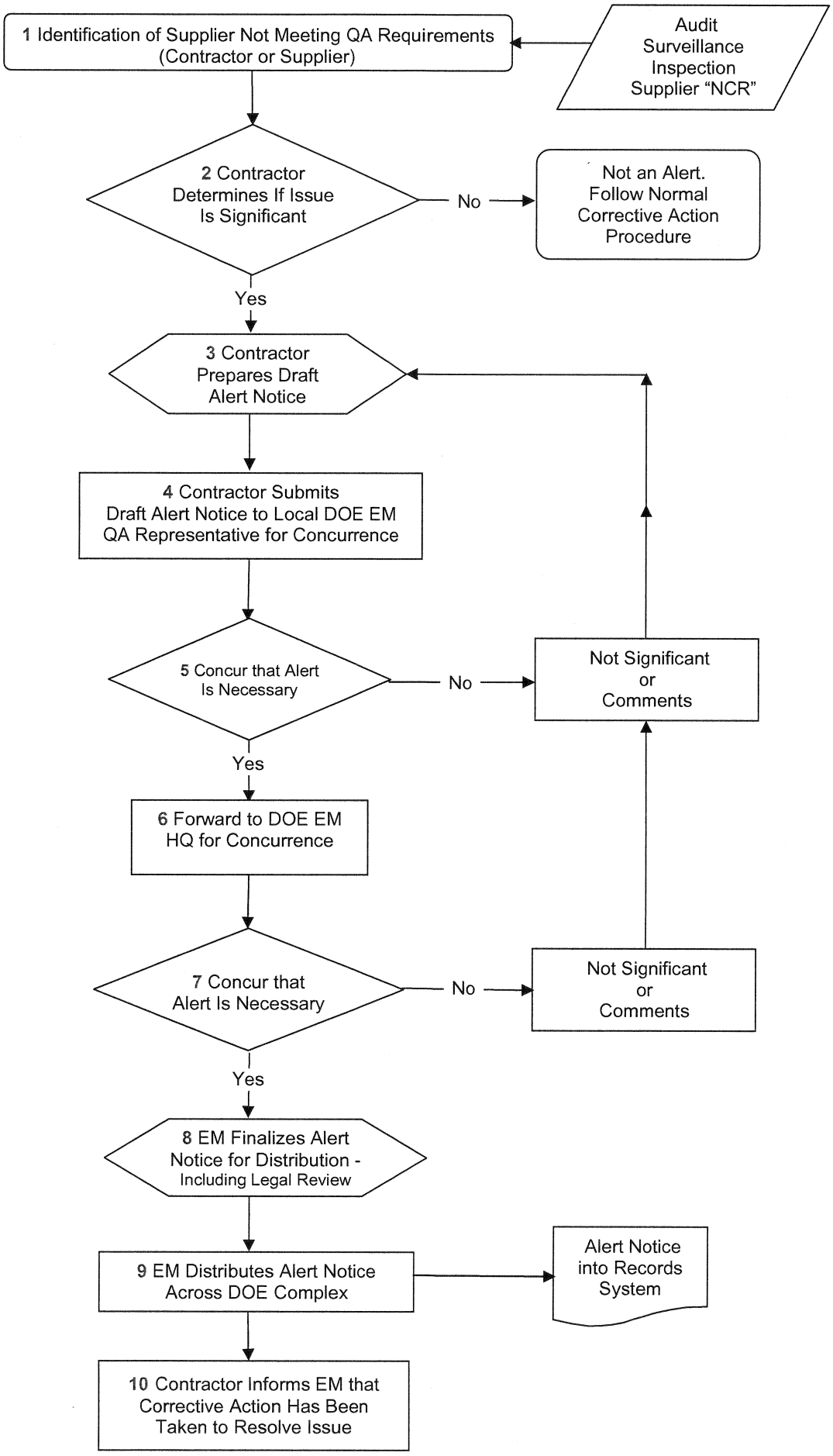
Step 9

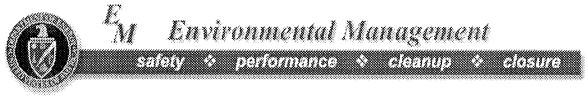
DOE HQ EM distributes the Alert Notice across the EM complex per a standard distribution list. Distribution includes DOE HSS for possible distribution across the DOE Complex, if warranted. If the issue could have implications beyond DOE, DOE HQ EM will notify other agencies as necessary. The Alert is entered into a records system at DOE HQ EM. Any supporting documentation is included to make a complete and retrievable record.

Step 10

The Contractor who identified the supplier issues that resulted in an Alert being issued is responsible for notifying EM when adequate corrective actions have been taken to resolve the issue. EM will provide this update to the organizations/individuals on the standard Alert distribution list.

Supplier QA Alert Process Flowchart





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Nuclear Suppliers ALERT

[Quality Assurance Concern]

No. **Date:**

PURPOSE:

BACKGROUND:

IMPLICATIONS:

RECOMMENDED ACTIONS:

POINT OF CONTACT:

Energy Facility Contractors Group

Office of Environmental Management
And
Energy Facility Contractors Group

Quality Assurance
Improvement Project Plan

Project Focus Area	Task # and Description	Deliverable
Project Area 3- Commercial Grade Item and Services Dedication Implementation	Task #3.4: Provide EM for review and concurrence recommended baseline requirements/guidance actions considered necessary for implementation of an effective CGI/Services dedication process within EM nuclear facilities.	Recommendation to EM

Approvals:	Yes/No/NA
Project Managers: S. Waisley, D. Tuttel (3/12/09)	Yes
Executive Committee: D. Chung, J. Yanek, N. Barker, D. Amerine	Yes
EM QA Corporate Board:	Yes

ATTACHMENT XXX-COMMERCIAL GRADE ITEM/SERVICES DEDICATION

Requirements:
Section 7.7 of the Environmental Management Quality Assurance Plan illustrates the relationship between Performance/Criterion 7-Procurement requirements and the ASME NQA-1 requirements used to implement them. To support standardized implementation of a commercial grade item/services dedication process by EM sites, the following additional requirements apply:

a. The Commercial Grade Item/Services dedication process shall be described in the DOE-approved QIP.
b. The Commercial Grade Item/Services dedication process shall be based on ASME NQA-1-2004, Requirement 7, Section 700 and Nonmandatory Appendix 7A-2.

Note: A more recent version of NQA-1 supplemented by an alternate guideline (i.e., EPRI NP 5652) may be used if approved by DOE in the QIP and determined consistent with the DOE EM Corporate QAP issued by the Deputy Assistant Secretary, Safety Management and Operations.

c. Technical evaluations for CGI/Services dedication shall be performed and documented by the appropriate technical authority for the item/service being dedicated.
d. Critical characteristics (i.e., dimension, configuration, material and operability) for CGI/Services dedication shall be determined and documented by the appropriate technical authority for the item/service being dedicated.
e. Acceptance method/criteria for critical characteristics shall be determined and documented by the appropriate technical authority for the item/service being dedicated.
f. Personnel responsible for performance and implementation of the CGI/Services dedication process shall be trained to develop the necessary skills to effectively execute the process.

GENERAL INFORMATION

Management Expectation:

The contractor's Commercial Grade Item/Services Dedication process shall be consistent with requirements established in this attachment, shall be described in the approved QIP, and effectively implemented for commercial items/services supporting nuclear safety applications.

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Quality Assurance
Improvement Project Plan

Project Focus Area	Task# and Description	Deliverable
Project Focus Area #5: Line Management Understanding of QA and Oversight	Task #5.8: Assessment Expectations for Federal Project Directors (FPDs) and Integrated Project Teams (IPTs) Review Attributes/Characteristics	Phases I, II, and II Project Requirements Tables for Quality Assurance Activities: Quality program definition, Performance, and Improvement

Approvals Needed:	Yes/No/NA
Project Managers: S. Waisley, D. Tuttel (3/6/09)	Y
Executive Committee: D. Chung, J. Yanek, N. Barker, D. Amerine	Y
EM QA Corporate Board:	Y

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

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

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

Energy Facility Contractors Group

Office of Environmental Management
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Quality Assurance
Improvement Project Plan

Project Focus Area	Task# and Description	Deliverable
Project Focus Area #5: Line Management Understanding of QA and Oversight	Task #5.8: Assessment Expectations for Federal Project Directors (FPDs) and Integrated Project Teams (IPTs) Review Attributes/Characteristics	Critical Decision (CD) Tables w/ Requirements and Performance Objectives, Measures, & Commitments (POMCs)

Approvals Needed:	Yes/No/NA
Project Managers: S. Waisley, D. Tuttel (3/6/09)	Y
Executive Committee: D. Chung, J. Yanek, N. Barker, D. Amerine	Y
EM QA Corporate Board:	Y

Assessment Expectations for Federal Project Directors (FPDs) and Integrated Project Teams (IPTs)
Review Attributes and Characteristics

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

CD-1 Requirements – Quality Assurance Activities			
DOE G 413.3-2	**QA Criterion (DOE O 414.1C)**	**CD-1 Requirements**	**Performance Objectives, Measures & Commitments (POMC)**
CD-1, Approval of Alternative Selection and Cost Range	Work Processes Documents & Records Design Procurement	-Conceptual Design Rpt. -Acquisition Strategy -Preliminary Project Execution Plan (PEP) -Line-Item Projects and Long-Lead Procurements	Verify that processes for preparing, reviewing, approving, issuing, using, and revising the Conceptual Design Report, Acquisition Strategy, PEP, line-item projects/long-lead procurements are described and implemented.
			Determine that a design process is implemented providing control of design inputs, outputs, verification, and configuration and design changes, including technical and administrative interfaces. Determine that design activities are verified and documented. Determine that significant QA participation is emphasized in the development and review of the Preliminary Project Execution Plan.
			Determine that a procurement (acquisition) process to ensure items and/or services provided by suppliers meets the requirements and expectations of the end user is developed and implemented and that quality level determination are factored into the acquisition strategy, especially when procuring services to perform work. Verify that QA personnel are utilized to assist with procurement (acquisition) planning.
			Ensure that work processes consist of a series of actions planned and carried out by qualified personnel using approved procedures, instructions, and equipment under administrative, technical, and environmental controls.
CD-1, Approval of Alternative Selection and Cost Range	Personnel Training & Qualification	-Federal Project Director Appointment -Integrated Project Team	Verify that policies and procedures that describe personnel selection, training, and qualification requirements for a Federal Project Director and the Integrated Project Team (IPT) are developed and implemented. Ensure that a QA representative is a member of the IPT.
			Determine that sufficient quality resources are planned and included in project baseline to support quality systems, processes, and procedures required for design work after CD-1 approval.
CD-1, Approval of Alternative Selection and Cost Range	Work Processes Documents & Records	-Environmental Documents and Permit Applications -Hi-Performance Building Considerations -Security Vulnerability Assessment Report -IT Projects -Conceptual Safety Design Rpt. for Hazard 1/2/3 Nuclear Facilities -Preliminary Hazard Analysis Report -Preliminary Safety Validation Report	Verify that processes for preparing, reviewing, approving, issuing, using, and revising documents that prescribe processes, requirements, and design are described and implemented.
			Verify that procedures, work instructions, or other appropriate means used to define work processes are documented and controlled.
			Verify that processes for specification, preparation, review, approval, and maintenance of records are developed and implemented.

CD-1 Requirements – Quality Assurance Activities (Cont'd)			
CD-1, Approval of Alternative Selection and Cost Range	Program Management Assessment	-QA Program Acceptability and Applicability	Verify that the QA Program describes the organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work. Verify the adequate resources have been identified for quality program activities, such as planning, auditing, supplier qualification, technical document review, inspection, calibration, etc. Verify that managers at every level periodically assess their organizations and functions to determine how well they meet customer and performance expectations and mission objectives, identify strengths or improvement opportunities, and correct problems.

CD-2 Requirements – Quality Assurance Activities			
DOE G 413.3-2	**QA Criterion (DOE O 414.1C)**	**CD-2 Requirements**	**Performance Objectives, Measures & Commitments (POMC)**
CD-2, Approval of Performance Baseline	Program Work Processes Documents & Records Design	-Performance Baseline -Project Execution Plan -Cost Estimate for Major System Projects -Preliminary Design -Preliminary Safety Design -Hazard Analysis -Preliminary Security Vulnerability Assessment Report -IT Projects -Safety Validation Report -Preliminary Environmental Stewardship -Final NEPA Documentation -QA Program	Verify that the QA Program describes the organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work.
			Verify that processes (which adequately addresses hazards) for grading the application of requirements are implemented.
			Verify the processes are implemented for personnel to achieve initial proficiency; maintain proficiency; and adapt to changes in technology, methods, or job responsibilities.
			Verify that processes for document preparation, review, approval, and change control are implemented. Verify that processes for specification, preparation, review, approval, and maintenance of records are implemented.
			Verify that work processes consist of a series of actions planned and carried out by qualified personnel using approved procedures, instructions, and equipment under administrative, technical, and environmental controls.
			Verify that processes for appropriate control of design inputs, outputs, verification, configuration and design changes, and technical and administrative interfaces are implemented. Verify that processes for verification of design activities are implemented.
			Verify that software quality assurance process implementation is performed in accordance with the Corporate DOE Office of Environmental Management Quality Assurance Program.
CD-2, Approval of Performance Baseline	Management Assessment Independent Assessment	-Performance Baseline Validation -Independent Cost Review for Major System Projects -Design Review of Preliminary Design -QA Prog. Acceptability/ Applicability -Quality Improvement	Verify the adequate resources have been identified for quality program activities, such as planning, auditing, supplier qualification, technical document review, inspection, calibration, etc.
			Verify that persons conducting reviews are technically qualified and knowledgeable in the areas to be reviewed.
			Verify that persons conducting independent reviews have sufficient authority and freedom from line management.
			Verify that processes to plan and conduct independent reviews to measure item and service quality and the adequacy of work performance and to promote improvement are implemented.
			Verify that processes for specification, preparation, review, approval, and maintenance of records are developed and implemented.

CD-3 Requirements – Quality Assurance Activities			
DOE G 413.3-2	**QA Criterion (DOE O 414.1C)**	**CD-3 Requirements**	**Performance Objectives, Measures & Commitments (POMC)**
CD-3, Approval of the Start of Construction	Program Personnel Training & Qualification Documents & Records Design	-Final Design -CD-2 Project Documentation -Preliminary Documented Safety Analysis Report -DOE Approval of Updated Hazard Analysis Report -Updated Preliminary Security Vulnerability Assessment Report -Updated Cyber Security Plan for IT Projects -Safety Evaluation Report Preparation -Construction Project Safety and Health Plan Preparation -Final Environmental Stewardship	Verify that design processes use sound engineering/scientific principles and appropriate standards; incorporate applicable requirements and design bases in design work and design changes; identify and control design interfaces; verify/validate the adequacy of design products using individuals or groups other than those who performed the work; verify/validate work before approval and implementation of the design.
			Verify that applicable design inputs (such as design bases, conceptual design reports, performance requirements, regulatory requirements, codes, and standards) are controlled and documented and changes from approved design inputs and reasons for the changes are identified, approved, documented, and controlled.
			Verify that processes for preparation, review, approval, issuance, use, and revision of documents that prescribe processes, requirements, and design are implemented.
			Verify that processes (which adequately addresses hazards) for grading the application of requirements are implemented.
			Verify that processes for specification, preparation, review, approval, and maintenance of records are implemented.
			Verify that suspect/counterfeit item process prevention is developed and implemented in accordance with the Corporate DOE Office of Environmental Management Quality Assurance Program.
			Verify the processes are implemented for personnel to achieve initial proficiency; maintain proficiency; and adapt to changes in technology, methods, or job responsibilities.
CD-3, Approval of the Start of Construction	Management Assessment Independent Assessment	-External Review for Construction or Execution Readiness -QA Program for Construction, Field Design Changes, and Procurement Activities	Verify that processes to plan and conduct independent reviews to measure item and service quality and the adequacy of work performance and to promote improvement are implemented.
			Verify that persons conducting reviews are technically qualified and knowledgeable in the areas to be reviewed.
			Verify that persons conducting independent reviews have sufficient authority and freedom from line management.
			Verify that managers at every level periodically assess their organizations and functions to determine how well they meet customer and performance expectations and mission objectives, identify strengths or improvement opportunities, and correct problems.

CD-4 Requirements – Quality Assurance Activities			
DOE G 413.3-2	**QA Criterion (DOE O 414.1C)**	**CD-4 Requirements**	**Performance Objectives, Measures & Commitments (POMC)**
CD-4, Approval of the Start of Operations or Project Completion	Quality Improvement Work Processes Independent Assessment	-Verification of Key Performance Parameters -Readiness Assessment or Operational Readiness Review	Verify that processes to identify, control, and correct items, services, and processes that do not meet established requirements are implemented.
			Verify that work is performed consistent with technical standards, administrative controls, and hazard controls adopted to meet regulatory or contract requirements using approved instructions, procedures, etc.
			Ensure that the planned scope of work demonstrates that work prerequisites have been satisfied, personnel have been suitably trained and qualified, detailed implementing documents and management controls are available and approved.
			Verify that persons conducting reviews are technically qualified and knowledgeable in the areas to be reviewed.
CD-4, Approval of the Start of Operations or Project Completion	Program Documents and Records Work Processes Design Inspection and Acceptance Testing	-Checkout, Testing, and Commissioning Plan -Transition to Operations Plan -Update of QA Plan -EM System Revision -Safety Analysis Reports Preparation -Construction Project Safety & Health Plan Update -Final Hazard Analysis Report -Final Security Vulnerability Assessment Report -Final Cyber Security Plan	Verify that processes for preparation, review, approval, issuance, use, & revision of documents that prescribe processes, requirements, and design are implemented.
			Verify that actions are planned and carried out by qualified personnel using approved procedures, instructions, and equipment under administrative, technical, and environmental controls.
			Verify that applicable design inputs (i.e., design bases, conceptual design reports, performance requirements, regulatory requirements, codes, and standards) are controlled and documented and changes from approved design inputs and reasons for the changes are identified, approved, documented, and controlled.
			Verify that design processes that provide appropriate control of design inputs, outputs, verification, configuration and design changes, and technical and administrative interfaces are implemented.
			Verify that processes for specification, preparation, review, approval, and maintenance of records are implemented.
			Verify that performance expectations, acceptance criteria, inspections and tests, & hold points are identified/considered early in design process and/or specified in the design output and procurement documents. Address calibration of measuring/testing equipment.
			Verify that processes to implement a quality management approach are established and implemented.
			Verify that the QA program describes the established organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work.
			Verify that processes to implement a quality management approach are established and implemented.
			Determine that sufficient quality resources are planned and included in the project baseline to support quality systems, processes, and procedures required for design work after CD-1 approval.

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

OECM = Office of Engineering and Construction Management

Proposed Standard Quality Assurance (QA) Language for EM Nuclear Contracts

The Contractor shall implement a DOE-approved Quality Assurance Program (QAP) (Deliverable X.X.X.X) in accordance with the EM Quality Assurance Program, EM-QA-001, prior to commencement of work affecting nuclear safety. The EM QAP provides the basis to achieve quality across the EM complex for all mission-related work while providing a consistent approach to Quality Assurance (QA).

EM requires that American Society of Mechanical Engineers (ASME) NQA-1, 2004, *Quality Assurance Requirements for Nuclear Facility Applications*, and addenda through 2007 be implemented as part of the Contractor's QA Program for work affecting nuclear safety. The required portions of NQA-1 to be implemented include: Introduction, Part I, and Part II. NQA-1 Parts III and IV are to be used as guidance for the Contractor's QAP and implementing procedures. The requirements contained within this document apply to EM (HQ), EM Field/Project Offices, and contractors as applicable to the work being performed by each entity.

Contractors have three options for complying with this contract requirement:

1. Develop and submit for DOE approval a new QAP;
2. Adopt the prior Contractor's DOE-approved QAP; or,
3. Modify the prior Contractor's DOE-approved QAP and submit it for DOE approval.

Development of a new QAP, or adoption of an existing or modified version of a QAP from a prior contractor, does not alter a contractor's legal obligation to comply with 10 CFR 830, other regulations affecting quality assurance (QA) and DOE Order 414.1C.

The Contractor's QAP shall describe the overall implementation of the EM QA requirements and shall be applied to all work performed by the Contractor (e.g., research, design/engineering, construction, operation, budget, mission, safety, and health).

The Contractor shall develop and implement a comprehensive Issues Management System using a "zero-threshold" level for the identification, assignment of significance category, and processing of nuclear safety-related issues identified within the Contractor's organization. The significance assigned to the issues shall be the basis for all actions taken by the contractor in correcting the issue from initial causal analysis, reviews for reporting to DOE, through completion of Effectiveness Reviews if required based on the seriousness of the issue.

The Contractor shall, at a minimum, annually review and update as appropriate, their QAP. The review and any changes shall be submitted to DOE for approval. Changes that reduce the level of commitments affecting nuclear safety shall be approved before implementation by the Contractor.