EM QUALITY ASSURANCE CORPORATE BOARD MEETING
Atlanta, Georgia
November 13 -14, 2008

Key Workshop Objectives:

1. Provide Board Members an Overview and Progress Accomplished with Actions from the 2nd Corporate Board Meeting on July 29-20, 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.

4. Discuss with Board Members the Results and Lessons Learned of the EM QA Corporate Performance Metrics Pilot Tests.

Desired Outcomes:

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

2. Executive Corporate Board Members Vote on the Proposed Path of QAP Implementation Path Forward for EM/HQ and Field Sites.

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

EM QUALITY ASSURANCE CORPORATE BOARD MEETING

Meeting Location: Renaissance Concourse Hotel Atlanta Airport, One Hartsfield Centre Parkway Atlanta, Georgia 30354 Main Number: 404-209-9999		
Room: Shannon One and Two		
DRAFT AGENDA for November 13, 2008		
8:00	**COFFEE**	**ALL**
8:30	Welcome and Opening Remarks	Dae Chung (EM/HQ) Joe Yanek (Fluor)
8:45	Introduction of Board Members and Other Participants; Agenda; and Logistics	Sandra Waisley (EM/HQ)
9:00	Lessons Learned: Signs of a Weak Quality Assurance Program	Mike Mason (Bechtel)
10:00	**Break**	**ALL**
10:15	EM/EFCOG Quality Assurance Improvement Project Review and Discussion of Completed Deliverables/Products: • Progress Report on Actions from 2nd Corporate Board Meeting • #1: Requirements Flow Down Project Action Plan - BNI Broad Based Review at WTP (Dave Jantosik) • #2: Adequate NQA-1 Suppliers Project Action Plan	 Sandra Waisley (EM/HQ) Dave Tuttel (EFCOG/WSRC) Butch Huxford(EM/HQ) Alice Doswell (Parsons) Bill Rowland (EM/SRS) Rich Campbell (Energy*Solutions*)
12:00	**LUNCH**	**ALL**
1:15	EM/EFCOG Quality Assurance Improvement Project Review and Discussion of Completed Deliverables/Products: • #3: Commercial Grade Dedication Implementation Project Action Plan • #4: Graded Approach to Quality Assurance Project Action Plan • #5: Line Management Understanding of QA and Oversight Project Action Plan	 Pat Carier (EM/ORP)* Shelby Turner (CH2M HILL) Al Hawkins (EM/RL)* Vince Grosso (WSRC/SRS) Steve Piccolo (URS/WGI) TJ Jackson (EM/CBC) Dave Hall (URS-WGH)
3:15	**Break**	**ALL**
3:30	Commercial Grade Dedication Discussion and Lessons Learned	John Adkins (Southern Co.)
4:30	LANL Lessons Learned: Chemistry and Metallurgy Research Replacement Facility Project QA Issues	Tim McEvoy (BNI, LANL QA Director)
5:00	**Adjourn: End Full Board Session**	**Dae Chung**
6:00 – 9:00	**Reception – DeGaulle Room**	**ALL**

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Meeting Location: Renaissance Concourse Hotel Atlanta Airport, One Hartsfield Centre Parkway Atlanta, Georgia 30354 **Main Number: 404-209-9999**		
Room: Shannon One and Two		
DRAFT AGENDA for November 14, 2008		
8:00	**COFFEE**	**ALL**
8:30	Opening Remarks	Dae Chung, (EM/HQ)
8:40	Progress Report on EM QA Improvement Initiatives: • EM QA Training Academy Course Feedback • Contract QA Language Strawman • Site QA Resources Summary	Dave Faulkner (EM/HQ) J. Craig (EMCBC)/J. Yanek (Fluor) Bob Toro (EM/HQ)
9:15	Corporate QA Performance Metrics Discussion and Results of Field Pilot Tests at Portsmouth/Paducah and Richland	Jim Davis (EM/HQ) Mike Hassell (WCH) Bill Murphie (PPPO)
10:00	**Break**	**ALL**
10:30	EM Corporate QA Program Implementation and Impact on Field Sites – Phased Approach	Bob Murray (EM/HQ)
11:30	Next Steps/Actions • Contractor Perspectives/Observations/Lessons Learned/Heads Up • Discuss/Finalize High Priority Action Items • Discuss Next Meeting Date/Logistics	EM Contractor Community Sandra Waisley (EM/HQ) Sandra Waisley (EM/HQ)
12:00	**Adjourn: End Full Board Session**	**Dae Chung**

* Pat Carier and Al Hawkins are not able to attend

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Energy Facility Contractors Group

Project Focus Area #1

FLOW DOWN OF DOE EM QA REQUIREMENTS – A MODEL

Atlanta, GA
November 13, 2008

Team Members

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

Additional Resources

- Tilak Verma and Juan Hernandez – Energy Solutions

Team Objectives

- Identify the process for ensuring appropriate quality assurance (QA) requirements are flowed down to suppliers and subcontractors - Deliverable: Flow diagram

- Develop approaches to provide assurance of the effectiveness of requirements flow-down processes - Deliverable: White paper explaining key attributes of the flow diagram

Quality Assurance Program Requirements - per NQA-1

- QA Requirements shall be specified in the procurement documents
- These requirements shall be consistent with the importance and/or complexity of the item or service being procured
- The procurement documents shall require the Supplier to incorporate appropriate QA requirements in sub-tier procurement documents

Objective 1- A Model

1. DOE Specification of QA Requirements for Nuclear Facilities conveyed by contract
2. Contractor identification of SSC/Service Significance
3. Contractor application of Graded Approach based on Significance
4. QA Flow-down to Suppliers and Sub-tier Suppliers
5. Supplier Evaluations (Pre-award capability determination)
6. Supplier/Sub-tier Supplier Oversight (Post-award compliance)
7. Off the Shelf / CGI Dedication

Model Assumptions

- Initial Quality Assurance Plan (QAP) approved by DOE and is in accordance with NQA-1 requirements
- Implementing procedures for functional classification are consistent with approved Safety Documentation
- Prime Contractors have developed implementing procedures for assigning quality levels based upon functional classification and other risk factors.

DOE Selection of QA Program Requirements for Nuclear Facilities

- Consistent Flow Down of QA requirements to all DOE Contractors
  - NQA-1 2004 is the Quality Standard consistent with the DOE-HQ QAP
  - Use QA Rule with Quality consensus standard
- Update contracts as needed

Contractor (Supplier) identification of SSC Significance

- Analyze Project/Facility SSCs and identify Safety Significance
  - e.g., Safety Analysis Report, Q-List
- Assign Quality Levels, e.g.,

QL-1	QL-2	QL-3
Safety Class	Safety Significant	Mission / Operations Important

Application of Graded Approach based on Significance

QL-1 or 2	- NQA-1 and - Compliance with independent verification requirements in National Consensus Standards (e.g., ASME Section VIII, AWS D.1.1, ASME B 31.3, etc.)
QL-3	- Tailored NQA-1 or ISO 9001 appropriate with Commercial Quality - Compliance with independent verification requirements in National Consensus Standards (e.g., ASME Section VIII, AWS D.1.1, ASME B 31.3, etc.)

QA Program Flow-down to Sub-tier Suppliers

For QL-1,2, & 3

- Develop consistent stand alone QA Specifications, or other approved standard methodology (e.g., CSI)
  - Flow-down applicable QA requirements
    - Applicability of QA requirements is based on scope, not on Quality Levels
  - Require flow down to sub-tier suppliers

Supplier Evaluations (Pre-award capability determination)

- Use evaluation methods described by NQA-1:
  - Direct
  - QA Records
  - Supplier History
- Require Direct Evaluation for QL-1 or 2 Suppliers for Engineered Items (that do not meet CGI definition)
- In the Project/Facility QA Program documents, define when National Accreditations may be acceptable for subcontractors providing services, such as for a Testing Laboratory

Supplier Evaluations (Pre-award capability determination)

- Business factors such as limited number of suppliers, prior performance history, etc. may drive increased effort to mentor suppliers to satisfy initial QA capability requirements
- QA needs to be part of the technical bid evaluation process for supplier selection

Supplier Oversight (Post-award compliance)

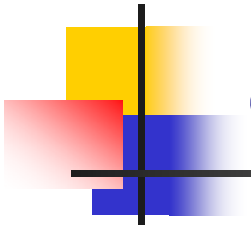
- Use the methods of acceptance described in NQA-1:
  - Source Verification
  - Receiving Inspection
  - Certificate of Conformance
  - Post-Installation Testing, or
  - A combination
- Require Source Verification for QL-1 and QL- 2 Engineered Items

Supplier Oversight (Post-award compliance)

- Requires early involvement with suppliers to ensure flow down requirements are clearly understood (e.g., kick-off meeting)
- Recognize need for increased QA resources to work with critical suppliers and sub-tiers during implementation
- Use a variety of tools including submittals, hold points, sub-tier audits, etc., to verify implementation of QA requirements prior to product acceptance

Off the Shelf / CGI Dedication

- Follow approved CGI Dedication Process
- Use Evaluated QL-1 or QL-2 Suppliers to perform additional Testing/Analysis as needed



Questions & Comments

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FCOG

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Project Focus Area #2

Adequate NQA-1 Suppliers

EM QA Corporate Board Meeting
Atlanta, Georgia
November 13-14, 2008

Team Members

- Team Leads:
  - Bill Rowland, DOE – SRS
  - Rich Campbell, Energy*Solutions*
- Team members:
  - Lynne Drake, SRNS
  - Cathy Nesser, WTS
  - Steven Stein, BNL
  - Robert Thompson, ICP
  - Paula Richards, Isotek

Background

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

Background (Cont'd)

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

Scope

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

Actions / Status

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

  Status: Complete

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

  Status: Complete

Actions / Status

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

  Status: Complete

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

  Status: Complete

Actions / Status

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

  Status: Complete

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

  Status: Complete

Actions / Status

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

  Status: Complete Held the DOE Nuclear Suppliers Outreach Event on July 31, 2008 in Denver, CO

- Task 2.8: Evaluate the applicability and completeness of the common commodities/ items/ services listing provided by the major EM contractors

  Status: Complete

Actions / Status

- Task 2.9: Evaluate inputs to determine if there are common suppliers being used for nuclear grade procurements within EM. Identify redundant supplier audits being performed by major EM contractors

  Status: Complete

- Task 2.10: Evaluate impact of “Buy American” clause on efforts to expand the supplier base within EM Program

  Status: Complete

Actions / Status

- Task 2.11: At the site level conduct a small business nuclear QA reach-out symposium similar to the EM Nuclear Protégé program.

  Status: In progress

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

  Status: In Progress

Actions / Status

- Task 2.13: Determine the feasibility of EM contractors performing joint audits of common suppliers. If feasible, recommend procedure and checklist requirements that would be needed to implement

  Status: In Progress

Actions / Status

- Task 2.14: Evaluate the possibility of integrating EM procurement activities with other supplier initiatives such as NEI, NIAC, NASA, etc.

  Status: In Progress

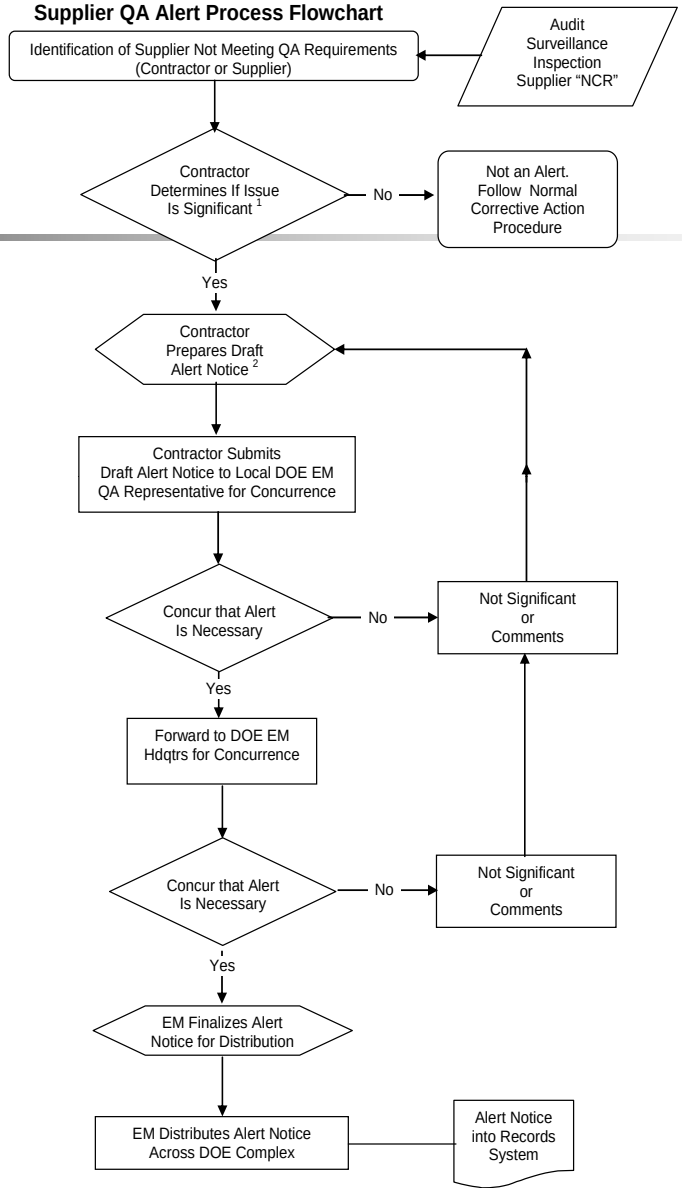
- Task 2.15: Develop a formal process or “alert” system for documenting and notifying the EM-complex and other DOE offices of nuclear suppliers not meeting QA requirements

  Status: In progress

Task # 2.15

DRAFT

Supplier QA Alert Process Flowchart



[1] Examples of significant issues are: Removed from ASL (Approved Supplier List), Falsified Documents, SCAQ (Significant Condition Adverse to Quality), etc.

[2] ALERTS only contain facts regarding failure to meet QA requirements.

Actions / Status

- Task 2.16: Provide draft deliverables and/or recommendations to Project Managers and Project Focus Area Leads for review and comment

  Status: Not Started

- Tasks 2.17 & 2.18: Receive and resolve comments from Project Managers and Project Focus Area Leads

  Status: Not Started

Actions / Status

- Task 2.19: Provide revised draft report to Project Executive Committee for review and comment

  Status: Not Started

- Tasks 2.20 & 2.21: Receive and resolve comments from Project Executive Committee

  Status: Not Started

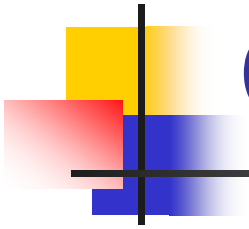
Actions / Status

- Task 2.22: Submit final report to Project Managers

  Status: Not Started

Challenges / Barriers

- Maintaining momentum, focus and resources to complete task on schedule.
- Obtaining buy-in from EM contractors to change process.
- Convincing new suppliers to enter nuclear supply chain. DOE competing with commercial nuclear plant new build for NQA-1 suppliers
- Establishing an EM Approved Supplier List: address/evaluate the legal issues and liabilities involved.



Questions & Comments

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Project Focus Area #3

Commercial Grade Item and Services Dedication Implementation

EM QA Corporate Board Meeting
Atlanta, Georgia
November 13-14, 2008

Team Members

Pat Carier	ORP	DOE Team Lead
Shelby Turner	FH	EFCOG Team Lead
Jim Davis	EM	
Scott Spencer	FH	
Michael McElroy	CH2M Hill	
Herb Berman	CH2M Hill	
Tony Hawkins	WSRC	
Jerry Southard	BEA	
Steven Foelber	BNI	
Gary Helton	Isotek Systems	

Background

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

Scope

- Provide EM with a recommended baseline scope and approach for the application of Commercial Grade Item (CGI) Dedication and Acceptance of Nuclear Services within EM consistent with code requirements (NQA-1, 2004)

Actions / Status

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

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

Status: Deliverables for these tasks have been submitted and approved.

Actions / Status (Cont'd)

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

Status: One benchmarking activity completed-contract awarded for additional activities. ECD 12/15/08

Tasks 3.4 – 3.5: Provide EM with recommended baseline requirements/guidance actions considered necessary for implementation of effective CGI dedication and acceptance of services processes within EM nuclear facilities.

Status: In progress ECD: 1/15/09

Actions / Status (Cont'd)

Task 3.8: EFCOG QA Working Group prepare a draft tutorial on what is/is not allowed by the ASME NQA-1 code (NQA-1, 2004) relative to dedication of commercial grade items and acceptance of services for nuclear applications (i.e., SC, SS, ITS, etc).

Status: Not started ECD: 2/13/09

Task 3.9: EFCOG QA Working Group issue a final tutorial on what is/is not allowed by the ASME NQA-1 code (NQA-1, 2004) relative to dedication of commercial grade items and acceptance of services for nuclear applications (i.e., SC, SS, ITS, etc).

Status: Not started ECD: 3/27/09

Recommendations to EM Under Consideration

- The CGI/Services dedication process shall be documented in the DOE-approved QAP.

- NQA-1-2004, Requirement 7, *Control of Purchased Items and Services* and Non-Mandatory Appendix 7A-2, *Guidance on Commercial Grade Items and Services*, shall be used as the basis for the DOE-approved CGI/Services dedication process or NQA-1-2004, Requirement 7 supplemented by EPRI NP-5652.

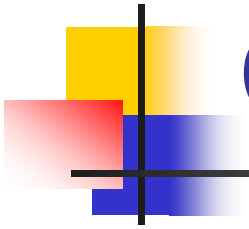
Note: A more recent edition of NQA-1 may be used if authorized in the DOE-approved QAP.

Recommendations to EM Under Consideration (Cont.)

- Technical evaluations for CGI/Services dedication shall be performed by the appropriate technical authority for the item/service being dedicated.
- Critical characteristics for CGI/Services dedication shall be determined by the appropriate technical authority for the item/service being dedicated.
- Acceptance method/criteria for critical characteristics shall be determined by the appropriate technical authority for the item/service being dedicated.
- Personnel responsible for implementation of the CGI/Services dedication process shall be trained to develop the necessary skills to effectively execute the process.

Challenges / Barriers

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



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Project Focus Area #4

Graded Approach to Quality Assurance

EM QA Corporate Board Meeting
Atlanta, Georgia
November 13-14, 2008

Team Members

- **Al Hawkins EM/RL**
  Mike Hassell WCH
  Vince Grosso WSRC
  Steve Piccolo WSRC

- Phyllis Bruce ATL
  Kyle Rankin EM/RL
  Clif Hoover FH
  Dave Shugars CWI
  Dale Cottingham Isotek Systems LLC
  Cathy Nesser Washington TRU Solutions
  David Faulkner EM/HQ
  Charlie Kronvall CHPRC
  Dave Jantosik BNI
  Sam Vega EM/ORP

Background & Scope

- EM needs consistency in the application of the graded approach
- The graded approach team will provide a model process for application of graded approach for both contractor and federal QA programs

Actions/Status

Task 4.1: List processes warranting application of formal graded approach

Status: Complete 6/27/08

Task 4.2: Provide draft position paper to Area teams for review

Status: Complete 9/28/08

Actions/Status

Task 4.3: Present draft EM Position Paper to the EM QA Corporate Board for review and discussion

Status:

- Working teleconference on comments from other Area teams - consensus reached on resolution
- Position Paper revised
- Position Paper put in EFCOG format
- Formal responses to non-editorial comments issued

- *Complete 11/6/08 – Provide for EM Corporate Board member (voting and non-voting) review*

Actions/Status

Task 4.4: Provide final draft EM Standard or Process on the graded approach to QA, based upon the EM Position Paper, to EM-60 for review and approval. Provide draft DOE Standard (due 3/31/09)

Status:

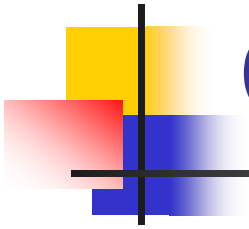
- Team examining processes in use
- Initial focus on Idaho process as rigorous, replicable
- CHPRC is examining adopting process – team will take lessons learned from this effort
- Interfacing with other EFCOG Teams (e.g., Engineering)

Key Graded Approach Lessons Learned

- Grading is about rigor, not requirements
- Precise and consistent use of terminology is essential
- Ensuring replicable results will require a standard method for assessing risk and performing grading

Challenges / Barriers

- Developing single approach applicable to the diverse situations found in EM (e.g., construction, operations, D&D, laboratories, R&D)
- Agreeing to a common set of definitions
- Establishing EM expectations for approval of the Graded Approach process



Questions & Comments

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Project Focus Area #5

Line Management Understanding of QA and Oversight

EM QA Corporate Board Meeting
Atlanta, GA
November 13 - 14, 2008

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
- Clark Vanderneit, EnergySolutions
- Tom Fallon, AMWTP

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.

  Status: Draft QPR Quad Chart was distributed to the Exec. Committee on 10/23/08 for review and comment. The new QPR Quad Chart is planned for use in the next scheduled QPR presentation.

Actions / Status

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

  Status: Complete. Training for the Federal QA Staff is ongoing.

Actions / Status

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

  Status: Complete. QAP was approved by EM-1 in November 2008.

Actions / Status

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

  Status: Complete. Memorandum issued in November to HQ and Sites .

Actions / Status

- Task 5.5 (NEW): Develop detailed QAP implementation guidance for EM-3.

  Status: Draft complete. This is an agenda item for open discussion for the Atlanta Board meeting.

Actions / Status

- Task 5.6: Develop Training modules on the value of a strong QA Program

  Status: Complete. Training Academy course was given in Oct. 2008 in NM. Positive feedback from attendees. Training to be provided twice yearly at different locations.

Actions / Status

- 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 QA Program.

  Status: Initial draft of training slides have been prepared. Currently undergoing internal group review. The second draft is due by 12/31/08.

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.

  Status: Corporate EM Performance Metrics issued and piloted at three EM facilities. More work required to apply the lessons learned from that and develop a guidance document. Due 3/31/09.

Actions / Status

- 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.

  Status: 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

EM QA Corporate Performance Metrics

EM QA Corporate Board Meeting
November 14, 2008
Atlanta, GA

Background

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

Overall Approach

- Consistent with ISMS Verification Process and Annual Declaration
- Addresses ASME NQA-1 and 10 CFR 830.120 Requirements
- Measurement Over Time (Compare to a Baseline)
- Focus on Feedback and Continuous Improvement

Overall Approach (Cont'd)

- Three Categories of Program Criteria: Management, Performance, and Assessment
- Three Levels: Phase I (Assessments), Phase II (Audits), and Feedback & Continuous Improvement (Annual Validation Process)
- Lines of Inquiry Developed for Each of the 10 Criteria of 10 CFR 830.120
- Scoring: Excellent (Blue); Good (Green); Yellow (Investigate); Red (Define Actions)
- Scored on Annual Basis

QA Performance Metrics Pilot Tests

- Pilot Tests Performed at Two Sites:
  - ✓ Washington Closure Hanford (WCH)–Richland, WA
    - WCH had Similar Metrics Developed Previously
    - Substantial Information Available for Evaluation
  - ✓ Portsmouth/Paducah Project Office – Ohio/Kentucky
    - ✓ Provided Significant Basis Information for Scoring
- Overall the Metrics Chart and Instructions Were Understood Easily and Could Be Completed
- Completing the Metrics Provided a Good High Level Assessment of QA Program Health

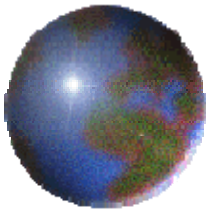
QA Performance Metrics Pilot Test Results

- Specific Comments Included:
  - Provide Additional Guidance on Completing "Basis" Information
    - Revise Format to Allow More Room for Responses
    - Include Column for Implementing Documents
    - Definition of Acceptable "Basis" Description
    - Request EM HQ Provide an Example of a Completed Metrics Table (Best Practice) to the Sites
  - LOI Clarification and Expansion
    - Provide Source References for LOI's
    - Add LOI's for SQA and S/CI
    - Clarification on Some LOI Wording
  - Provide Definition of Scoring Colors for Consistency
  - Provide More Guidance on Selection and Timing of the Evaluation Phases

Next Steps

- Incorporate Comments from Pilots and Other Site Specific Performance Measures to Refine the Metrics

- Distribute the Revised Corporate QA Performance Metrics System to the Sites by December 31, 2008.



Commercial Grade Items and the NQA-1 CGI Criteria

EM Quality Assurance Corporate Board Meeting

Atlanta, GA

November 13, 2008

By John G. Adkins

jgadkins@southernco.com

Today's Presentation

- What is CGI and how we got here
- NQA-1's CGI history
- NQA-1, Subpart 2.14, QA Requirements for CGI NEW
- How to implement a CGI program in EM

Definitions

- ***commercial grade item***

  a structure, system, or component, or part thereof, that affects its safety function, that was not designed and manufactured in accordance with the requirements of this Standard*.

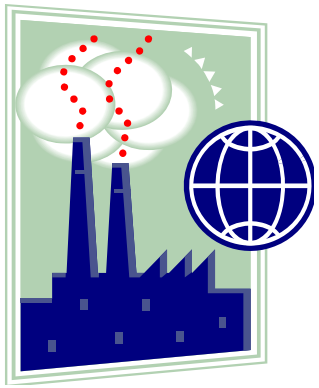
- ***commercial grade service***

  a service that was not provided in accordance with the requirements of this Standard* that affects the safety function of a basic component.

* Standard means NQA-1

CGI Concept

Commercial Grade Item



Dedication Process (Acceptance & Documentation)

Part 21 and/or NQA-1

Safety Functio n

10 CFR 50 App B or DOE 830

Regulatory Basis for CGI

- NRC regulated facilities have 10 CFR Part 21 to establish criteria
  - Created consistency

- DOE facilities do **not** have a similar regulatory basis
  - No centralized controlling approach

NRC and EPRI Documents

- **1977** – 10 CFR Part 21, *Reporting of Defects and Noncompliance*
- **1988** – EPRI NP-5652*, Guideline for the Utilization of Commercial - Grade Items in Nuclear Safety-Related Applications (NCIG-07)*
- **1989** – NRC Generic Letter 89-02, *Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products*
- **1989** – EPRI NP-6406, Guidelines for the Technical Evaluation of Replacement Items in Nuclear Power Plants (NCIG-11)
- **1991** – NRC Generic Letter 91-05, Licensee Commercial-Grade Procurement and Dedication Programs
- **1991** – EPRI NP-7218, Guideline for the Utilization of Sampling Plans for Commercial - Grade Item Acceptance (NCIG-19)
- **1996** – NRC Inspection Procedure (IP) 38703, *Commercial-Grade Dedication*
- **2006 –** EPRI TR 1008256 *Guidelines for the Technical Evaluation of Replacement Items in Nuclear Power Plants Rev. 1* (Revision of NP-6406)
- **2007** – NRC Inspection Procedure (IP) 43004, Inspection of Commercial-Grade Dedication Programs

10 CFR Part 21

- Originally and still a reporting document for defects and noncompliance
  - Defined “safety related” and “basic component”
  - Defined “non-safety related” as commercial grade item, in a 3 part definition
    - Not subject to design or specification requirements that are unique to those facilities or activities;
    - Used in applications other than those facilities or activities; and
    - To be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (for example, a catalog).

10 CFR Part 21

- Major change in 1995
- NRC was in a “no new regulation” era
- Established different CGI criteria for Part 50 utilities by revising and adding definitions
  - Added a new utility definitions for CGI
  - Added dedication criteria in the definitions
- Left the other facilities without any dedication criteria

10 CFR Part 21

- Part 21 CGI dedication criteria presents several issues for NQA
  - Part 21 compliance is not optional, so NQA must conform to CGI definitions
  - Original 3 part CGI definition of 1977 is not tied to dedication
  - No proven alternate dedication criteria exist for non-part 50 utilities or DOE
  - Part 21 does **not** apply to DOE facilities

10 CFR Part 21

- 10 CFR Part 21 includes services

  In all cases, basic component includes safety-related design, analysis, inspection, testing, fabrication, replacement of parts, or consulting **services** that are associated with the component hardware whether these **services** are performed by the component supplier or others.

- 2007 NRC Inspection Manual, IP-43004, Inspection of Commercial – Grade Dedication Programs address services in several areas, i.e.

  43004-02.01 Verify that the dedicating entity has established adequate controls for performing technical evaluations of items or **services** to be dedicated.

- NQA-1 address commercial grade services

NQA-1's CGI History

NQA-1's CGI History

- NQA-1-1979
  - No CGI in the Standard
- NQA-1-1986
  - Original CGI three part definition from Part 21
  - Alternate procurement process in Supplement 7S-1
- NQA-1a-1995
  - No significant change to Requirement 7
  - Added CGI guidance in Appendix 7A-2

NQA-1's CGI History

- NQA-1-2004
  - Added new CGI definitions
  - Placed CGI criteria in Requirement 7
  - Revised Appendix 7A-2 to prevent conflict with Req. 7
- NQA-1-2008
  - Linked Requirement 7 to Subpart 2.14
  - Relocated Appendix 7A-2 to a NQA Part II, Subpart 2.14 requirement document
    - Only changed "should" to "shall"

Note: An NQA Part II, Subpart is a requirement if the organization performs the specified activity.

NQA-1's CGI History

- NQA-1a-2009 Addenda
  - Introduction
    - Relocated some CGI definitions to Subpart 2.14
  - Requirement 3 – Design
    - Reconfirmed the selection of critical characteristics is a design function
  - Requirement 7 – Control of Purchased Items and Services
    - Removed dedication criteria from Requirement 7
    - Cross reference to Subpart 2.14

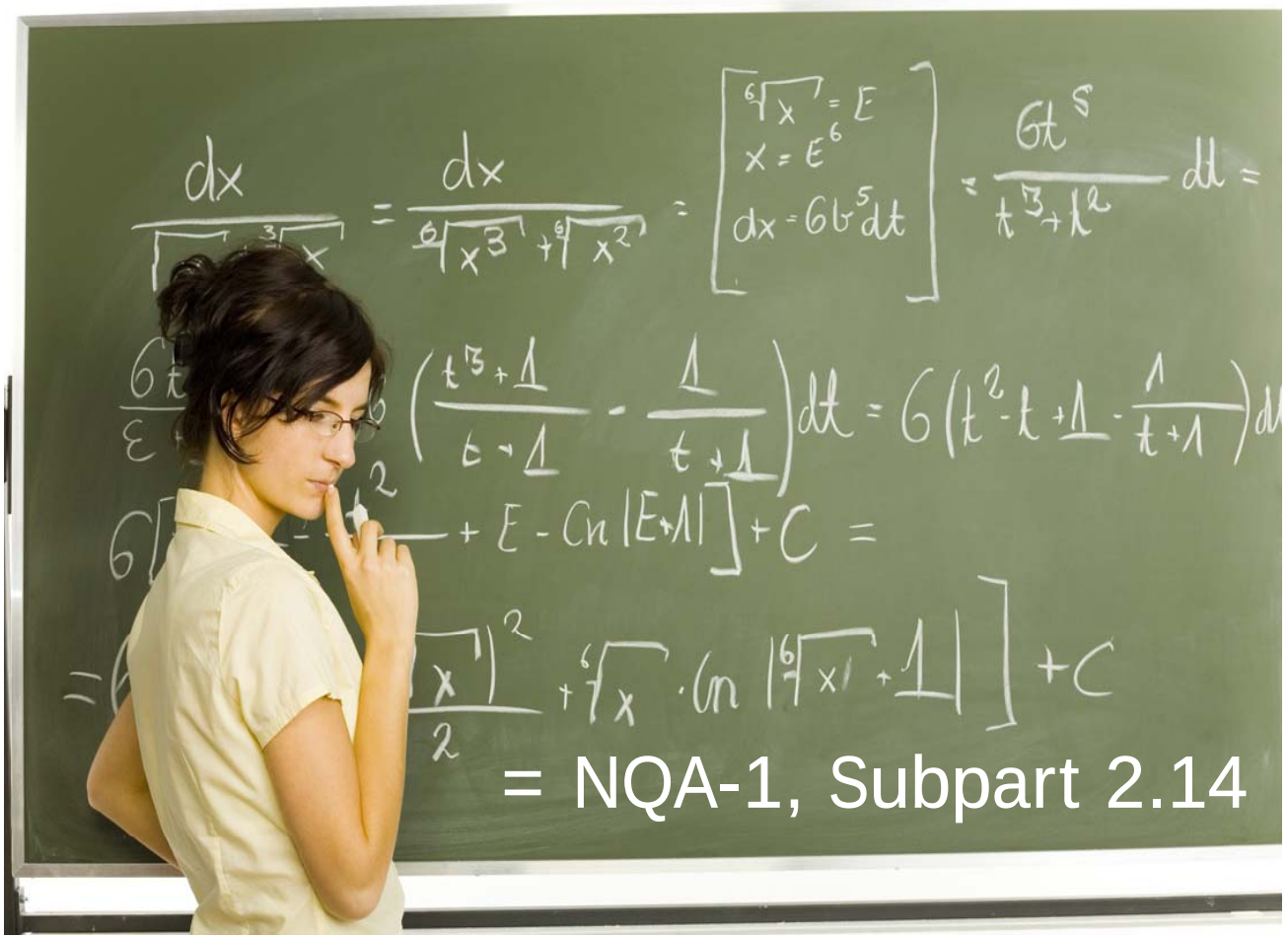
NQA-1's CGI History

- NQA-1a-2009 Addenda (continued)
  - Subpart 2.14 – QA Requirements for CGI
    - Relocated CGI definitions to Subpart 2.14
    - Relocated Req. 7 CGI criteria to Subpart 2.14
    - Reorganized Subpart 2.14
    - Added CGI like-for-like and equivalent replacement items
  - Created a stand-alone document

EM Question

- What edition of NQA should EM use?
  - All edition before NQA-1-2004 do not provide adequate CGI dedication requirements
  - NQA-1a-1995 to NQA-1- 2008 have the basic CGI concepts in Req. 7 and/or Appendix 7A-2
  - New NQA-1a-2009 will be published in the 1st quarter of 2009 and will contain the consolidated CGI criteria in Subpart 2.14

NQA Subpart 2.14



NQA Subpart 2.14

- Developed by NQA Task Group consisting of:
  - EPRI, Electric Power Research Institute*
    - Joint Utility Task Group, JUTG, program manager and 3 utility representatives
  - NRC QA specialist (4 staff members)
  - NQA members and NQA Standard review process
    - Task Group Chairman: John Adkins

*EPRI provide expertise and direct user input into the development of this revision to assure an approach consistent with current industry practices. EPRI developed most of the CGI process documents and continues to be a leader in CGI activities.

NQA Subpart 2.14

- Developmental Concepts
  - Single, comprehensive document that is available to all nuclear facilities, suppliers and regulators
    - Provides a industry Standard for reference in procurement documents
    - Document available to all types of organizations
    - Regulatory endorsement will promote use
  - No new NRC regulatory requirements
  - Added the process of procuring replacement CGI parts

NQA Subpart 2.14

- 100 GENERAL
  - Addresses items and **services**
  - Amplified requirements to provide reasonable assurance that a CGI or service will perform its safety function
    - CGI is **not** required if one purchases “safety” items
  - Used in conjunction with requirements of Part I
    - CGI dedication activities are a safety function
  - Adequate for all nuclear facilities
    - This means **YOU**

NQA Subpart 2.14

- 101 Definitions
  - Multiple definitions for CGI are a result of regulatory requirements – Read the footnotes
- 200 CGI DEFINITION APPLICATIONS
  - Use the definition to determine if the item or service can or needs to be procured commercial grade
  - An item or service performing a **safety function** that does not meet the CGI definition is subject to the requirements in Part I of the Standard.

NQA Subpart 2.14

- 300 UTILIZATION
  - Determination that the item or service performs a safety function;
  - Confirmation that the item or service meets the applicable CGI definition;
  - Identification and documentation of the critical characteristics, including acceptance criteria; and
  - Selection, performance, acceptance and documentation of the dedication method(s) for determining compliance with the critical characteristic acceptance criteria.

NQA Subpart 2.14

- 400 TECHNICAL EVALUATION
  - Determine the safety function(s)
  - Identify performance requirements, the component/part functional classification, and applicable service conditions
  - Identify the critical characteristics, including acceptance criteria
  - Identify the dedication method(s)
  - Determine if a replacement item is a like-for-like or equivalent item

NQA Subpart 2.14

- 400 TECHNICAL EVALUATION (con't)
  - Addresses credible failure modes or use of the item's design parameters and allowables
  - Like-for-like
    - Established criteria
    - Dedication is still required
  - Equivalent Items
    - Changes in design, material, manufacturing process, form, fit or function
    - Evaluation and confirmation changes do not affect safety function and dedication is still required

NQA Subpart 2.14

- 500 CRITICAL CHARACTERICTICS
  - Critical characteristics selected for acceptance shall be identifiable and measurable attributes based on the complexity, application, function, and performance of the item or service for its intended safety function
    - Consider facility location criteria/design basis conditions
    - Seismically or environmentally qualified equipment must include critical characteristics to maintain qualification

NQA Subpart 2.14

- 600 METHODS OF ACCEPTING COMMERCIAL GRADE ITEMS AND SERVICES
  - **Method 1**: inspections, tests, or analyses performed after delivery
  - **Method 2**: commercial grade survey of the supplier
  - **Method 3**: source verification of the item or service
  - **Method 4**: acceptable supplier/item performance record
- Dedication activities are a safety activity and are required to be performed under the QA program

NQA Subpart 2.14

- 700 COMMERCIAL GRADE SERVICES
  - Document recognizes there are commercial grade services
  - Requirement 7, Section 507 addresses acceptance of services only and should be used, if applicable
  - Identifies option of working under facility QA program
  - Established relationship between service and characteristics of items

NQA Subpart 2.14

- 800 DOCUMENTATION
  - Documentation - traceable to the item, group of items or services
    - Dedication plans or procedures
    - Procurement documents
    - Technical evaluations, including like-for-like and equivalency evaluations
    - Critical characteristic and acceptance criteria
    - Test and inspection reports or results
    - Commercial grade survey reports
    - Source verification reports
    - Historical performance information
    - Dedication report containing sufficient data to accept the item or service

How to Implement a CGI Program

Contracts

- Potential restrictions of old NQA criteria references in existing contracts
- Use the latest possible edition of NQA
- The “old’ 3 part CDI definition is limiting
- Request exception/permission to use later NQA editions
- NQA-1a-2009, Subpart 2.14 could be incorporated into existing programs, since it is consistent with previous NQA concepts

Facility QA Program

- Address CGI in the facility QA program
  - Brief and general statements
  - Address the applicability and definition issue
  - Dedication activities are under the QA program
  - Define the key organizational responsibilities
    - Design is responsible for
      - Technical evaluation
      - Selection of critical characteristics and acceptance criteria

CGI Procedure

- Typical Table of Contents
  - 1.0 Purpose
  - 2.0 Applicability
  - 3.0 References
  - 4.0 Definitions
  - 5.0 Responsibilities
  - 6.0 Requirements
  - 7.0 Materials and Equipment
  - 8.0 Precautions and Limitations
  - 9.0 Procedure
  - Figure 1 – Commercial Grade Dedication Process Flowchart
  - Figure 2 – Commercial Grade Dedication Plan
  - Figure 3 – Commercial Grade Dedication Report

CGI Procedure

- Document the procurement decision process
  - New or replacement item
  - Safety, Non-Safety or unknown
  - Available or not available as a safety item
  - Safety cost vs. dedication cost
  - Schedule – ASAP or stock item
  - Replacement item is like-for-like or equivalent

Typical Dedication Plan

Commercial Grade Dedication Plan

Facility Name

COMMERCIAL GRADE DEDICATION PLAN

PLAN No._____

ITEM _____

Prepared by: _____ Date: _____

Reviewed/Approved by: _____ Date: _____

Typical Dedication Plan

- I. Item Description
- II. Definition and Safety Function
- III. Procurement Basis
- IV. Technical Evaluation
- V. Environmental/Seismic Qualification
- VI. Critical Characteristic and Acceptance Method

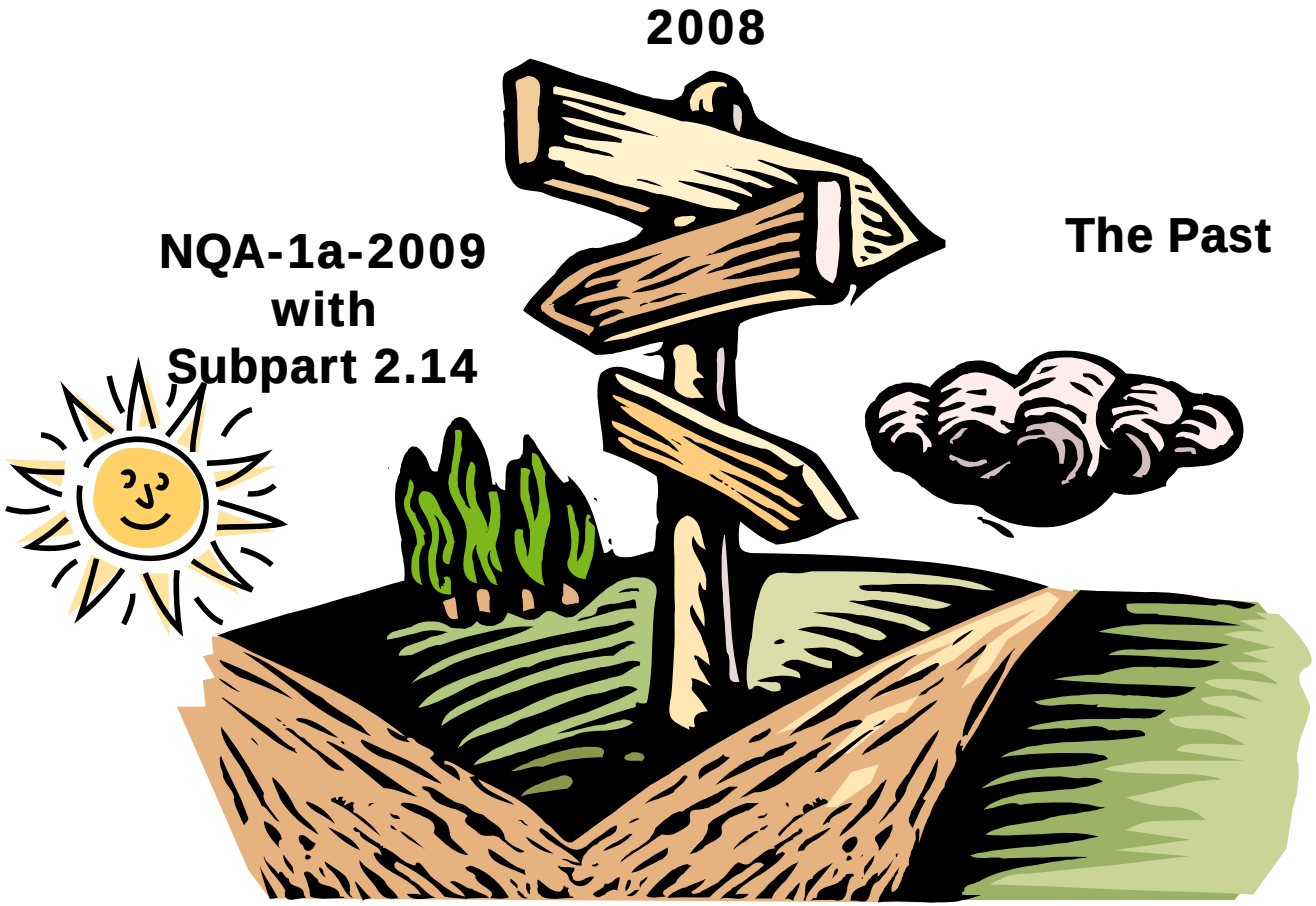
Typical Dedication Plan

Plan No. _____ Item No. _____ CRITICAL CHARACTERISTICS, ACCEPTANCE CRITERIA & METHOD OF ACCEPTANCE			
CRITICAL CHARACTERISTIC	**ACCEPTANCE CRITERIA & RANGE**	**METHOD 1 2 3 4**	**RESULTS**
	Sample Size:		___ Accept ___ Reject Signature _____ Date: _____
	Sample Size:		___ Accept ___ Reject Signature _____ Date: _____
	Sample Size:		___ Accept ___ Reject Signature _____ Date: _____
Post Installation Test: (Specify or N/A)			___ Accept ___ Reject Signature _____ Date: _____

Typical Dedication Report

- Cover Sheet with review and approval
- Part identification and summary description of the specific dedication process
- Documents to confirm completion of the dedication plan (indexed & attached)
- Attach the dedication plan or reference it, as a minimum
- Stand-alone reports are desirable as a complete quality record

THE FUTURE IS BRIGHT



Regulatory Suggestion

- DOE should provide regulatory endorsement of NQA-1a-2009 with special emphasis to Subpart 2.14
  - Should consider some type of quality back-fit statement that Subpart 2.14 meets or exceeds previous criteria in NQA-1 editions

IDEAS & COMMENTS

LAUR-08-0153

Quality Assurance Lessons Learned For Chemistry and Metallurgical Research Replacement (CMRR) Project

Tim J. McEvoy
Quality Assurance Division Leader
Los Alamos National Laboratory

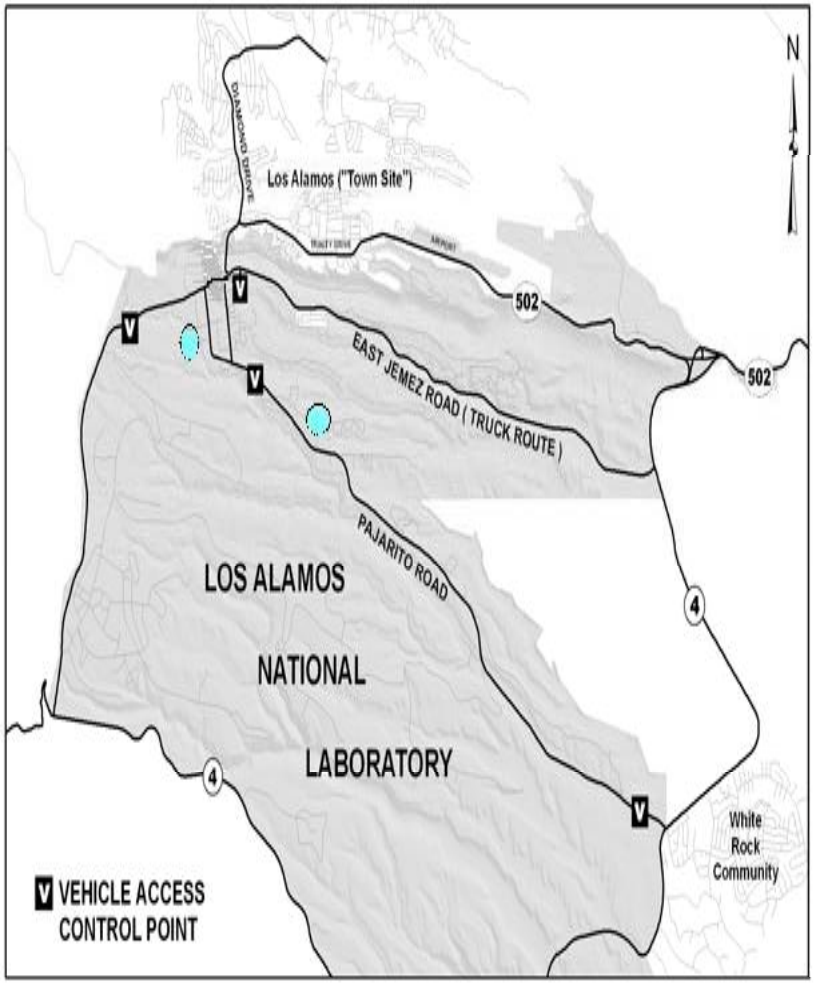
November 13, 2008

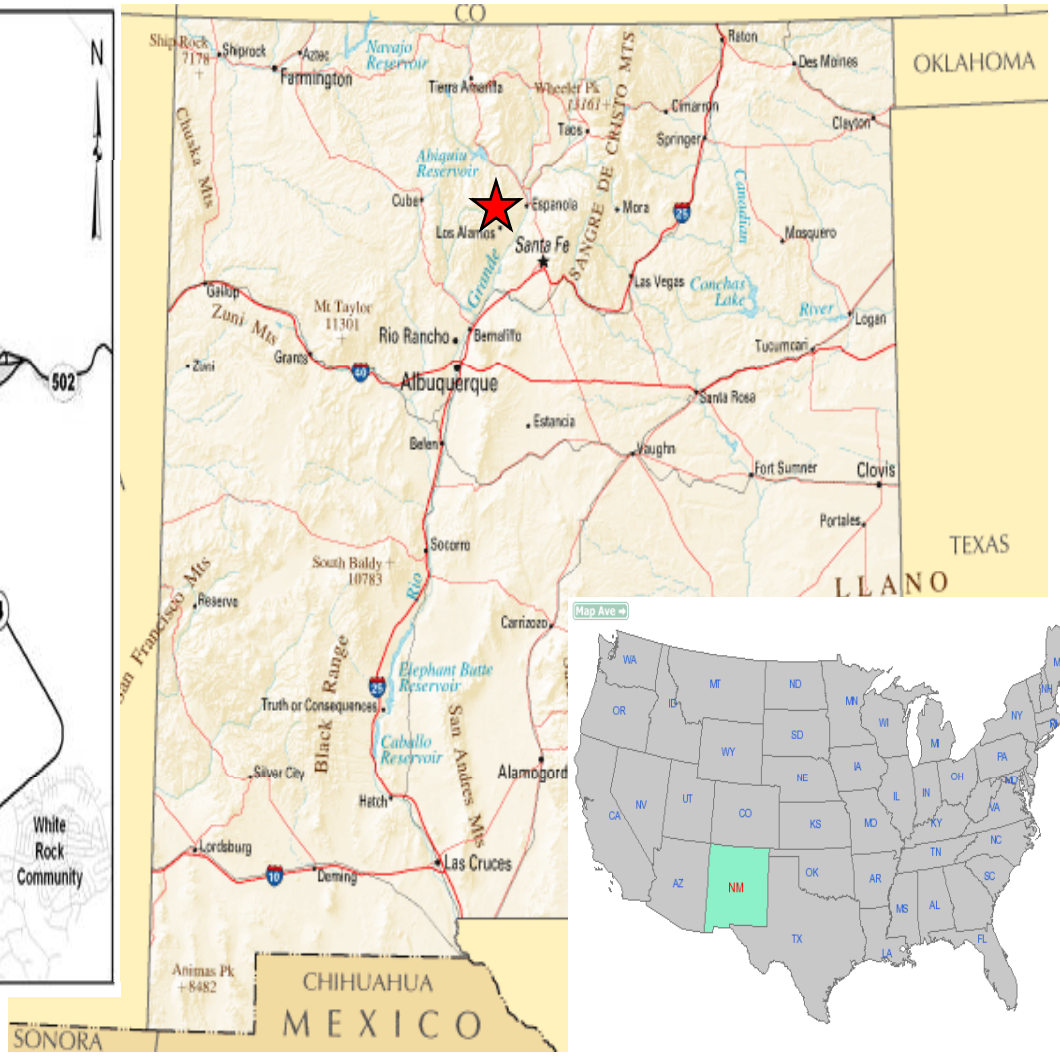
Operated by the Los Alamos National Security, LLC for the DOE/NNSA

Discussion Points

- CMRR Overview
- QA Program/organizational structure
- RLUOB QA History
- Conclusions/Lessons Learned

CMRR Overview





Los Alamos
NATIONAL LABORATORY
EST.1943

NNSA

CMRR Overview – Mission Need

- LANL will have an enduring nuclear mission for the foreseeable future
- Missions require Analytical Chemistry (AC)
- Materials Characterization (MC) and Actinide Research and Development (R&D) support exists at the current CMR Facility but is not available elsewhere
- CMR, built early 1950s, has a limited life expectancy
- CMRR will provide the responsive infrastructure necessary to sustain nuclear programs at LANL.
- Mission need Approved by NNSA – March 2005

The primary mission of CMRR is to replace mission critical capabilities at CMR that will soon be lost.

CMRR Overview - Pu Infrastructure

PF-4
Began Operations: 1978
Facility Size: 233,000 GSF
Missions Supported: Pit Manufacturing, Pit Surveillance, Special Recovery, Pu-238RTG development and manufacturing, Disposition of Pits

CMR
Began Operations: 1951
Facility Size: 570,000 GSF
Missions Supported: Pit Surveillance, Advanced Fuel Studies, Detonator Surveillance, Pit Manufacturing, Enhanced Surveillance, Other

CMRR Overview – Project Scope

CMRR Project

Radiological Lab Utility Office Building (RLUOB)

Facility Performance Baseline ($164M TPC):

- 19,500 nsf radiological lab space (<8.4g 239 Pu equivalent)
- Centralized utilities/services for all CMRR facility elements
- Office space for 350 CMRR workers
- Consolidated TA-55 training facility
- Facility incident command; emergency response capabilities

RLUOB Equipment Installation
Performance Baseline established FY08:

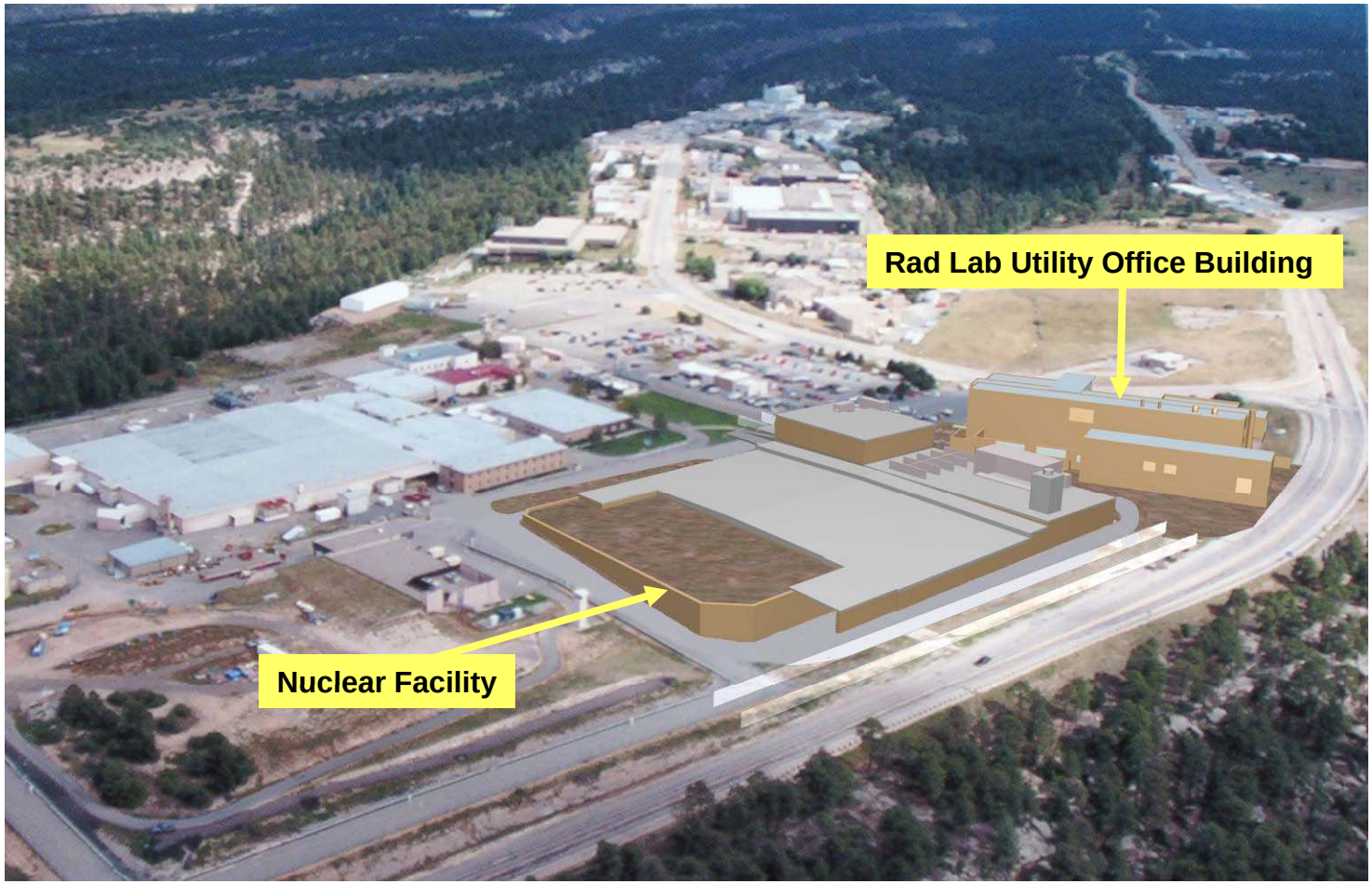
- Lab Room Equipment and finishes
- Security Equipment & Telecommunications
- Final Lab Ops Tie-ins & Lab filtration
- Office furnishing

Nuclear Facility (NF)

Baseline under Development:

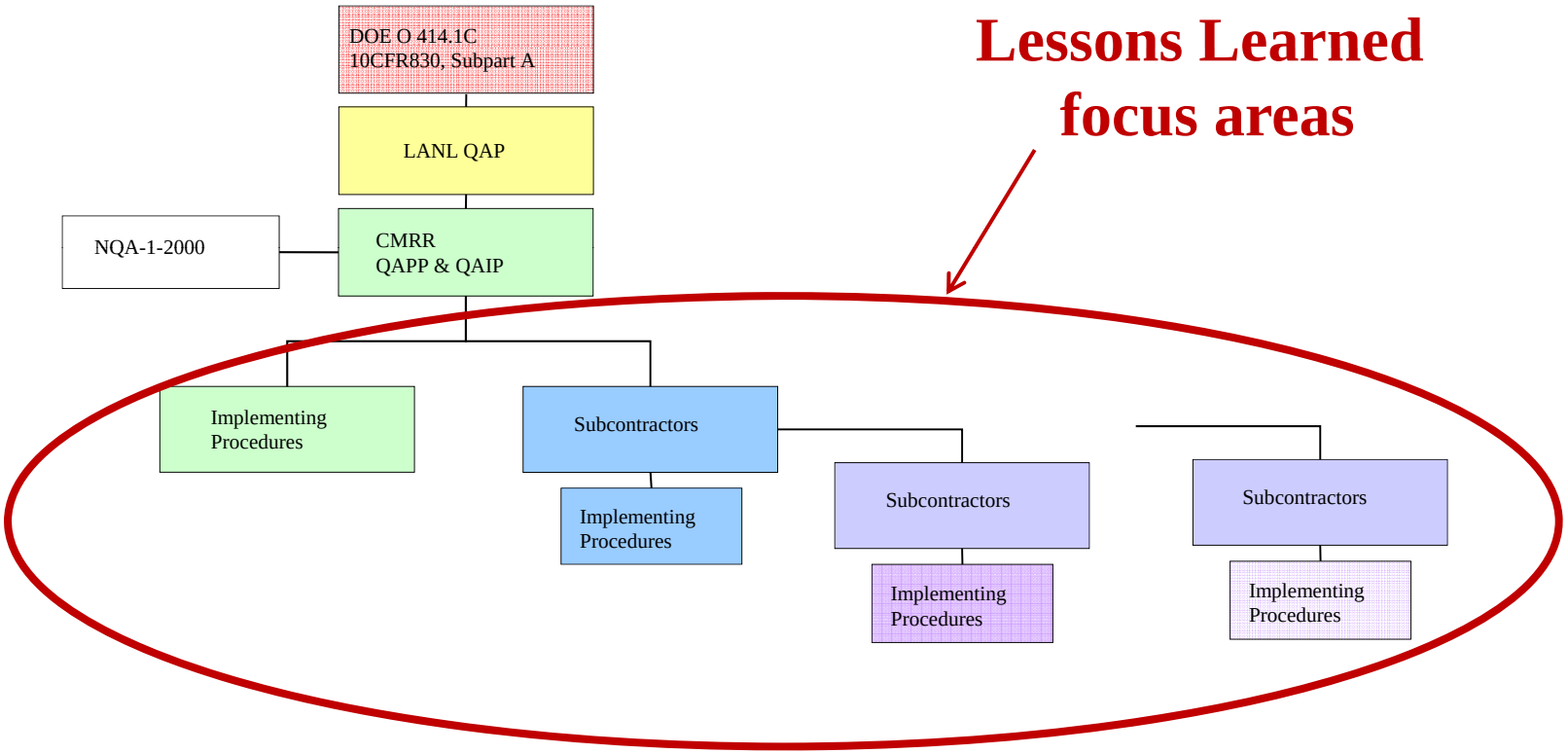
- AC/MC Chemistry Replacement Capability at TA-55
- 22,500 nsf lab space
- Security Category 1/Hazard Category 2
- Special Nuclear Material storage (6M tons)
- Large Vessel Handling
- Special Facility Equipment

CMRR Overview - at TA-55

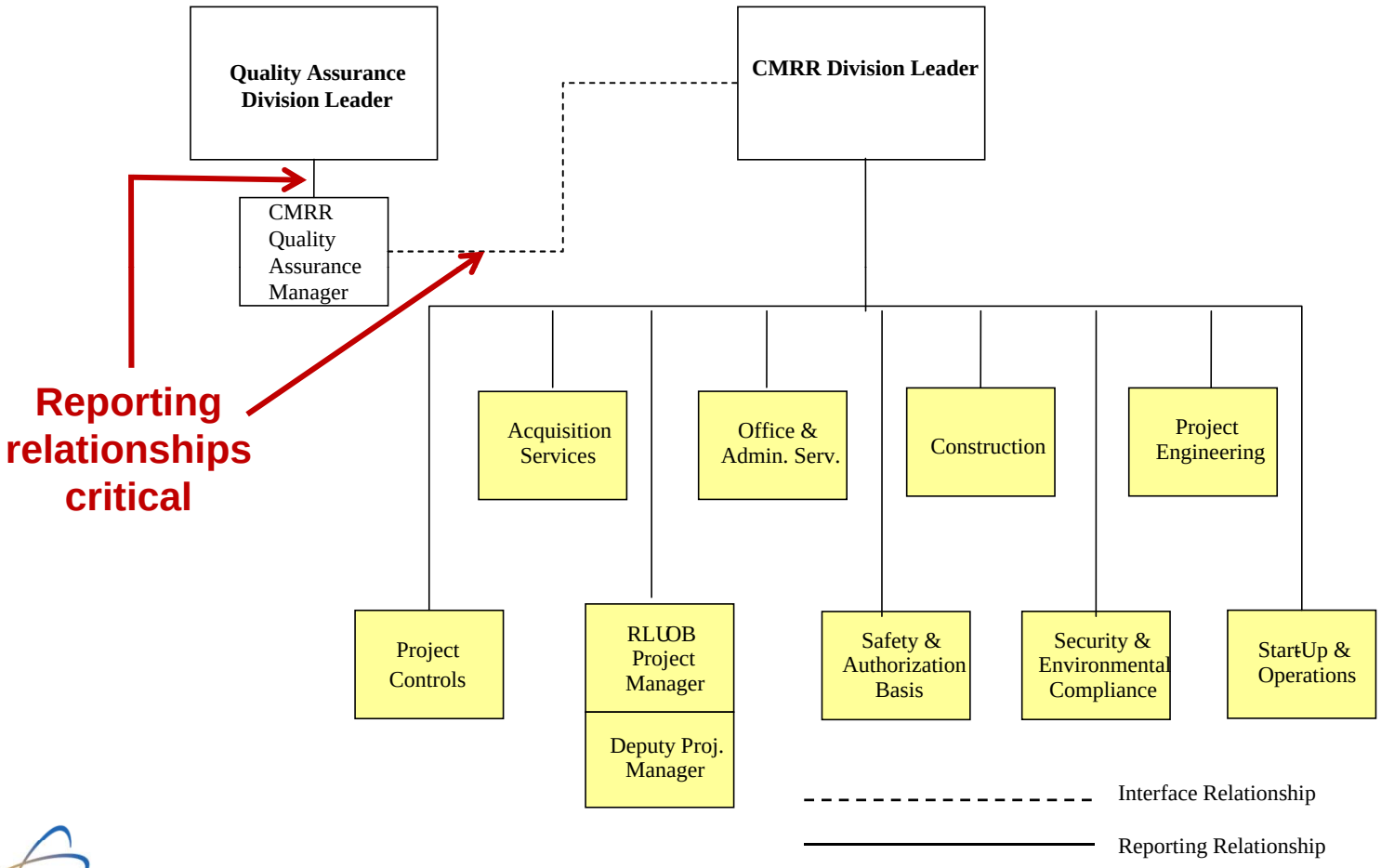


CMRR Overview – RLUOB Construction ~50%

QA Program requirements flow-down



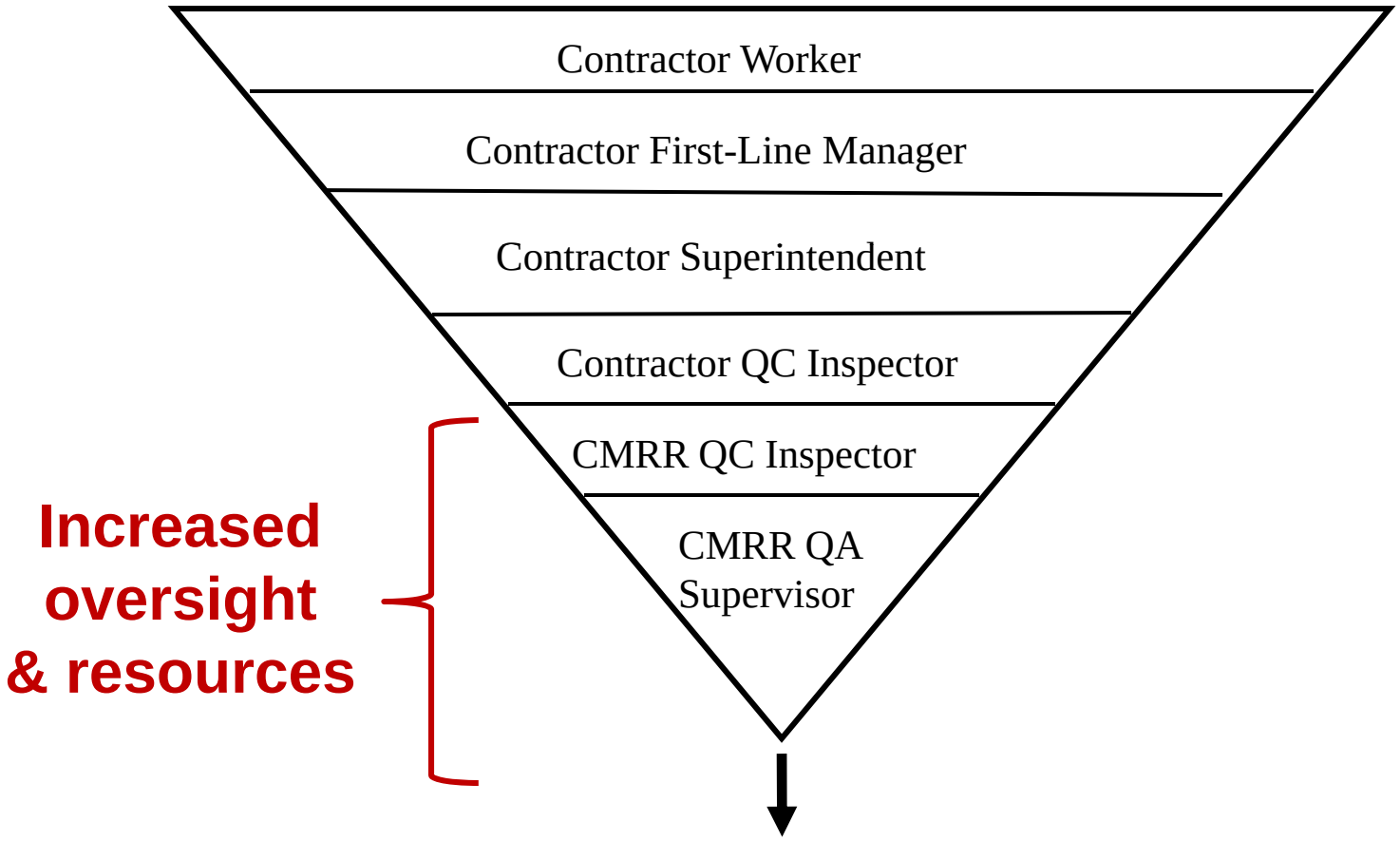
CMRR Organization



RLUOB QA History

- General contractor had no experience executing to rigorous QA program
  - Lack of understanding of NQA-1 requirements (e.g. building to design)
  - Insufficient QA & QC resources budgeted
  - Weak direction to subcontractors
  - Inadequate response to QA issues (NCRs, findings, etc.)
- Increased LANL oversight (Layered Defense)
  - QA resources
  - QC resources (source & field inspections)
  - Schedule implications
- Lack of institutional processes

RLUOB QA History – Layered Defense



Conclusions/Lessons Learned

- Plan for contractors without nuclear experience (or atrophy by those with experience)
- Expect to mentor contractors in Quality (processes, culture & execution) – Consider conferences to discus expectations
- Plan for and execute a layered defense approach including additional QA & QC oversight
- Establish realistic cost and schedule contingency to address considerable QA risks
- Evaluate encompassing subcontractor under site QA program – not easy
- Utilize senior management to drive quality from inception

Need to go beyond flow-down of requirements

Performance Metrics

Lessons Learned from WCH Pilot

Mike Hassell

Lessons Learned

- Content
- Structure
- Expectations

Content

- Uses Standard 10 Criteria Approach
- DOE O 414 has two extra “elements”
  - Suspect/Counterfeit Item
  - Software

- Recommendation
  - Add these two elements to front end

Line of Inquiry

- Uses base language from Order, NQA-1, Assessment Guide
- Could be better written from an “intent” perspective that would set the stage to frame the answer from an analysis perspective and not from an audit perspective.
- Need to have each LOI focused on one intention – currently several overlap

Expectations

- Could Benefit from additional guidance on “how” to complete the metric
- High level – How to document – tell a short story for each LOI of how you are implementing and an additional summary story for the overall area
- Specifics – Use program, performance, and feedback as a basis for the story

Conclusion

- Metric setup provides a tool to substantiate the reporting of the health of the QA program at a facility
- Once completed, provides a baseline that can be updated periodically to show trends
- Provides a common approach that all contractors can use so that the Project Offices can compare their contractors and EM can get a better feel for all projects across the complex.

EM Corporate QA Performance Metrics

Quality Program Criteria Summary

Situs: _____ Evaluation Level: _____ Period: FY09

Critical Decision				10 CFR 830.122		Score	
1	2	3	4	Criterion		Previous Period	Current Period
				Management	1. Program		
					2. Personnel Training and Qualification		
					3. Quality Improvement		
					4. Documents and Records		
				Performance	5. Work Processes		
					6. Design		
					7. Procurement		
					8. Inspection & Acceptance Testing		
				Assessment	9. Management Assessment		
					10. Independent Assessment		
				Supplementals	SQA	CA	S/CI

Performance Score

Excellent Good Investigate Define Actions

EM Corporate QA Performance Metrics

10 CFR 830.122

Criterion		Requirements
1.	Program	(1) Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work. (2) Establish management processes, including planning, scheduling, and providing resources for the work.
2.	Personnel Training & Qualification	(1) Train and qualify personnel to be capable of performing their assigned work. (2) Provide continuing training to personnel to maintain their job proficiency.
3	Quality Improvement	(1) Establish and implement processes to detect and prevent quality problems. 2) Identify, control, and correct items, services, and processes that do not meet established requirements. (3) Identify the causes of problems and work to prevent recurrence as a part of correcting the problem. (4) Review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement.
4	Documents and Records	(1) Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design. (2) Specify, prepare, review, approve, and maintain records.
5.	Work Processes	(1) Perform work consistent with technical standards, administrative controls, and other hazard controls adopted to meet regulatory or contract requirements, using approved instructions, procedures, or other appropriate means. (2) Identify and control items to ensure their proper use. (3) Maintain items to prevent their damage, loss, or deterioration. (4) Calibrate and maintain equipment used for process monitoring or data collection. (5) Verify or validate work before approval and implementation of the design.
6	Design	(1) Design items and processes using sound engineering/scientific principles and appropriate standards. (2) Incorporate applicable requirements and design bases in design work and design changes. (3) Identify and control design interfaces. (4) Verify or validate the adequacy of design products using individuals or groups other than those who performed the work.
7.	Procurement	(1) Procure items and services that meet established requirements and perform as specified. (2) Evaluate and select prospective suppliers on the basis of specified criteria. (3) Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.
8.	Inspection & Acceptance Testing	(1) Inspect and test specified items, services, and processes using established acceptance and performance criteria. (2) Calibrate and maintain equipment used for inspections and tests.
9	Management Assessment	Ensure managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.
10	Independent Assessment	(1) Plan and conduct independent assessments to measure item and service quality, to measure the adequacy of work performance, and to promote improvement. (2) Establish sufficient authority, and freedom from line management, for the group performing independent assessments. (3) Ensure persons who perform independent assessments are technically qualified and knowledgeable in the areas to be assessed.

EM Corporate QA Performance Metrics

Quality Program Criteria

Situs: _____ Evaluation Level _____ Period: FY09

MANAGEMENT/ PROGRAM		**10 CFR 830 Criterion #1**	**SCORE**
ASME NQA-1, 2004 1. Organization 2. Quality Assurance Program	**Supported ISM Guiding Principles** Line Management Responsibility Clear Roles and Responsibilities Competence Commensurate with Responsibilities		
Lines of Inquiry	**Score**		
	Basis	Supporting Documents	**Item**
A The quality management system (QMS) defines and documents the established organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work including overall expectations for effective implementation of the quality assurance program.	A. The QAPD directly addresses organizational structure for WCH and functional responsibilities for QA program specific implementation. The QAPD defers to the Project Management Plan for general functional responsibilities, levels of authority, and interfaces. The QMS has gone through a recent improvement campaign to better align with NQA-1 consensus standard requirements addressing previously noted weaknesses. B. The QAPD identifies the QA organization and describes the roles and responsibilities of the QA organization. Specific training requirements for QA Inspection and assessment personnel are addressed. C. The QAPD describes the grading process and how it is implemented at WCH. Recent revision to the QAPD clarified the strategy on how the graded approach is developed, implemented, and verified addressing previous weakness. Due to the closure contract nature of WCH, a tiered or multi-level approach has not been developed at WCH (no QA levels). However, key processes that benefit from grading such as training, work control, procurement, and assessments have been developed reflecting a varied approach based on risk and consequences to ensure hazards associated with work activities are appropriately addressed. Implementation of organization and graded approach is deemed effective based on completion of the ISMS Phase II verification (November 2007) and QA verification of implementing procedures (July 2008). Key improvement initiatives for 2007 was a complete re-write of the QAPD to better incorporate NQA1-2000 into the QAPD and to develop an implementation matrix that shows all procedures credited for implementing QAPD requirements. Overall excellent grade applied due to the combination of Senior management support and buy-in to the QA program, sufficient staffing in QA and the Projects to ensure in process quality controls and oversight is performed, and the recent re-write of the program to true up with DOE 414.1C and NQA-1.	ISMS Phase II verification (November 2007) QA verification of implementing procedures (July 2008).	
B The QMS describes a quality assurance organization that has sufficient resources and qualifications to perform its functions.			
C The QMS defines a process for grading the application of requirements and this process adequately address hazards and mission.			

Performance Score

 Excellent  Good  Investigate  Define Actions

Legend

Previous Period  Current Period

EM Corporate QA Performance Metrics

Quality Program Criteria

Situs: _____ Evaluation Level _____ Period: FY09

MANAGEMENT/ PERSONNEL TRAINING AND QUALIFICATION		10 CFR 830 Criterion #2	SCORE
ASME NQA-1, 2004	**Supported ISM Guiding Principles**		
2. Quality Assurance Program	Line Management Responsibility Clear Roles and Responsibilities	Competence Commensurate with Responsibilities	
Lines of Inquiry	**Score**		
	Basis	Supporting Documents	**Item**
A The methodology is well described for establishing requirements to indoctrinate, train and qualify personnel performing or managing activities affecting quality.	A.		
B Adequate resources have been identified to support the selection, training, and qualification of personnel conducting work.			
C Requirements are defined and implemented for the qualification and/or certification of personnel in the various functional areas (e.g., audit personnel, subject matter experts, inspection and test personnel, welders, etc.).			

Performance Score

Excellent | Good | Investigate | Define Actions

Legend

Previous Period | Current Period

EM Corporate QA Performance Metrics

Quality Program Criteria

Situs: _____ Evaluation Level _____ Period: FY09

MANAGEMENT/ QUALITY IMPROVEMENT		10 CFR 830 Criterion #3	SCORE
ASME NQA-1, 2004		**Supported ISM Guiding Principles**	
2. Quality Assurance Program 15. Control of Nonconforming Items	16. Corrective Action	Operations Authorization	

Lines of Inquiry	Score		
	Basis	Supporting Documents	Item
A The organization has established, implemented, and documented processes and leading indicators to detect and prevent quality problems such as conditions adverse to quality and nonconforming items.	A.		
B The QMS describes methods for addressing cause, extent, and remedial and preventative actions for continuous improvement of quality problems.			
C A process is identified to review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement.			

Performance Score

Excellent | Good | Investigate | Define Actions

Legend

Previous Period | Current Period

EM Corporate QA Performance Metrics

Quality Program Criteria

Situs: _____ Evaluation Level _____ Period: FY09

MANAGEMENT/ QUALITY IMPROVEMENT (cont)		10 CFR 830 Criterion #3	
Lines of Inquiry	**Score**		
	Basis	Supporting Documents	**Item**
D Controls provide for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, and for notification to affected organizations.	D.		
E Conditions adverse to quality are identified promptly and corrected as soon as practicable and in the case of a significant condition adverse to quality, the cause of the condition is determined and corrective action taken to preclude recurrence.			
F A nonconformance and corrective action tracking and trending program in place and is effective.			

Performance Score

Excellent | Good | Investigate | Define Actions

Legend

Previous Period | Current Period

EM Corporate QA Performance Metrics

Quality Program Criteria

Situs: _____ Evaluation Level _____ Period: FY09

MANAGEMENT/ DOCUMENTS AND RECORDS		10 CFR 830 Criterion #4	SCORE
ASME NQA-1, 2004	**Supported ISM Guiding Principles**		
5. Instructions, Procedures, and Drawings 6. Document Control 17. Quality Assurance Records	Balanced Priorities Identification of Safety Standards	Hazard Controls Tailored to Work Operations Authorization	

Lines of Inquiry	Score		
	Basis	Supporting Documents	Item
A Functions and activities affecting quality and services are effectively described and performed in approved, documented, and controlled instructions, procedures, or drawings that include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished.	A.		
B Quality assurance records are traceable to associated items and completed work activities from applicable documents, such as design specifications, procurement documents, test procedures, and operational procedures; properly identified classified and specified; authenticated, controlled and maintained; and their final disposition is specified.			
C Documents have been developed and effectively implemented that prescribe processes to oversee contractors and suppliers.			
D The QMS describes how procedures are prepared, reviewed, approved, issued, used, and revised to prescribe processes, specify requirements, or establish design.			

Performance Score

Excellent | Good | Investigate | Define Actions

Legend

Previous Period | Current Period

EM Corporate QA Performance Metrics

Quality Program Criteria

Situs: _____ Evaluation Level _____ Period: FY09

PERFORMANCE/ WORK PROCESSES		10 CFR 830 Criterion #5	SCORE
ASME NQA-1, 2004		**Supported ISM Guiding Principles**	
5. Instructions, Procedures, & Drawings 8. Identification & Control of Items 9. Control of Special Processes 12. Control of Measuring & Test Equipment	13. Handling, Storage, & Shipping 14. Inspection, Test, & Operating Status Subpart 2.7 SQA	Balanced Priorities Identification of Safety Standards Hazard Controls Tailored to Work Operations Authorization	

Lines of Inquiry	Score		
	Basis	Supporting Documents	Item
A Core functions and guiding principles of the DOE Integrated Safety Management System are addressed consistent with DOE O 450.1, DOE P 450.4 and applicable chapters in DOE O 5480.19 such that work is performed consistent with technical standards, administrative controls, and other hazard controls adopted to meet regulatory or contract requirements using approved instructions, procedures, or other appropriate means.	A.		
B The quality management system provides methods to identify and control items to ensure their proper use consistent with DOE G 414.1-3 and it addresses suspect counterfeit items.			
C The method to maintain items to prevent their damage, loss, or deterioration is adequately described. This method addresses the requirements (e.g., DOE O 433.1, Maintenance Management Program for DOE Nuclear Facilities, dated 6-1-01).			

Performance Score

Excellent | Good | Investigate | Define Actions

Legend

Previous Period | Current Period

EM Corporate QA Performance Metrics

Quality Program Criteria

Situs: _____ Evaluation Level _____ Period: FY09

PERFORMANCE/ WORK PROCESSES (cont)		10 CFR 830 Criterion #5	
Lines of Inquiry	**Score**		
	Basis	Supporting Documents	**Item**
D Special processes that control or verify quality, such as those used in welding, heat treating, and nondestructive examination, are performed by qualified personnel using approved procedures or instructions compliant with the requirements of applicable codes and standards, including acceptance criteria for the process.	D.		
E Tools, gauges, instruments and other measuring and test equipment used for activities affecting quality are controlled and calibrated at specific periods, adjusted and maintained to required accuracy limits.			
F Status of inspection and test activities are identified either on the items or in documents traceable to the items where it is necessary to ensure that required inspections and tests are performed and to ensure that items which have not passed the required inspections and tests are not inadvertently installed, used, or operated.			

Performance Score

Excellent Good Investigate Define Actions

Legend

Previous Period Current Period

EM Corporate QA Performance Metrics

Quality Program Criteria

Situs: _____ Evaluation Level _____ Period: FY09

PERFORMANCE/ DESIGN		10 CFR 830 Criterion #6	SCORE
ASME NQA-1, 2004	**Supported ISM Guiding Principles**		
3. Design Control Subpart 2.7 SQA	Balanced Priorities Identification of Safety Standards	Hazard Controls Tailored to Work Operations Authorization	
Lines of Inquiry	**Score**		
	Basis	Supporting Documents	**Item**
A The quality management system describes a process for design verification and/or validation for design products including software related to safety systems, before approval and implementation of the design. The process requires the use of individuals or groups other than those who performed the work.	A.		
B Design items and processes use sound engineering/scientific principles and appropriate Standards and Orders (i.e., DOE O 420.1A). The process addresses change control (changes to design inputs, final designs, field changes and temporary and permanent modifications to operating facilities).			
C Design interfaces are identified and controlled, within the design authority and externally with customers and suppliers, including subcontractors.			

Performance Score

Excellent | Good | Investigate | Define Actions

Legend

Previous Period | Current Period

EM Corporate QA Performance Metrics

Quality Program Criteria

Situs: _____ Evaluation Level _____ Period: FY09

PERFORMANCE/ DESIGN (cont)		10 CFR 830 Criterion #6	SCORE
Lines of Inquiry	**Score**		
	Basis	Supporting Documents	**Item**
D The extent of the design verification is a function of importance to safety, complexity of the design, degree of standardization, state-of-the-art, and similarity with previously proved designs.	D.		
E Procedures implementing configuration management requirements are established and documented at the earliest practical time prior to facility operation, including authority and responsibilities of the organizations whose functions affect the configuration of the facility, such as operations, design, maintenance, construction, licensing, and procurement.			
F Software design requirements are identified and documented and their selection reviewed and approved (operating system, function, interfaces, performance requirements, installation considerations, design inputs, and any design constraints of the computer program).			

Performance Score

 Excellent

 Good

 Investigate

 Define Actions

Legend

Previous Period  Current Period

EM Corporate QA Performance Metrics

Quality Program Criteria

Situs: _____ Evaluation Level _____ Period: FY09

PERFORMANCE/ PROCUREMENT		10 CFR 830 Criterion #7	SCORE
ASME NQA-1, 2004	**Supported ISM Guiding Principles**		
4. Procurement Document Control 7. Control of Purchased Items and Services Subpart 2.7 SQA	Balanced Priorities Identification of Safety Standards	Hazard Controls Tailored to Work Operations Authorization	

Lines of Inquiry	Score		
	Basis	Supporting Documents	Item
A The requirements for the procurement of items and services are established. The requirements include performance and quality specifications provided by the design authority and quality organization and the requirements ensure that procured items and services will meet established requirements and perform as expected.	A.		
B The system to evaluate and select prospective suppliers based on specified criteria performs satisfactorily.			
C Processes are established and implemented to ensure that approved suppliers continue to provide acceptable items and services. Application is graded to ensure safety-related items and mission critical items are subject to more rigorous methods (e.g., inspection and testing at the manufacturer and upon receipt).			

Performance Score

Excellent | Good | Investigate | Define Actions

Legend

Previous Period | Current Period

EM Corporate QA Performance Metrics

Quality Program Criteria

Situs: _____ Evaluation Level _____ Period: FY09

PERFORMANCE /INSPECTION AND ACCEPTANCE TESTING		10 CFR 830 Criterion #8	SCORE
ASME NQA-1, 2004		**Supported ISM Guiding Principles**	
8. Identification & Control of Items 10. Inspection 11. Test Control	12. Control of Measuring and Test Equipment Subpart 2.7 SQA	Operations Authorization	

Lines of Inquiry	Score		
	Basis	Supporting Documents	Item
A Inspections and tests are specified for items, services, and processes. Acceptance and performance criteria are established and used.	A.		
B The system for documenting the results of inspections and tests performs satisfactorily.			
C Inspection and test equipment is controlled by a process to ensure it is calibrated and maintained.			

Performance Score

Excellent | Good | Investigate | Define Actions

Legend

Previous Period | Current Period

EM Corporate QA Performance Metrics

Quality Program Criteria

Situs: _____ Evaluation Level _____ Period: FY09

ASSESSMENT/ MANAGEMENT ASSESSMENT		10 CFR 830 Criterion #9	SCORE
ASME NQA-1, 2004	**Supported ISM Guiding Principles**		
2. Quality Assurance Program 18. Audits	Operations Authorization		
Lines of Inquiry	**Score**		
	Basis	Supporting Documents	**Item**
A The QMS describes how managers, at all levels, assess their management processes.	A.		
B The QMS provide for the identification and correction of problems that hinder the organization from achieving its objectives.			
C Managers take responsibility for, and directly participate in, the assessments.			

Performance Score

Excellent | Good | Investigate | Define Actions

Legend

Previous Period | Current Period

EM Corporate QA Performance Metrics

Quality Program Criteria

Situs: _____ Evaluation Level _____ Period: FY09

ASSESSMENT/ INDEPENDENT ASSESSMENT		10 CFR 830 Criterion #10	SCORE
ASME NQA-1, 2004		**Supported ISM Guiding Principles**	
1. Organization 2. Quality Assurance Program 10. Inspection 11. Test Control	15. Control of Nonconforming Items 16. Corrective Action 18. Audits	Operations Authorization	

Lines of Inquiry	Score		
	Basis	Supporting Documents	Item
A Independent assessments (e.g., audits) are planned and conducted to measure item and service quality, to measure the adequacy of work performance, and to promote improvement.	A.		
B The organization acts on assessments in a manner that results in continuous improvement.			
C The group performing independent assessments has sufficient authority and freedom from line management (i.e., not directly responsible for the work being assessed) and the persons who perform independent assessments are technically qualified and knowledgeable in the areas to be assessed.			
D Management of the audited organization or activity investigate adverse audit findings, schedule corrective action, including measures to prevent recurrence of significant conditions adverse to quality, and notify the appropriate organization in writing of action taken or planned.			

Performance Score

Excellent Good Investigate Define Actions

Legend

Previous Period Current Period

EM Corporate Performance Metrics

Quality Program Criteria

Performance color	Item score	Sum based on average of Items
Excellent	4	3.5 – 4.0
Good	3	2.75 – 3.5
Investigate	2	2.0 – 2.75
Define Actions	1	Below 2.0

Level definition

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

Performance reporting legend

Previous period  Current period

Previous period is shown by covered circle lightly shaded and Current period is full, brightly colored

Lesson Learned
WCH Pilot of EM Metrics

In September, 2008, the Office of Environmental Management (EM) developed Corporate Performance Metrics for QA Programs as a means to provide for a consistent uniform basis for which all EM sites and Headquarters can report on their QA program performance. Washington Closure Hanford (WCH), LLC, was requested to perform a pilot of these metrics. The pilot metric was performed in September/October and then, subsequent to an EM QA Audit performed in late October, was updated to reflect information gained.

The EM audit showed good agreement with the pilot metric with the exception that some weaknesses in sub-elements associated with documents and records, procurement, design, and software controls were identified. While the issues did result in a change in the value of performance for some of the specific lines of inquiry, none of these resulted in a change to the overall evaluation of the health of the areas at the criterion level.

As part of performing this pilot test, WCH identified some lessons learned that should be evaluated for incorporation into the roll out of the metric effort that can be characterized into three general categories:

- Content Issues – the overall strategy for the major elements to be monitored
- Line of Inquiry (LOI) Structure – the specific attributes that each element is assessed against
- Expectations – the expectations for substantiating the assessment results

<u>Content Issues</u>

The overall content strategy of the metrics uses the 10 element approach to mirror the criteria listed in DOE O 414.1C that each QA program needs to meet. The last two changes to DOE O 414.1 added two specific processes that warranted sections of their own to identify critical attributes of implementation. Consistent with this approach, the metric should be expanded to include Suspect Counterfeit control program and Software programs as separate entities to be evaluated.

While these two areas are arguably two work processes that could be rolled up under criterion 5, they also overlap with criteria 3, 4, 6, 7, and 8 to fully implement them. As such, there would be benefit to listing these two areas separately to ensure the criterion application to these areas is captured in one area and evaluated on a whole instead of by parts.

A secondary issue under content deals with integration. Under the Integrated Safety Management System, and within DOE O 414.1C, there is an expectation to integrate our programs. This goes beyond just ISMS and QA, but also includes other DOE directives,

orders, and programs. Where practical, these interfaces should be included within the content of the metrics. There is an example under criterion 5 where this was done to interface with DOE O 433.1, Maintenance Management Program for DOE Nuclear Facilities. Other criteria could benefit from the same type of interface; for example, criterion 2 could benefit from an interface with DOE O 5480.20, Personnel Selection, Qualification, and Training Requirements for DOE Nuclear Facilities. The challenge with this recommendation is in identifying only those that are truly relevant to the major criteria and being clear as to where we stop at the interface level.

LOI Structure

The lines of inquiry within the metric are often quotes from the source documents (either DOE O 414.1C or NQA-1). In several cases, the structure of the LOIs could benefit from a separation of issues so that each LOI is focused on unique attributes of the criterion. One example is in criterion 3, LOI "C" where the topic overlaps LOI "A", "D", and "F".

As this metric is largely based on subjective analysis of the implementation of the criterion, in lieu of quoting critical attributes listed from the Order or consensus standard, the LOIs might better be served written from an "intent" perspective. An example could be demonstrated in Criterion 3 where the LOIs are structured to ask the following:

- Is there a corrective action management program in place to facilitate the timely documentation and resolution of quality problems that addresses the following critical attributes:
    - Significance
    - Cause
    - Extent of Conditions
    - Correction Actions
    - Verification
- Is there a trending program in place to detect adverse trends (add any critical attributes)
- Is there a nonconformance control process in place (add any critical attributes)
- Are there performance indicators to monitor the health of the quality improvement element (add any critical attributes)

This type of approach helps frame the context of the written analysis that is needed to defend any performance evaluation for the element.

Expectations

Additional guidance on how to complete the metric could be beneficial to the performing organization to ensure consistency in reporting throughout the DOE EM complex. The two major areas to address are expectations at a high level about how to document the evaluation, and at a specific level, guidance on how to use program, performance, and feedback as a basis for evaluating performance.

Guidance should be provided that for each LOI the contractor will provide a writeup that explains the current status of the process implemented to meet the LOI. [Mike – this sentence lost me as well – again this is what I think you mean.] This would be the point where the implementing organization could provide rationale for the construct of the process (how the system is implemented via a graded approach for example). Additionally, as continuous improvement or trend analysis is critical to a successful organization, a discussion regarding how the current health compares to the previous health indicator should be provided when a change is identified.

From a "how to" perspective, guidance could be provided to include three critical attributes of the program, specifically: How is the expectation implemented (process description), what, if any, performance indicators are used to monitor the health (performance), and what information is provided by assessment and problem reporting information (feedback) regarding the health of the implementation of the process.

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

Quality Assurance Improvement Project Plan
Rev. 2

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)

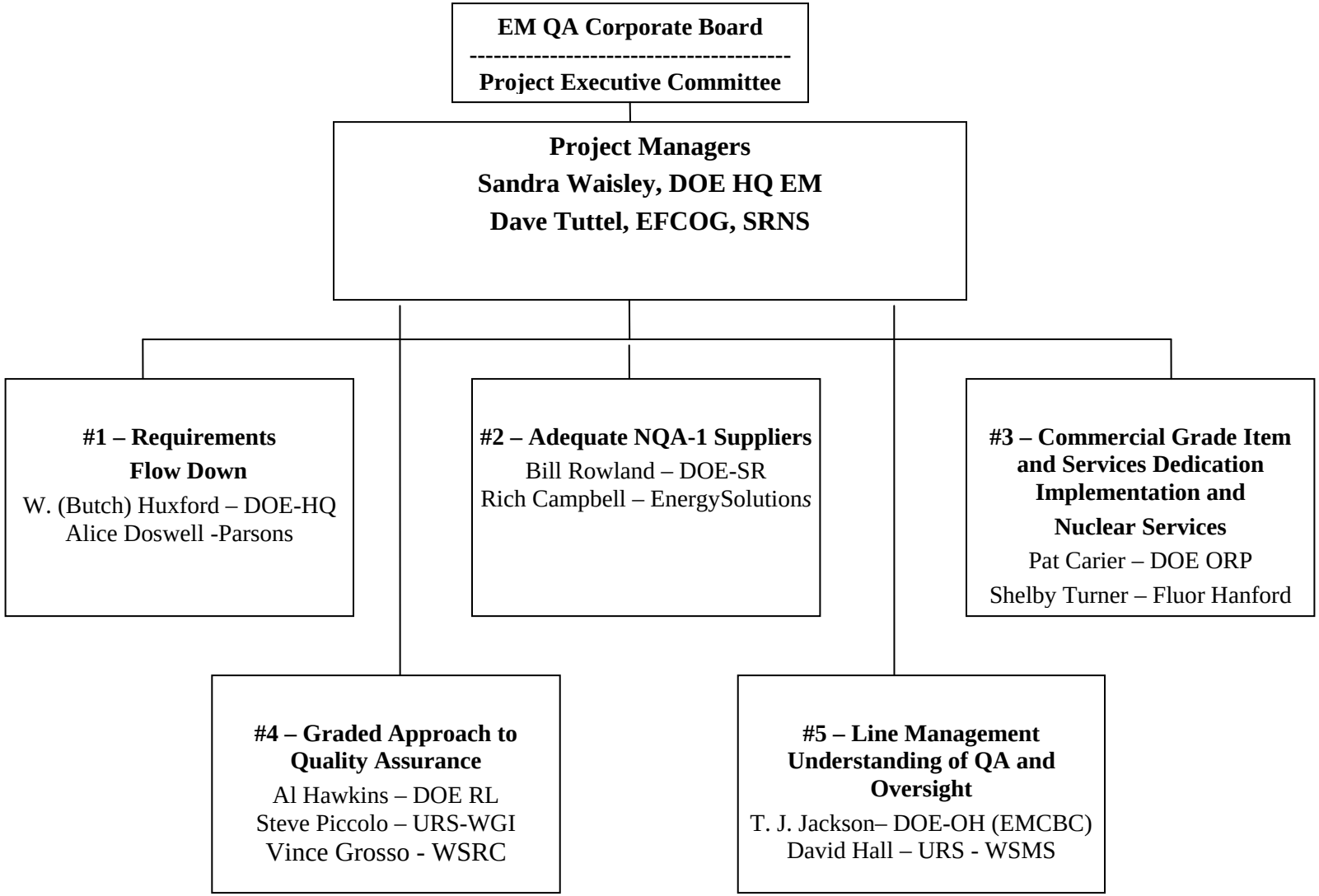
7.0 COMMUNICATIONS

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: September 5, 2008

Background

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

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

Scope

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

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

Support Team: Don Paine, SRNS
Amy Ecclesine, LANL

Project Milestones

Task #	Estimated Due Date	Task Description	Deliverable
1.1	6/16/08	Develop a brief questionnaire to send out to both commercial and EM contractors to describe their current approach for identifying the applicable QA requirements for subcontractors, tailoring the requirements based upon risk, process for working with procurement to ensure QA requirements are incorporated into subcontracts, and implementing verification of requirement flow-down by their suppliers, subcontractors, and sub-tiers.	Completed
1.2	7/7/08	Request targeted EM contractors to respond to questionnaire.	Completed
1.3	8/1/08	Solicit similar input from a few commercial nuclear contractors to compare with the DOE processes.	Completed
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 contractor and commercial processes used.	Summary of Completed Analysis of Commercial and DOE Contractor Processes
1.6	9/10/08	Develop a composite flow-down process including best practices from both DOE and the commercial sector and provide recommendations to EM for its action.	Completed Draft Decision Tree Flow-down Diagram
1.7	10/15/08	Review Working Group #5 product for consistency with Flow-down Diagram.	Completed Issuance of Comments to Working GP #5
1.8	10/15/08	Review draft Flow-down Diagram with Pat Carier, ORP to solicit input.	Resolve Comments with ORP
1.9	10/30/08	Work closely with Working Group #4 -Graded Approach to Quality Assurance Implementation - to amend the Flow-down Diagram with implementation guidance notes. This will make certain that the Flow-down Diagram has	Amended Flow-down Diagram Incorporating Implementation Guidance Notes

		considerations for contractor oversight, and vendor submittals to ensure that requirements are evidenced in the products delivered for use and there are adequate oversight functions to ensure all of the above issues are addressed.	
1.10	10/30/08	Circulate draft Flow-down Diagram to EM Corporate Board and Team Leads.	Incorporate Comments
1.11	11/13/08	Present Flow-down Diagram at Corporate Board Meeting for discussion and approval.	Incorporate Comments
1.12	11/30/08	Issue final product and back-up information to EM and the EFCOG Committee.	Flow-down Diagram w/ Implementation Guidance Notes

Project Area 2 – Adequate NQA-1 Suppliers
Target Completion Date: February 27, 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
Steven Stein, BNL
Robert Thompson, ICP
Paula Richards, Isotek Systems

Project Milestones

Task #	Estimated Due Date	Task Description	Deliverable
2.1	6/9/2008	Request a current list of commodities/ items/ services from major EM contractors.	Completed List from Contractors
2.2	6/9/2008	Request a list of the current points of contact for Supplier Quality Assurance from each of the major EM contractors.	Completed List of Points of Contacts
2.3	6/13/2008	Attend the NEI Manufacturing Outreach Workshop to gain insight into NEI efforts to attract nuclear suppliers.	Completed Trip Report
2.4	6/23/2008	Request the names of current suppliers that are providing nuclear grade (Safety Class, Safety Significant, and Important to Safety) materials, equipment, items and services from each major EM contractor.	Completed List of Suppliers
2.5	6/23/2008	Request the procedures used for qualifying nuclear grade suppliers from each major EM contractor.	Completed Collection of Procedures
2.6	7/18/2008	Evaluate procedures being used by major EM contractors for consistency.	Completed Evaluation Report
2.7	7/31/2008	Hold a one day Nuclear Suppliers Day, in conjunction with other groups, EFCOG, NEI, etc. Location: Denver, Co	Completed Event
2.8	8/29/2008	Evaluate the applicability and completeness of the listing of common commodities/items/ services provided by the major EM contractors.	Completed Final List
2.9	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
2.10	11/3/2008	Evaluate impact of “Buy American” clause on efforts to expand the supplier base within EM.	Evaluation Report
2.11	11/14/2008	At the site level, conduct a small business nuclear QA reach out symposium similar to the EM nuclear protégé program.	Develop Recom-mendations and Draft Plans for Symposium
2.12	11/28/2008	Determine the feasibility of issuing a consolidated nuclear grade approved/qualified supplier list for EM. Evaluation should include legal and liability issues as well as any restrictions that would be needed on use of list by EM contractors.	Evaluation Report

2.13	12/5/2008	Determine the feasibility of EM contractors performing joint audits of common suppliers. If feasible, recommend procedure and checklist requirements that would be needed to implement.	Evaluation Report
2.14	12/5/2008	Evaluate the possibility of integrating EM procurement activities with other supplier initiatives such as NEI, NIAC, NASA, etc.	Evaluation Report
2.15	12/5/2008	Develop a formal process or "Alert" system for documenting and notifying the EM-complex and other DOE offices of nuclear suppliers not meeting QA requirements.	Draft Process Description
2.16	1/16/2009	Provide draft deliverable and/or recommendations to Project Managers and Project Focus Area Leads for review and comment.	Draft Report
2.17	1/30/2009	Receive comments from Project Managers and Project Focus Area Leads.	Written Comments
2.18	2/13/2009	Resolve comments from Project Managers and Project Focus Area Leads.	Revised Draft Report
2.19	2/13/2009	Provide revised draft report to Project Executive Committee for review and comment.	Revised Draft Report
2.20	2/20/2009	Receive comments from Project Executive Committee.	Written Comments
2.21	2/27/2009	Resolve comments from Project Executive Committee.	Revised Report
2.22	2/27/2009	Submit Final Report to Project Managers.	Final Report

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, 2000).

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

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

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.	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 dedication process within EM nuclear facilities.	Recommendation to EM
3.5	01/15/09	Provide EM for review and concurrence recommended baseline requirements/guidance actions necessary for implementation of an effective acceptance of nuclear services process within EM nuclear facilities.	Recommendation to EM
3.6	2/26/09	Issue final baseline requirements/guidance actions considered necessary for implementation of an effective CGI dedication process within EM nuclear facilities.	Baseline Requirements Issued to EM Complex
3.7	2/26/09	Issue final baseline requirements/guidance actions necessary for implementation of an effective acceptance of nuclear services process within EM nuclear facilities.	Baseline Requirements Issued to EM Complex
3.8	2/13/09	EFCOG QA Working Group prepare a tutorial for review and concurrence on what is/is not allowed by the ASME NQA-1 code (NQA-1, 2004) relative to dedication of commercial grade items and acceptance of services for nuclear applications (i.e., SC, SS, ITS, etc).	Draft Tutorial
3.9	3/27/09	Issue final tutorial what is/is not allowed by the ASME NQA-1 code (NQA-1, 2004) relative to dedication of commercial grade items and acceptance of services for nuclear applications (i.e., SC, SS, ITS, etc).	Final Tutorial

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

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

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

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

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

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

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

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

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

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

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

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

Project Milestones

Task #	Estimated Due Date	Task Description	Deliverable
4.1	06/27/08	With input from EM contractors, develop a listing of the processes (i.e., Engineering, Procurement, Inspection, etc.) warranting application of a formal graded approach to QA.	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.	Draft EM Position Paper on Graded Approach Issued to Corporate Board members
4.4	03/31/09	Provide final draft EM Standard or Process on the graded approach to QA, based upon the EM Position Paper, to EM-60 for review and approval.	Memorandum to EM-60 Forwarding Draft EM Standard on Graded Approach to QA for Review and Approval.

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

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

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

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

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

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

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

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

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

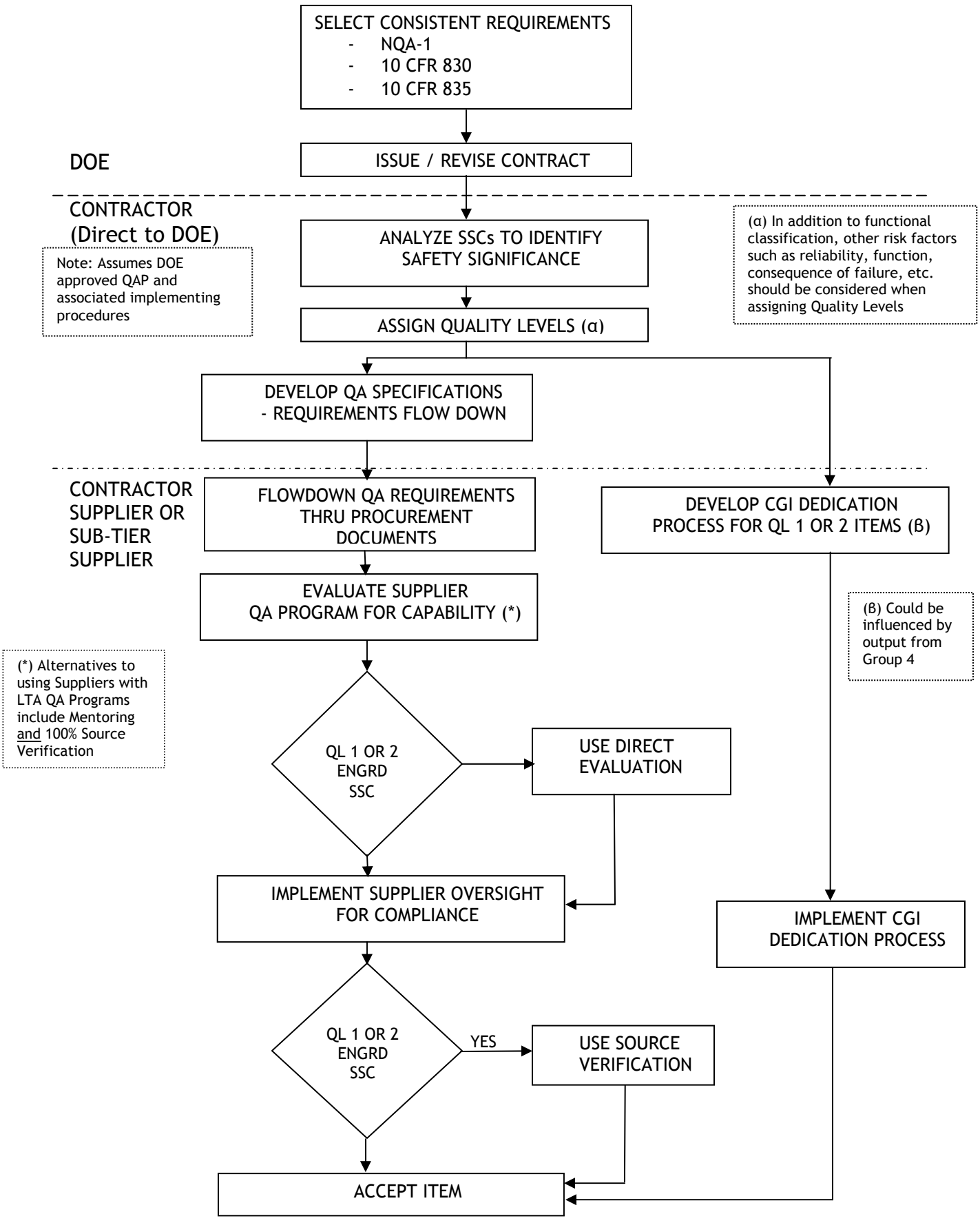
Project Milestones

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
5.5	11/30/08	More detailed QAP implementation (QIP) - next steps and guidance - will be issued by EM-3 following the EM-1 Memorandum. Draft presented to Corporate Board for review and discussion.	EM-3 Memo to Field Sites on Path Forward
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.	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-64 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	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

FLOW DOWN OF DOE EM QA REQUIREMENTS FOR SAFETY RELATED APPLICATIONS - A MODEL

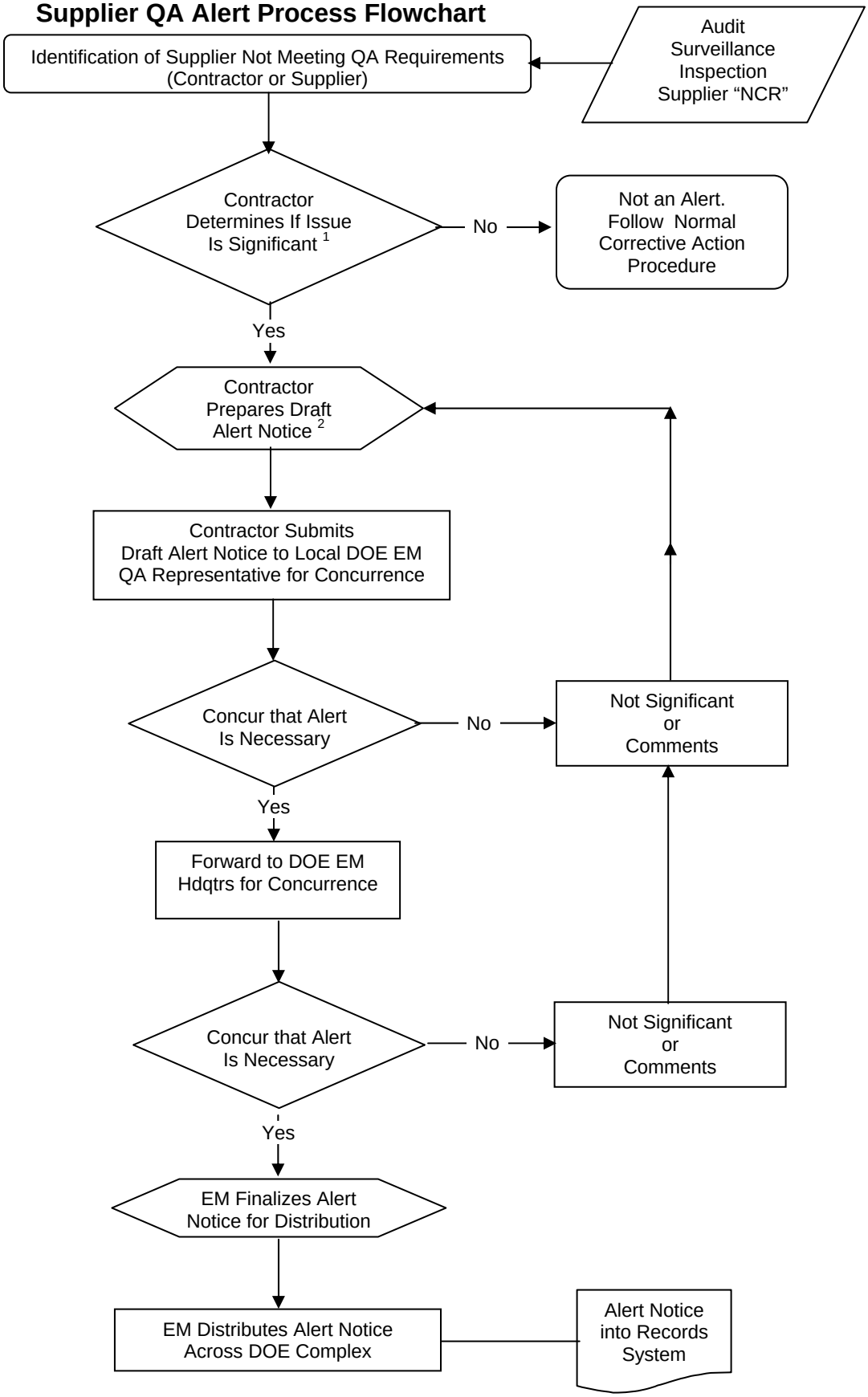


11/04/08

Project Area 2 - Adequate NQA-1 Suppliers
Task # 2.15

DRAFT

Supplier QA Alert Process Flowchart



[1] Examples of significant issues are: Removed from ASL (Approved Supplier List), Falsified Documents, SCAQ (Significant Condition Adverse to Quality), etc.

[2] ALERTS only contain facts regarding failure to meet QA requirements.

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Quality Assurance
Improvement Project Plan

Project Focus Area	Task # and Description	Deliverable
Project Focus #Area 3: Commercial Grade Item and Services Dedication	3.1-Complete a survey of selected EM contractors 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

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

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EM/EFCOG Quality Assurance Improvement Project Plan
Project Focus Area #3 -Commercial Grade Item and Services Dedication Implementation and Nuclear Services
Task #3.1: Commercial Grade Item (CGI) Dedication Survey Summary

1. Purpose:

   This survey was conducted to obtain input from EM contractors on processes used to perform Commercial Grade Item (CGI) dedication. The intended use of this information is to form the basis for providing a recommendation to EM for a standard process for CGI dedication.

2. Survey Approach and Response:

   A formatted survey request (Attachment 1) was sent to contractor points-of-contact across the DOE complex. Nine responses were received.

3. Survey Results (results align with question numbers in Attachment 1):

   1) Seven of 9 contractors providing a response use a CGI dedication process. Two contractors providing a response do not have Safety Class/Safety Significant Structures, Systems or Components; therefore, do not use a CGI dedication process.

   2) Seven of 7 responders using a CGI dedication process follow the process described in a DOE-approved Quality Assurance Program.

   3) Five of 7 responders control the CGI dedication process using a cross-cutting functional organization procedure. Two responders use project/organization specific procedures.
   Five of 7 responders cite Engineering as the principal organization responsible for the CGI dedication process. One organization cites Quality Assurance and one organization cites the organization originating the CGI dedication.

   4) Industry standards used as the basis for the CGI dedication process vary:

      a. Four of 7 responders cite NQA-1-2000.
      b. Three responders cite NQA-1-2004.
      c. Three responders cite EPRI NP-5652 in addition to NQA-1-2000 or 2004.

   5) Seven of 7 responders use CGI dedication for Safety Class and Safety Significant Structures, Systems and Components. One responder allows CGI dedication for items not classified as Important to Safety as determined by the responsible functional organization.

   6) Acceptance methods for CGI dedication vary:

      a. Five of 7 responders use Special Tests and Inspections, Commercial Grade Survey of Supplier, Source Verification and Acceptable Supplier/Item Performance.
      b. Two of 7 responders use only Special Tests and Inspections and Commercial Grade Survey of the Supplier.

   7) Six of 7 responders use a design output document to specify a commercial grade item for use in a nuclear safety application. One responder uses a special form for this approval.

   8) Seven of 7 responders indicate written guidance is provided for selection of critical characteristics. However, the level of detail in this guidance varies significantly.

9) Seven of 7 responders indicate testing/verification of critical attributes is self performed. One responder indicated self-performed testing/verification is minimal.

10) Seven of 7 responders indicated critical characteristics for CGI acceptance are documented. Four of 7 indicated special forms are used for this documentation.

11) Organizational responsibility for accepting a CGI for use varies:

    a. Three responders indicated that Engineering and Quality Assurance are responsible for item acceptance.
    b. Three responders indicated Quality Assurance/Quality Inspection is responsible for item acceptance.
    c. One responder indicated Quality Assurance and the Functional Department Manager are responsible for item acceptance.

4. Summary:

Commercial Grade Item dedication is widely used at EM sites. Engineering, Procurement and Construction (EPC) projects use CGI dedication much more extensively than EM contractors performing more standardized retrieval and waste treatment work. With few exceptions, processes used for CGI dedication are controlled by cross-cutting functional organization procedures, and requirements are relatively consistent. Standards used as the basis for the CGI dedication program and organizational responsibility for acceptance of CGI for use are not standardized and vary from contractor to contractor. However, no specific problems were identified related to CGI dedication other than those reported by EPC projects.

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COMMERCIAL GRADE ITEM DEDICATION SURVEY

1. Is a Commercial Grade Item (CGI) dedication process used by your organization?	☐ Yes	☐ No
2. Is the CGI dedication process described in a DOE-approved Quality Assurance Program (QAP)?	☐ Yes	☐ No
3. Is the CGI dedication process controlled by a cross-cutting functional organization procedure?	☐ Yes Identify Functional Org.:	☐ No
4. What industry standard is used as the basis for the CGI dedication process?	☐ NQA-1 (version) ☐ EPRI (version)	☐ Other (specify)
5. What nuclear safety item classifications are included in the CGI dedication process?	☐ Safety Class ☐ Safety Significant ☐ Safety Related ☐ Important to Safety	☐ Other (Specify)
6. What acceptance methods are used for CGI dedication? (Check all that apply.)	☐ Special Tests and Inspections ☐ Commercial Grade Survey of Supplier ☐ Source Verification ☐ Acceptable Supplier/Item Performance Record	☐ Other (Specify)
7. What design output documents are used to specify a commercial grade item for use in a nuclear safety application?	☐ System Drawings ☐ Component Drawings ☐ Equipment Specs/Data Sheets ☐ Equipment/Component Lists ☐ System Design Descriptions	☐ Other (Specify)
8. Is written guidance provided for selection of critical characteristics?	☐ Yes	☐ No
	"When selecting critical characteristics for CGI acceptance, how is "reasonable assurance" defined or utilized to assure the item will	

	perform its intended function?"	
	**COMMERCIAL GRADE ITEM DEDICATION SURVEY**	
9. Do you perform your own testing or verification of Critical Attributes?	☐ Yes	☐ No
	Do you perform tests for ☐ Hardness ☐ Alloy ID ☐ Meggar ☐ Dimensions Other:	
10. Where are critical characteristics for acceptance documented?	☐ System Drawings ☐ Component Drawings ☐ Equipment Specs/Data Sheets ☐ Equipment/Component Lists ☐ Acceptance Tests/Plans	☐ Other (Specify)
11. Briefly describe how acceptance of an item for its intended service is documented.	What organizations are responsible for accepting an item for use?	
	Is a receipt inspection performed on an item slated for CGI dedication?	
	How is CGI dedication documentation prepared and retained?	
	Other	
Comments (Include Lessons Learned):		

Name/Title:	Company:

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Project Focus Area	Task # and Description	Deliverable
Project Focus #Area 3-Commercial Grade Item and Services Dedication	3.2-Complete a survey of selected EM contractors requesting them to identify the process and basis for the process used to accept **Nuclear Services.**	Completed Survey

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

ISM

EM/EFCOG Quality Assurance Improvement Project Plan
Project Focus Area #3 -Commercial Grade Item and Services Dedication Implementation and Nuclear Services
Task #3.2: Commercial Grade Services Dedication Survey Summary

1. Purpose:

   This survey was conducted to obtain input from EM contractors on processes used for Commercial Grade Services dedication. The intended use of this information is to form the basis for providing a recommendation to EM for a standard process for Commercial Grade Services dedication.

2. Survey Approach and Response:

   A formatted survey request (Attachment 1) was sent to contractor points-of-contact across the DOE complex. Seven responses were received.

3. Survey Results (results align with question numbers in Attachment 1):

   - Four of 7 contractors providing a response use a Commercial Grade Services dedication process. Two contractors providing a response do not have Safety Class/Safety Significant Structures, Systems or Components; therefore, do not use a Commercial Grade Services dedication process. One responder uses only evaluated suppliers for nuclear services.
   - Four of 4 responders using a Commercial Grade Services dedication process have the process described in a DOE-approved Quality Assurance Program.
   - Two of 4 responders using a Commercial Grade Services dedication process utilize a cross-cutting functional organization procedure. Two responders control the process on a case-by-case basis using work process documents such as a statement of work or a work package.
   - One responder cites Engineering as the organization with responsibility for the Commercial Grade Services dedication process. One responder cites Quality Assurance and two responders cite the organization procuring the service with Quality Assurance support.
   - Industry standards used as the basis for the CGI dedication process vary:
     - One of four responders cites NQA-1-2000.
     - Three responders cite NQA-1-2004.
     - Two responders cite EPRI NP-5652 in addition to NQA-1-2004
   - Four of 4 responders use one or a combination of methods for Commercial Grade Services acceptance such as:
     - Technical verification of data produced,
     - Surveillance/audit of the activity,
     - Review of objective evidence for conformance to procurement document requirements. Two of 4 responders provide written guidance for selection of critical characteristics for Commercial Grade Services dedication.
   - Documentation of services acceptance varies significantly:
     - Two responders use a Critical Characteristics acceptance form.
     - One responder uses a Quality Assurance assessment report.
     - One responder uses a Statement of Work deliverable.

4. Summary:

Commercial Grade Services dedication is not as widely used at EM sites as CGI dedication. Engineering, Procurement and Construction (EPC) projects use Commercial Grade Services dedication more extensively than EM contractors performing more standardized retrieval and waste treatment work. Processes used for Commercial Grade Services dedication are controlled by cross-cutting functional organization procedures by the one responding EPC contractor and one M&O Contractor. However, other contractors establish the acceptance process on a case-by-case basis. Standards used as the basis for the Commercial Grades Services dedication process vary from contractor to contractor and the organization assigned responsibility for acceptance of the service varies significantly. No specific problems related to Commercial Grade Services dedication were identified by the survey.

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COMMERCIAL GRADE SERVICES ACCEPTANCE SURVEY

1. Is a commercial grade services acceptance process used by your organization?	☐ Yes	☐ No
2. Is the commercial grade services acceptance process described in a DOE-approved Quality Assurance Program (QAP)?	☐ Yes	☐ No
3. Is the commercial grade services process controlled by a cross-cutting functional organization procedure?	☐ Yes Identify Functional Org.:	☐ No
4. What industry standard is used as the basis for the commercial grade services acceptance process?	☐ NQA-1 (version) ☐ EPRI (version)	☐ Other (specify)
5. What methods are used for acceptance of services? (Check all that apply.)	☐ Technical verification of data produced ☐ Surveillance/audit of the activity ☐ Review of objective evidence for conformance to procurement document requirements	☐ Other (Specify)
6. Are critical characteristics documented for acceptance of services?	☐ Yes	☐ No
7. Is written guidance provided for selection of critical characteristics?	☐ Yes	☐ No
FCOG	**COMMERCIAL GRADE SERVICES ACCEPTANCE SURVEY**	

8. Briefly describe how acceptance of a service for its intended service is documented? For example:	If critical characteristics are defined, how are they documented?
	What organizations are responsible for acceptance of services?
	Other
9. Comments (Include Lessons Learned):	
Name/Title:	Company:

Position Paper on Application of the Graded Approach in Environmental Management

Introduction

This Position Paper (paper) is part of Environmental Management's (EM's) project to improve quality assurance performance across its operations. It responds to the fourth of the five project focus areas identified during the initial EM QA Corporate Board meeting held in Las Vegas, Nevada on March 13, 2008. It was prepared by the Project Area 4 team of Department of Energy (DOE) and Contractor participants broadly representing EM (Attachment 1) using consensus decision making.

This team began by examining approximately 15 approaches to grading currently used across DOE and extracting the common elements and best practices. The team also examined EM goals and objectives from both the EM Quality Assurance (QA) Improvement Project Plan (Plan) and the draft EM QA Program.

This paper is deliverable 4.2 of the Plan. The paper lays out the essential elements of grading where the team felt common understanding and agreement was necessary before preparing a standard EM grading process.

The paper is preliminary to documenting a standard EM grading process (deliverable 4.4 due March 31, 2009). It is provided for the Third Level of Review (EM QA Corporate Board Members - voting and non-voting Full Members) as defined in the Plan and represents completion of milestone 4.3.

Purpose

Document the essential elements of grading including basis, process steps, and common definitions. Seek agreement and support from the EM QA Corporate Board to use these elements in preparing a standard EM grading process.

Background

EM understands a standard grading process for Quality Assurance can be applied consistently in EM 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.

Grading as defined in 10 CFR 830.3 and 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 (DOE G 414.1-2A) advocates grading the application of quality assurance controls to activities and in the design and construction of systems, structures and

components (SSCs). Some DOE elements limit their application of the graded approach to the design and construction of SSCs based on their importance to nuclear safety, 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").

Discussion

The Area 4 team proposes the following basis, essential elements of the grading process, and standard definitions be used in developing a standard EM grading process.

EM Standardized Graded Approach Basis

a. The graded approach applies to items, services, and activities affecting quality

b. The appropriate Subject Matter Expert (SME) is responsible for grading the item, service, or activity

c. The grading process result should be clear to a third party and results should generally be replicable when performed by a different person or group

d. Each organization is required to document the basis of the graded approach used, and submit that documentation to EM

e. The grading process shall not be used to circumvent applicable quality assurance, legal, or contractual requirements

f. The graded approach may not be used in implementing the unreviewed safety question (USQ) process or in implementing technical safety requirements

g. The graded approach for items, services, and activities affecting quality must not be used to "grade to zero"

h. Even in the least stringent application, compliance with applicable portions of stated requirements is mandatory unless an exemption is documented and approved

i. For services and activities the graded approach is applied at a programmatic level during the development of project acquisition, design, engineering, and procurement documents or procedures and not during day-to-day operations

j. When performing an activity there is no option to "grade" compliance with the procedure – the grading was established when the procedure was written

k. Grading is completed prior to issuing procurement documents.[1] Suppliers do not have the option to decide what requirements they meet – these are established using the approved grading process when the purchase specification is written. Suppliers cannot modify the requirements for the products or services they provide. If a supplier has an approved QA program and they meet the requirements, they may use their grading system to establish the rigor of their applied QA controls

l. Deviations (but not exemptions) from the grading processes for special needs and customer requirements (e.g., research and development) may be allowed. Deviations should be based on established standards (e.g., where regulators or others have specified the requirements to be met, eliminating the ability to apply grading). Provision for such deviations is documented in the approved Quality Assurance Program

Deviations to meet conflicting regulatory requirements that apply to nuclear facilities subject to 10 CFR 830 must, as a minimum, meet the CFR requirements

Training on Standardized Graded Approach

m. The EM Training Academy will modify their existing graded approach training module as necessary to reflect the requirements of the agreed-to EM grading process

n. EM Headquarters, EM Field/Project Offices, and EM contractors will prepare site-specific training on grading and train appropriate personnel

o. EM will develop a common set of definitions related to grading to be included with the standard grading process

Essential Elements of the Grading Process

1. Define responsibility for grading, including the relationship between the SME and QA

2. Identify the minimum requirements that must be met

The SME determines the technical requirements and with support from QA determines the quality attributes and acceptance criteria that must be verified

[1] 10 CFR 830.206 allows "…DOE may authorize the contractor to perform limited procurement and construction activities … if DOE determines that the activities are not detrimental to public health and safety and are in the best interests of DOE." In this limited case grading may not have been completed before issuing procurement documents. However DOE G 421.1-2 notes granting authorization must be weighed against "…the possibility that the PDSA [Preliminary Documented Safety Analysis] may not find the procured or constructed item to be an approved part of the project."

The procurement process provides the techniques to ensure that requirements and associated acceptance criteria are flowed down to all tiers of subcontractors and suppliers

3. Identify risk and determine amount of rigor required

For items, consider the following:

- Degree of uncertainty regarding operation and performance
- End use/application
- Special nature
- Manufacturing lead time
- State of the art
- Engineered vs. commercial
- Exotic materials or processes
- Degree to which function or performance can be demonstrated by inspection or test
- Critical characteristics
- Quality history and degree of standardization of the item
- Availability of suppliers
- Product history and/or documentation
- Supplier history
- Environment qualifications
- Potential for health, safety, security, environmental, schedule, and/or programmatic impacts resulting from failure, error, or inadequacy
- Difficulty of repair or replacement
- Complexity
- Potential for contamination in use
- Is it cost effective to conduct the grading process

For activities and services, consider the following:

- Importance, complexity, or special nature of the activity or service
- Customer focus/expectation
- Need for special controls, surveillance, inspection, or independent assessment
- Requirement for evaluated suppliers
- Need for a record that the activity was performed correctly

In grading the most risk sensitive classification requires a rigorous application of QA requirements. Grading is generally expressed as Quality Level 1, 2, or 3 with Quality Level 1 the most risk sensitive classification, requiring a rigorous application of QA requirements.

Examine whether it is cost effective to have multiple grades. If a single or uniform method of applying a more stringent requirement to items, services, and/or activities adds value and reduces risk, the application of the more stringent requirement is accepted. For example, if a project has nuclear and non-nuclear

applications for a particular bolt, it may be more cost effective and provide greater risk reduction to buy all bolts to the more stringent nuclear QA standard rather than segregate and control bolts purchased to two standards.

4. Documentation

   The evaluation to determine the level of grading shall be documented and that documentation retained as a QA record.

5. Q-lists and Bills of Material can be used to support the grading process

Definitions

Bills of Material: A list of the materials, parts and components necessary to produce or assemble an end item, assembly, or system

Critical Characteristics: Important design, material, and performance characteristics of a commercial grade item that, once verified, will provide reasonable assurance that the item or service will perform its intended safety function. [Source: ASME NQA-1-2004]

Grading/Graded Approach: A process by which the level of analysis, documentation, actions, activities, and control features that will be applied are determined based on safety, quality and/or project risk. The Graded Approach determines the appropriate level of effort and degree of rigor in applying quality requirements or management controls necessary to attain and document the acceptability of the item, service, or activity

Q-List: A listing of items and/or services and the associated quality level based on the grading process

Quality: The condition achieved when an item, service, or process meets or exceeds the user's requirements and expectations. [Source: 10 CFR 830.3]

Quality Assurance: All those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service. [Source: ASME NQA-1-2004 – note: includes services and activities within DOE]

Quality Assurance Program: The overall program or management system established to assign responsibilities and authorities, define policies and requirements, and provide for the performance and assessment of work. [Source: 10 CFR 830.3]

Quality Level: A designation determined by the probability and consequence of failure in a specified end use application that is assigned to systems, subsystems,

structures, components, documents, or services based upon health and safety, environmental, operations, programmatic, and performance considerations

Subject Matter Expert (SME): An individual with expertise in the subject matter to be documented. This person is an expert in a particular area with special, in-depth, knowledge of the area. Sometimes called the technical authority, design authority, cognizant system engineer, responsible engineer, or technical representative

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. [Source: ASME NQA-1-2004]

Summary Recommendations:

The Area 4 Team recommends the EM QA Corporate Board adopt the above approach and authorize the team to proceed with the development of a standard process for use across EM.

Sources

The following documents were used as sources:

- DOE O 414.1C
- 10 CFR 830.7
- NQA-1-2008 especially Part III, Subpart 3.1, Section 502, "Graded Approach," Part IV, Subpart 4.2, "Guidance on Graded Application of Quality Assurance (QA) for Nuclear-Related Research and Development,"
- ASME Nuclear Quality Assurance Committee, Applications Subcommittee, "White Paper on Programmatic Risk Consideration for Applying the ASME NQA-1 Quality Assurance Standard to Unregulated Mission Critical Programs, Projects and Facilities (Record #07-1906)

In addition, approximately 15 approaches to grading from across the DOE complex were examined for common elements.

Proposed Standard Quality Assurance (QA) Language for EM contracts:

The Contractor shall develop, submit for DOE approval, and implement a Quality Assurance Program (Deliverable X.X.X.X) that implements the Environmental Management (EM) Quality Assurance Program (QAP), EM-QA-001, within 30 days of contract inception for new EM contracts in which an existing approved QAP does not exist. For those contracts where an approved, compliant QAP exists, the contractor shall adopt the QAP as written or submit the QAP with recommended changes prior to assumption of the contract **(this red section needs word smithing)**. The Contractor may choose to adopt the EM QAP in lieu of developing its own QAP. Each contractor will submit for DOE approval, an organization-specific Quality Assurance Implementation Plan (QIP) describing how the applicable requirements of the EM QAP are implemented and are passed down to lower-tier organizations. This requirement does not alter a contractor's legal obligation to comply with 10 CFR 830 or other regulations affecting 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. It is expected that EM contractors will incorporate additional site-specific, local, state, and federal regulations and ASME NQA-1 requirements into their QIP based on applicability to activities being performed (e.g., Federal repository-related work; nuclear and non-nuclear facility operations and associated activities; transuranic [TRU] waste disposal activities; environmental media, waste characterization, and effluent discharge sampling and analysis operations driven by the Environmental Protection Agency [EPA] QA requirements associated with CERCLA, RCRA, Clean Water Act, Clean Air Act, and TSCA regulations; special processes; inspections and testing; use of measuring and test equipment; safety software, suspect counterfeit items, graded approach, etc.). The contractor QAMP shall describe the overall implementation of the EM QA requirements. The contractor's quality assurance program shall be applied to all work performed by the contractor (e.g., mission, safety, and health).

Within 60 days after assumption of the DOE contract, the Contractor shall develop and incorporate into their QAP/QIP, submit for DOE approval, and implement an Assurance System Description (Deliverable X.X.X.X), as required by DOE O 226.1A, *Oversight Policy*, to identify and address program and performance deficiencies, opportunities for improvement, processes **(correct word?)** to report deficiencies to the responsible managers and authorities, establish and effectively implement corrective and preventive actions, and share lessons learned across all aspects of the work scope. The Contractor shall annually review and update, as appropriate, their QAP/QIP and the Assurance System Description and resubmit updates to DOE for approval. 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 for all issues raised across all levels of 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. **(Need to discuss this red section)**

Note: this language needs to be aligned with the new EM corporate QAP language and EM-3 guidance for QIP development in HQ and the field sites.

Quality Assurance Clause
Office of River Protection Tank Farm Contract

"C.3.2.4 Quality
The Contractor shall develop, submit for DOE-ORP approval, and implement a Quality Assurance Program Description (Deliverable C.3.2.4-1) hat describes the overall implementation of DOE quality assurance (QA) requirements. The QAP shall be applied to all (not just ES&H) work performed by the Contractor. The Contractor shall obtain DOE-ORP approval for Quality Assurance Program Description updates as required.
The Quality Assurance Program Description shall implement the requirements of:
* 10 CFR 830 Nuclear Safety Management, Subpart A, Quality Assurance Requirements;
* DOE O 414.1C, Quality Assurance;
* DOE/CBFO-94-1012, DOE Carlsbad Field Office, Quality Assurance Program Description, Revision 8, for WIPP-related activities;
* DOE/RW-0333P, DOE Office of Civilian Radioactive Waste Management, Quality Assurance Requirements and Description, Revision 18, for activities related to disposal at Yucca Mountain; and
* ASME NQA-1-2004 (or latest edition and addenda), Quality Assurance Requirements for Nuclear Facility Applications, as the national consensus standard for TOC workscope implementing QA Criteria of 10 CFR 830 Subpart A and O 414.1C. The Contractor shall implement Parts I and II of the NQA-1 standard and indicate within the QA Program those portions of NQA-1 Parts III and IV that are applied to Contractor's workscope. If additional standards are required to address unique/specific work activities, the standards shall be identified within the Contractor's QA Program."

"The Contractor shall develop, submit for DOE-ORP approval, and implement an Assurance System Description (Deliverable C.3.2.4-2) to identify and address program and performance deficiencies, opportunities for improvement, provide the means and requirements to report deficiencies to the responsible managers and authorities, establish and effectively implement corrective and preventive actions, and share lessons learned across all aspects of the workscope. The Contractor shall annually update and re-submit the Assurance System Description to OE-ORP for approval.

The Contractor shall use a "zero-threshold" issue reporting system to capture, in one system, the issues raised across all Contractor organizations and working levels."

EM Corporate QAP Implementation Roadmap

Pre-Decisional
11/6/08

EM-1

Issue EM Corporate Quality Policy & QAP

Key Elements of EM Corporate QA Policy

- DOE O 414.1C
- 10 CFR 830-120
- NQA-1 2004, addenda thru 2007

EM-3

Issue memorandum (guidance and criteria) to implement Corporate QAP

Key Attributes of Corporate QA Policy application

- Tailored application of NQA-1 to HQ, Field, Contractors
- Reflect mission, project lifecycle, and risk
- Graded to nuclear/non-nuclear operations
- Perform Gap Analysis
- Update QAP
- Develop QIP for review, approval, and implementation

Approve and issue EM-HQ QIP for implementation

EM-HQ
(10, 20, 30, 40, 50, 60)

Assess extent and impact of applicability to EM-HQ Offices

Review and comment on EM-HQ QIP

Review, comment, and approve Field/ Contractor QIPs (as delgated)

Implement EM-HQ QIP
(staff training and resources)

Provide oversight of EM-HQ QIP

EM-HQ
(EM-64)

Provide Implementation guidance and criteria

Identify Gap between current EM-HQ QAP and corporate QAP

Develop updated EM-HQ QAP

Develop draft EM-HQ QIP

Develop final EM-HQ QIP

Support implementation & oversight of EM-HQ & Field QIPs

EM
Field/Project Offices

Assess extent and impact of applicability to Field/ Project offices

Identify Gap between current Field QAP and Corporate QAP

Develop updated Field QAP

Develop Field QIP for HQ review and approval

Review and approve contractor QIP (as delgated)

Develop final Field QIP

Implement approved Field QIP
(staff training and resources)

Provide oversight of QAP/QIP

EM
Contractors

Assess extent of applicability to Contractor QAP & Flow down to all subcontractors

Identify Gap between current contractor QAP and Corporate QAP

Develop updated contractor QAP

Develop contractor QIP for review and approval

Develop final Contractor QIP

Implement approved Contractor QIP
(staff training and resources)

Provide oversight of QAP/QIP

EM-QAP Implementation Roadmap Overview

- Methodical and consistent phased approach to implementation of the EM Corporate Quality Assurance Program (QAP)
  - Tailored and graded to site-specific and contract-specific conditions
  - Deadlines are reflective of known status of current QA programs in place at DOE sites
  - Flow down of QAP requirements is a critical element
- Leverages other ongoing corporate QA-related initiatives
  - DOE-EM/EFCOG Quality Assurance Improvement Project Plan, Rev. 2
- Scope, rigor, and extent of applicability are functions of:
  - Current site QAP--- most EM Sites have already adopted NQA-1
  - Nuclear vs. non-nuclear operations
  - Existing contract vs. new contract
  - Project life-cycle phase
- Effective integration and implementation of QA in EM are highly dependent on:
  - Line management understanding of QA
  - Staff training and resources
  - Outreach and awareness
  - Discipline, structure, ongoing monitoring, and continuous improvement

EM-QAP Implementation Roadmap
Basis for Tailoring/Graded Approach

- Consistent with planned EM Standard/Process on the graded approach to QA:
  - Task 4.4 - Project Area 4 – Graded Approach to Quality Assurance

- Balances the following:
  - Nuclear vs. non-nuclear operations
  - Project lifecycle
  - Baseline-minimum requirements that must be met
  - Risk identification and risk management alternatives

- EM will provide technical resources and assistance to ensure consistency in application of graded approach:
  - Gap analysis
  - Applicability of requirements and criteria
  - Implementing procedures (i.e., QIP)

Key Steps Associated with the Implementation of EM QAP

Who	What	When
EM-1 EM-3	**Issue EM Corporate Quality Policy and QAP** ▪ Tailored application of NQA-1 2004 to all EM Activities ▪ Assess extent of QAP impact and applicability-Conduct Gap Analysis ▪ Development of organization-specific QIP using graded approach ▪ EM-3 Memorandum (expectations & criteria) to implement QAP	Issued on 11/5/2008
EM-HQ EM Field & Project Offices EM Contractors	**Develop Organization-specific Quality Assurance Implementation Plan (QIP)** ▪ Tailored to mission, project lifecycle, and risks ▪ Based on gap analysis relative to current QAP ▪ Graded to reflect nuclear/non-nuclear operations ▪ References implementing procedures ▪ Demonstrates flow down to subcontractors	***If site/contractor is already subject to NQA-1, then by no later than*** 3/31/2009 Otherwise by no later than 6/30/2009
Respective Approval Authority *(or delegated)*	**Review and Approve the QIP** ▪ Accounts for staff training & oversight ▪ Responsive to POMCs ▪ Meets EM-3 expectations and criteria	***If site/contractor is already subject to NQA-1, then by no later than*** 6/30/2009 Otherwise by no later than 9/30/2009
EM-HQ EM Field & Project Offices EM Contractors	**Fully Implement QAP/QIP** • Monitor, assess, and continuous improvement	***If site/contractor is already subject to NQA-1, then by no later than*** 9/30/2009 Otherwise by no later than 12/31/2009

Specific/Details Associated with the Key Steps

Who	What	When
EM-1	**Issue EM Corporate Quality Policy and QAP**	Issued on 11/05/2008
EM-64 Action Items	▪ **Ensure consistency with EM/EFCOG QA Improve Project Plan, including planned EM Standard/Process for graded approach – Focus Group #4.** ▪ **Develop criteria/guidance to assess impact of corporate QAP and conduct of gap analysis** ▪ **Coordinate with Focus Group #5 – Management Understanding of QA -- in developing draft EM-3 memorandum.** ▪ **Assist EM-3 in preparing implementation memorandum (defining impact and expectations at HQ and Project/Field Offices, key milestones, schedule for completion).**	
EM-3	**Issue Memorandum to Implement Corporate QAP**	

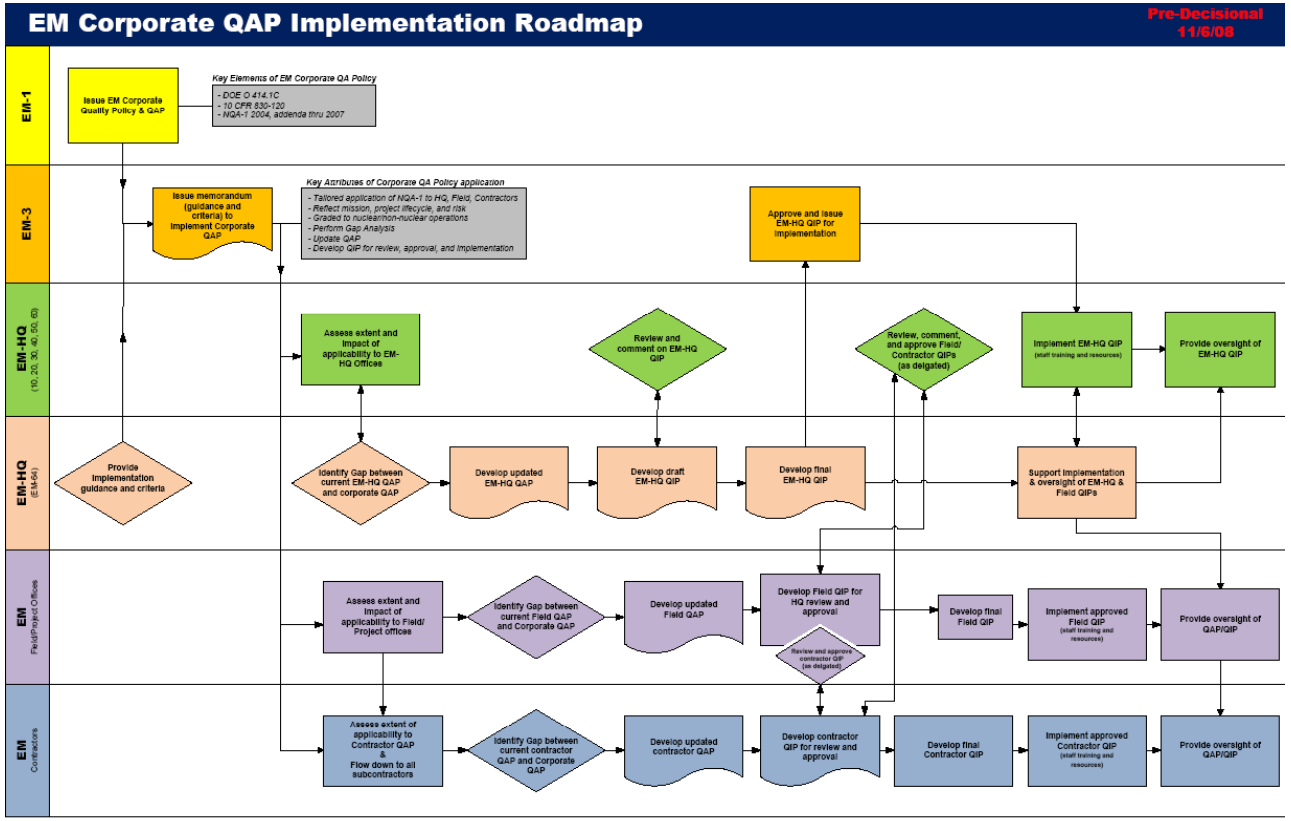
Specific/Details Associated with the Key Steps (Cont'd)

Who	What	When
EM-HQ EM Field & Project Offices EM Contractors	**Develop Organization-specific Quality Assurance Implementation Plan (QIP)**	***If site/contractor is already subject to NQA-1, then by no later than*** 3/31/2009 Otherwise by no later than 6/30/2009
EM-64 Action Items *(Lead development of EM-HQ QIP)*	▪ **Coordinate development of HQ-QIP----work with EM-HQ offices to determine extent of applicability** ▪ **Perform gap analysis between existing HQ QAP and corporate QAP** ▪ **Develop scope and plan to address identified gaps** ▪ **Develop updated HQ-QAP** ▪ **Develop draft HQ-QIP consistent with updated HQ-QAP--Submit draft QIP for HQ office review** ▪ **Resolve HQ comments/finalize EM-HQ QIP for EM-1/EM-3 issuance, approval and distribution**	
HQ	▪ **Review draft EM-HQ QIP and submit comments to EM-64** ▪ **Review and approve Field/Contractor QIP, as delegated**	
EM Field & Project Offices (Develop Field QIP and Review/Approve Contractor QIP)	▪ **Assign independent assessment team to conduct gap analysis** ▪ **Use gap analysis results to develop QIP consistent with QAP** ▪ **Direct contractors to perform gap analysis and develop QIP** ▪ **Submit draft Field Office QIP for HQ review and approval** ▪ **Resolve HQ comments and finalize QIP for Project/Field Office issuance, approval and distribution** ▪ **Ensure that Corporate QAP requirements are flowed down to contractors/subcontractors for integration or for QIP development** • **Review and approve contractor developed QIP**	***If site/contractor is already subject to NQA-1, then by no later than*** 6/30/2009 Otherwise by no later than 9/30/2009
EM-64 QA Support	▪ **Coordinate EM-HQ review and approval of Field/Contractor QIP** ▪ **Provide technical assistance, as requested, to support Field in gap analysis, graded approach and development of QIP**	

Specific/Details Associated with the Key Steps (Cont'd)

Who	What	When
EM-HQ Field Offices Contractors	**Fully Implement QIP** • **Monitor, assess, and continuous improvement**	***If site/contractor is already subject to NQA-1, then by no later than*** 9/30/2009 Otherwise by no later than 12/31/2009

EM QAPP Implementation Decision Tree



PROGRAM FAILURES

- THESE ISSUES ARE DIRECTLY RELATED TO A PLANT'S "FALL FROM NRC GRACE".
- THE PLANT HAD BEEN LISTED BY THE NRC AS ONE OF THE TOP NUCLEAR PLANTS FOR 10 CONSECUTIVE YEARS.

FAILURES IN MANAGEMENT OF THE QA PROGRAM

- THE QA ORGANIZATION LACKED MANAGEMENT SUPPORT:
  - PROMOTED THE VIEW OF QAULITY AS AN SECONDARY RESPONSIBILITY
- NO PROCESS FOR ESCALATING ISSUES:
  - ISSUES REMAIN UNRESOLVED
  - ISSUES DO NOT RECEIVE MANAGEMENT ATTENTION

FAILURES IN MANAGEMENT OF THE QA PROGRAM

- NO ONE PERSON/ORGANIZATION RESPONSIBLE FOR MANAGING ISSUES TO CLOSURE:
  - ISSUES REMAIN UNRESOLVED DUE TO CONFLICTS WITH DAY-TO-DAY PRIORITIES
  - WITH NO ONE BEING HELD ACCOUNTABLE ISSUES REMAIN UNRESOLVED

FAILURES IN MANAGEMENT OF THE QA PROGRAM

- REPORTS TO MANAGEMENT ON QUALITY WENT FROM MONTHLY TO QUARTERLY TO ANNUALLY:
  - DOES NOT PROVIDE MANAGEMENT FEEDBACK ON THE HEALTH OF THEIR ORGANIZATION

FAILURES IN MANAGEMENT OF QA RESOURCES

- NO REPLACEMENT OF OVERSIGHT PERSONNEL AS A RESULT OF ATTRITION:
  - HAMPERS THE ABILITY OF THE ORGANIZATION TO RESPOND TO ISSUES
  - INHIBITS THE ABILITY TO IDENTIFY ISSUES IN A TIMELY MANNER
- TRAINING OF OVERSIGHT PERSONNEL WAS MARGINAL:
  - LACK OF QUALIFIED INDIVIDUALS

FAILURES IN MANAGEMENT OF THE CA PROGRAM

- THE CORRECTIVE ACTION REVIEW BOARD (CARB) WAS INEFFECTIVE, I.E., MET INFREQUENTLY AND HAD THE INCORRECT LEVEL OF MANAGEMENT ON THE BOARD:
  - ALLOWED ISSUES TO REMAIN UNRESOLVED
  - SIGNIFICANT ISSUES WERE BEING DISPOSITIONED BY INDIVIDUALS NOT FAMILIAR WITH THE “BIG PICTURE”.

FAILURES IN MANAGEMENT OF THE CA PROGRAM

- THE PLANT HAD A CA REVIEW PROCESS:
  - INCLUDED REVIEW BY MANAGEMENT
  - MANAGEMENT TEAM REJECTED APPROXIMATELY 5% OF CA RESPONSES
  - QA REJECTED APPROXIMATELY 50% OF CA RESPONSES.
    - THE DISPARITY WAS ATTRIBUTED TO MARGINAL TRAINING FOR REVIEWERS
    - INCORRECT LEVEL OF MANAGEMENT PARTICIPATING IN THE REVIEWS

FAILURES IN MANAGEMENT OF THE CA PROGRAM

- THE SEVERITY LEVEL OF CARs WAS DOWNGRADED REGULARLY:
  - INTRODUCES THE ABILITY TO APPLY INAPPROPRIATE RIGOR TO CARs
- GRANTING EXTENSIONS TO CA DUE DATES
- RELAXATION OF CLOSURE/RESPONSE DATES (RESPONSE TIME WENT FROM 30 DAYS 60):
  - ALLOW ISSUES TO CONTINUE IN AN UNRESOLVED STATUS WHICH COMPOUNDS THE OVERALL IMPACT
  - SENDS A MESSAGE FROM MANAGEMENT RELATIVE TO THE SIGNIFICANCE OF THE ISSUE

FAILURES IN MANAGEMENT OF THE CM PROGRAM

- THE CONFIGURATION MANAGEMENT PROCESS WAS INEFFECTIVE:
  - ONE DRAWING HAD TEN (10) FIELD CHANGES ASSOCIATED WITH IT. ENGINEERING DEPARTMENT ISSUED 10 SEPARATE DRAWINGS FOR CONSTRUCTION TO WORK TO
    - CAUSED CONFUSION IN THE FIELD WHICH RESULTED IN ERRORS DURING ERECTION

MANAGEMENT FAILURES

- ACKNOWLEDGEMENT AND ACCEPTANCE OF THEIR NRC RECOGNIZED POSITION:
  - RESULTED IN THE PLANT NOT CONDUCTING BENCHMARKING EXERCISES
  - REMAINING ALOOF FROM COUNTERPARTS
  - ACCEPTING AND EMBRACING THE CONCEPT THAT OPERATIONS WERE BEING WELL CONDUCTED WITHOUT STRONG INDEPENDENT OVERSIGHT TO CONFIRM THEIR PERCEPTIONS.

MANAGEMENT FAILURES

- THE PLANT CONCLUDED THEIR PROGRAM EXHIBITED:
  - A HIGH LEVEL OF ARROGANCE
  - A HIGH LEVEL OF ISOLATIONISM
  - A HIGH LEVEL OF COMPLACENCY