EM QUALITY ASSURANCE CORPORATE BOARD MEETING
Knoxville, Tennessee
August 27-28, 2009

Key Workshop Objectives:

1. Provide Board Members a Summary of Actions Accomplished since the last Corporate Board Meeting in March 2009.

2. Review and Discuss the EM/EFCOG Quality Assurance Improvement Project Action Plan Focus Areas' Progress and Completed Deliverables.

3. Obtain industry and DOE perspectives on concerns and lessons learned pertaining to Counterfeit, Suspect, and Fraudulent Items and Commercial Grade Dedication.

Desired Outcomes:

1. Vote by Board members on EM/EFCOG Quality Assurance Improvement Initiative Project Plan Deliverables for FY 2009.

2. Develop EM/EFCOG QA Improvement Project Plan Work Scope for FY 2010.

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

EM QUALITY ASSURANCE CORPORATE BOARD MEETING

Meeting Location: Knoxville Convention Center, 701 Henley Street Knoxville, TN **Main Number: 865-522-5669**		
Room: 300A		
AGENDA for August 27, 2009		
1:00 pm	**Welcome and Opening Remarks** • Introduction of Board Members • Agenda and Logistics	**Dae Chung (EM/HQ)** **Steve Krahn (EM/HQ)**
1:15	EM/EFCOG QA Improvement Project Plan Status Report: Project Focus Areas #1 – 5	Sandra Waisley (EM/HQ) Dave Tuttel (*EnergySolutions*)
1:30	Discussion of Completed Project Focus Area Deliverables: • #4: Graded Approach to Quality Assurance #1: Requirements Flow Down	Al Hawkins (EM/RL) Vince Grosso (SRR) Mike Hassell (WCH) Butch Huxford(EM/HQ) Alice Doswell (Parsons)
2:45 – 3:00	**Break**	**ALL**
	• #2: Adequate Nuclear Suppliers Update	Bill Rowland (EM/SRS) Rich Campbell (*EnergySolutions*)
	• #3: Commercial Grade Item/Services Dedication Deliverables Update	Pat Carier (EM/ORP) Shelby Turner (CH2M Hill)
	• #5: Line Management Understanding of QA and Oversight Deliverables Update	TJ Jackson (EM/CBC) Dave Hall (URS-WGI)
4:30 – 5:30	EM Contractor Perspectives and Update on ARRA Implementation	Contractor Board Members
5:30	**Adjourn: End Full Board Session**	**Steve Krahn (EM/HQ)**
AGENDA for August 28, 2009		
8:00 am	**Welcome and Opening Remarks**	**Steve Krahn (EM/HQ)**
8:15	NRC Perspective on Counterfeit, Suspect, and Fraudulent Items	Dan Pasquale (NRC) Paul Prescott (NRC)
9:15	DOE/HSS Perspective on Counterfeit, Suspect, and Fraudulent Items (Protocols)	William Roege (DOE/HSS)
9:45	DOE/IG Perspective on Counterfeit, Suspect, and Fraudulent Items (Oversight)	Randall Kizer (DOE/IG)
10:15 – 10:30	**Break**	**ALL**
10:30	CGD Lessons Learned at ORP: WTP and Tank Farms	Pat Carier (EM/ORP)
11:00	Planning Session for FY 2010 Corporate Board Project Focus Areas	Open Discussion
12:00 Noon	**Adjourn: End Full Board Session**	**Steve Krahn (EM/HQ)**

Quality Assurance Improvement Project Plan

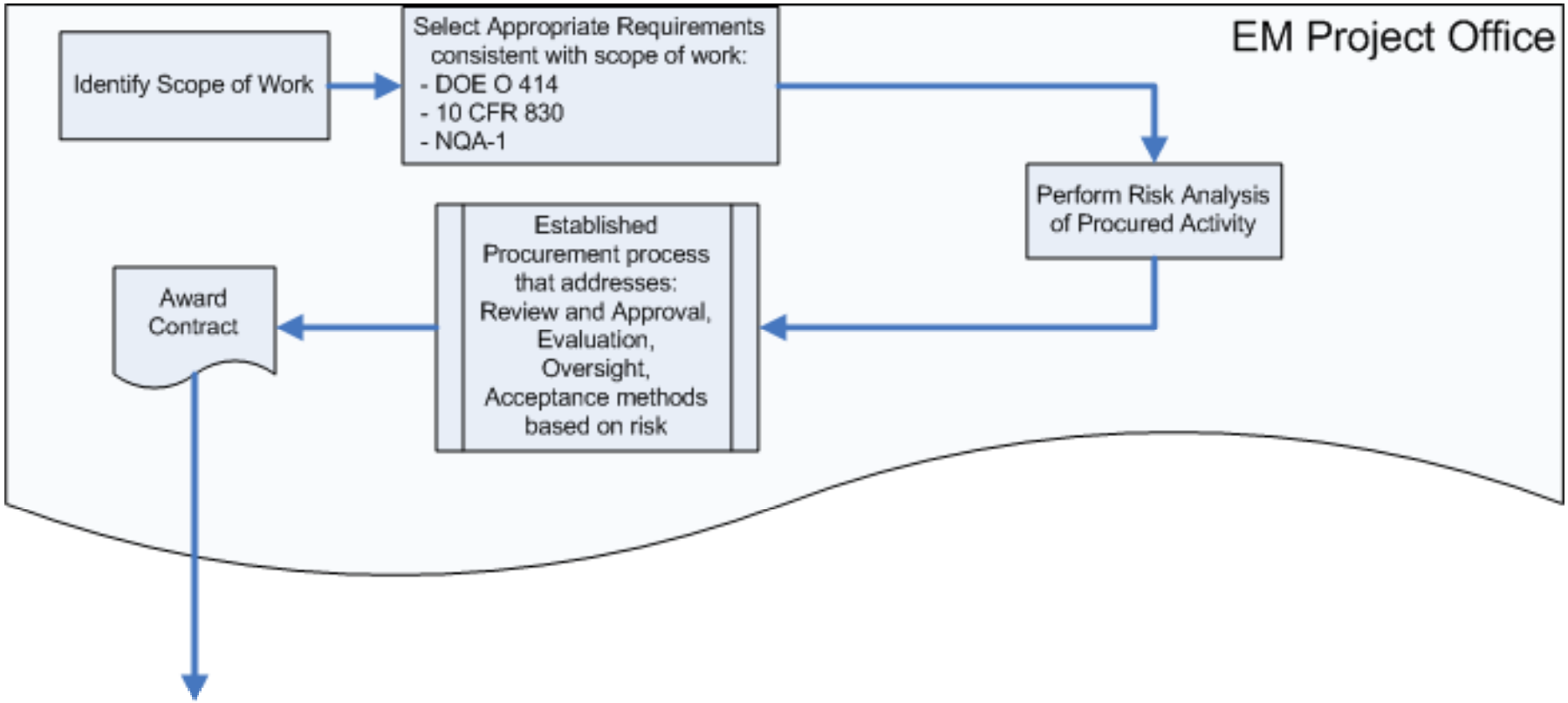
Graded Approach

Task Team #4

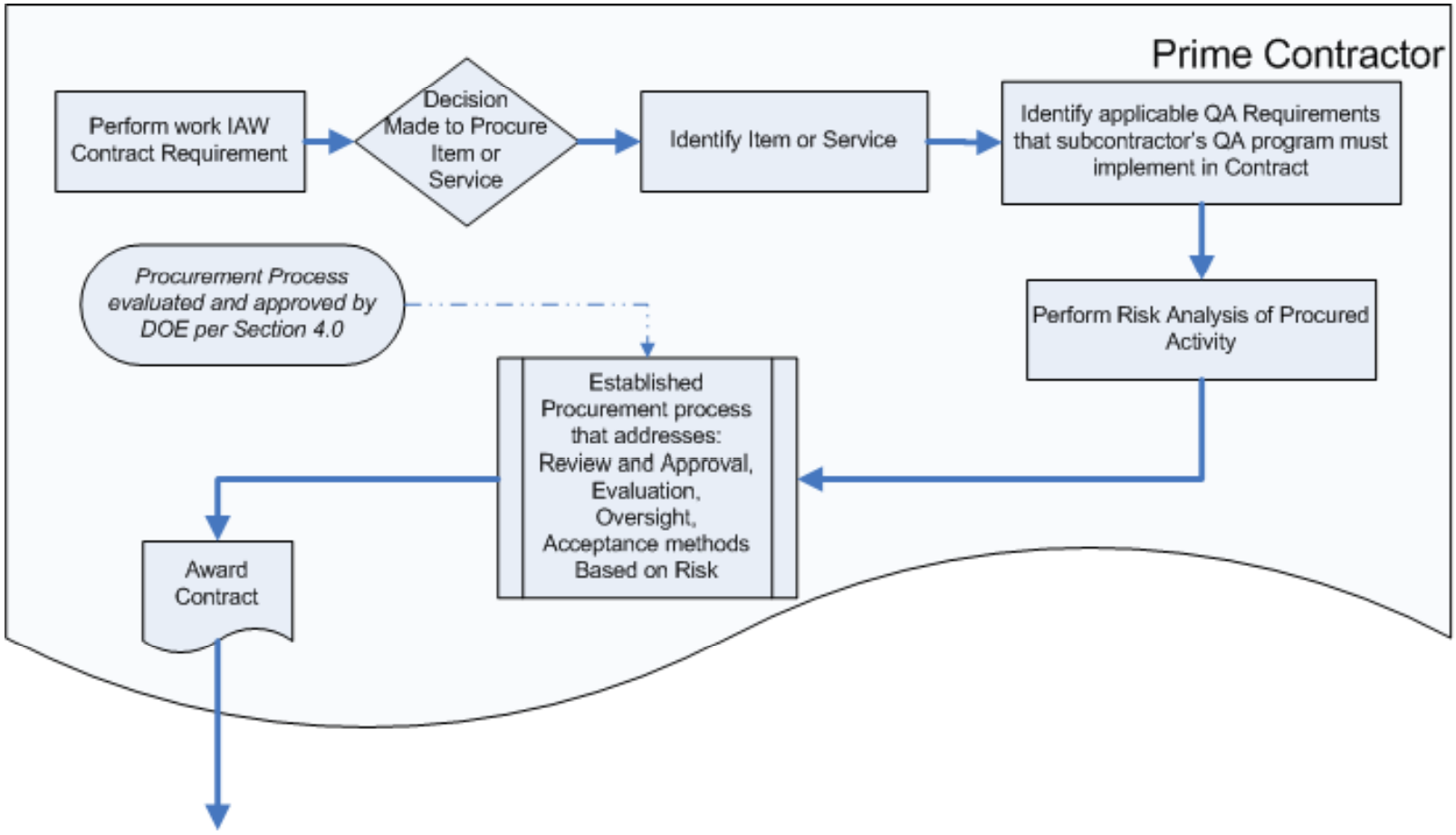
Graded Approach to Procurement

- Current product combines Task Team #1 and #4 deliverables
  - Quality Assurance Requirements Flow Down and Graded Approach Application (procurement specific)
- Primary Attributes of process
  - Requirements Flow Down addresses “WHAT” requirements are applicable
  - Risk assessment process characterizes the overall “Risk” associated with procurement activity
  - Graded Approach addresses managerial controls on “HOW” requirements are implemented – commensurate with risk.

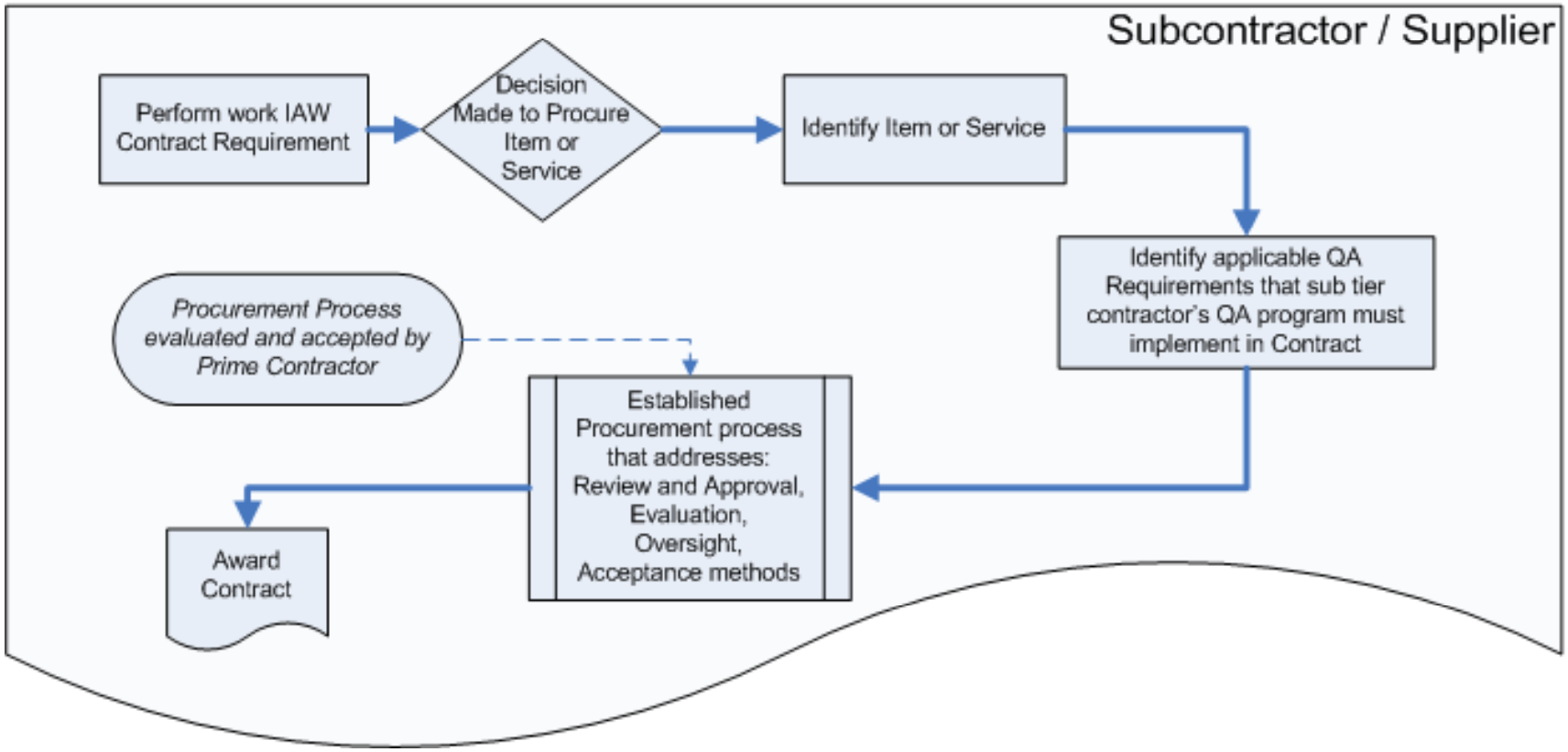
Requirements Flow Down
EM to Prime Contractor



Requirements Flow Down
Prime Contractor to Subcontractor



Requirements Flow Down Subcontractor to Subtier



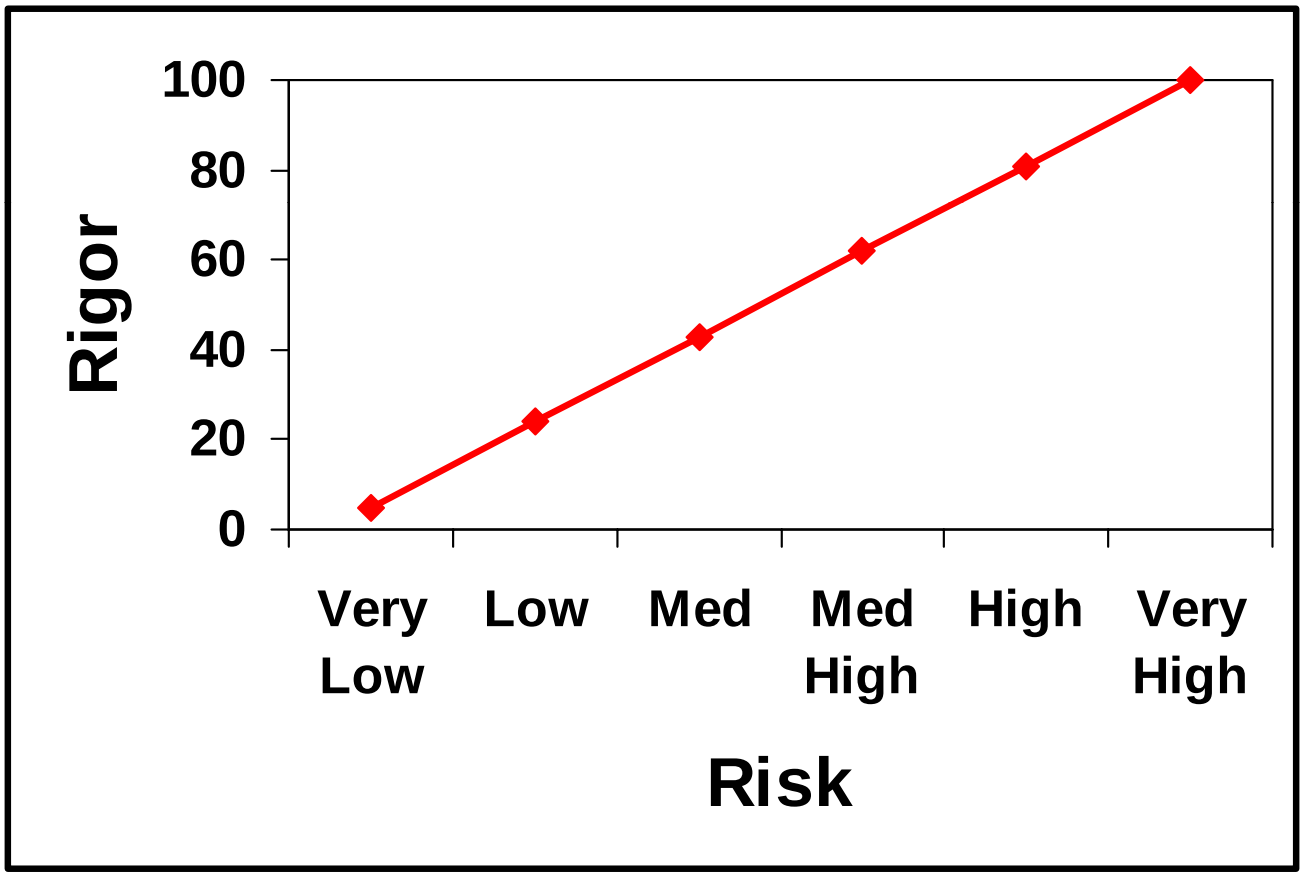
Risk Assessment Process

- EM would be the owner/provider of the risk assessment software tool
- Contractors modify “answers” to questions to establish risk profiles suited to their activities
- System asks a series of questions to determine overall risk
    - Credited in DSA?
    - Failure consequence?
    - Mission critical?
    - Failure potential?

Graded Approach Baseline Assumptions

- Quality Assurance program applies to all activities performed by the contractor for the Department of Energy
- Procurement requirements of the QA program apply to all procurements made by the contractors
- Quality Levels (QL) define the rigor by which requirements are implemented commensurate with the risk/importance of the procurement
- While “QL” is used, projects may use terms with same meaning – i.e. Procurement Levels (PL), Quality Control Levels (QCL), etc.

Rigor Commensurate with Risk



Procurement Requirements that Support Varying Managerial Controls

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

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Procurement Requirements that Support Varying Managerial Controls

- Content of Procurement Documents
- Procurement Document Review → Review & Approval
- Procurement Document Changes
- Supplier Evaluation and Selections
- Bid Evaluation
  → Supplier Evaluation
- Control of Supplier Generated Documents
- Supplier Performance Monitoring → Monitoring
- Acceptance of Item or Service → Acceptance
- Control of Supplier Non-conformances
- Commercial Grade Items and Services → Task Group 5

Graded Approach Procurement

Risk Assessment

- Credited in DSA?
- Failure consequence
- Mission critical?
- Failure potential

High	→	QL-1
Med	→	QL-2
Low	→	QL-3
Very Low	→	QL-4

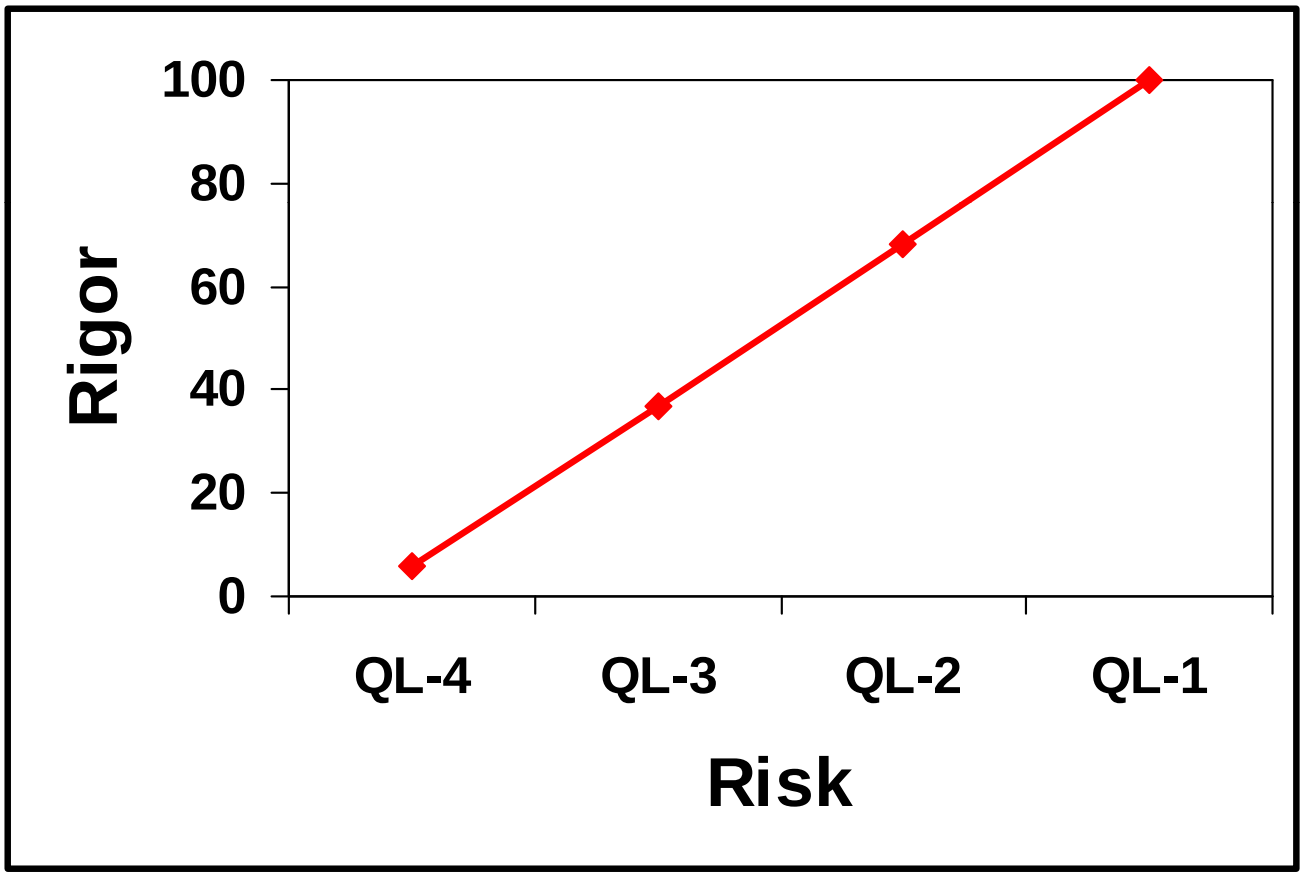
Graded Approach Baseline Assumptions

Review/
Approval

Evaluation

Acceptance

Monitoring



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

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

ICP

IDAHO CLEANUP PROJECT

Quality Level Determination Process Implementing a Graded Approach

CH2M•WG IDAHO, LLC

Bill Kerley, ICP Chief Engineer
August 27-28, 2009

SAFELY PLAN • MOTIVATE • DELIVER

Points of Contact:

- Bob Thompson – Quality Assurance Director
  - 208-521-0767
  - Robert.Thompson@icp.doe.gov
- Bill Kerley – ICP Chief Engineer
  - 208-533-0240
  - William.Kerley@icp.doe.gov
- Tom Fewell – Engineering Programs
  - 208-533-0260
  - Thomas.Fewell@icp.doe.gov

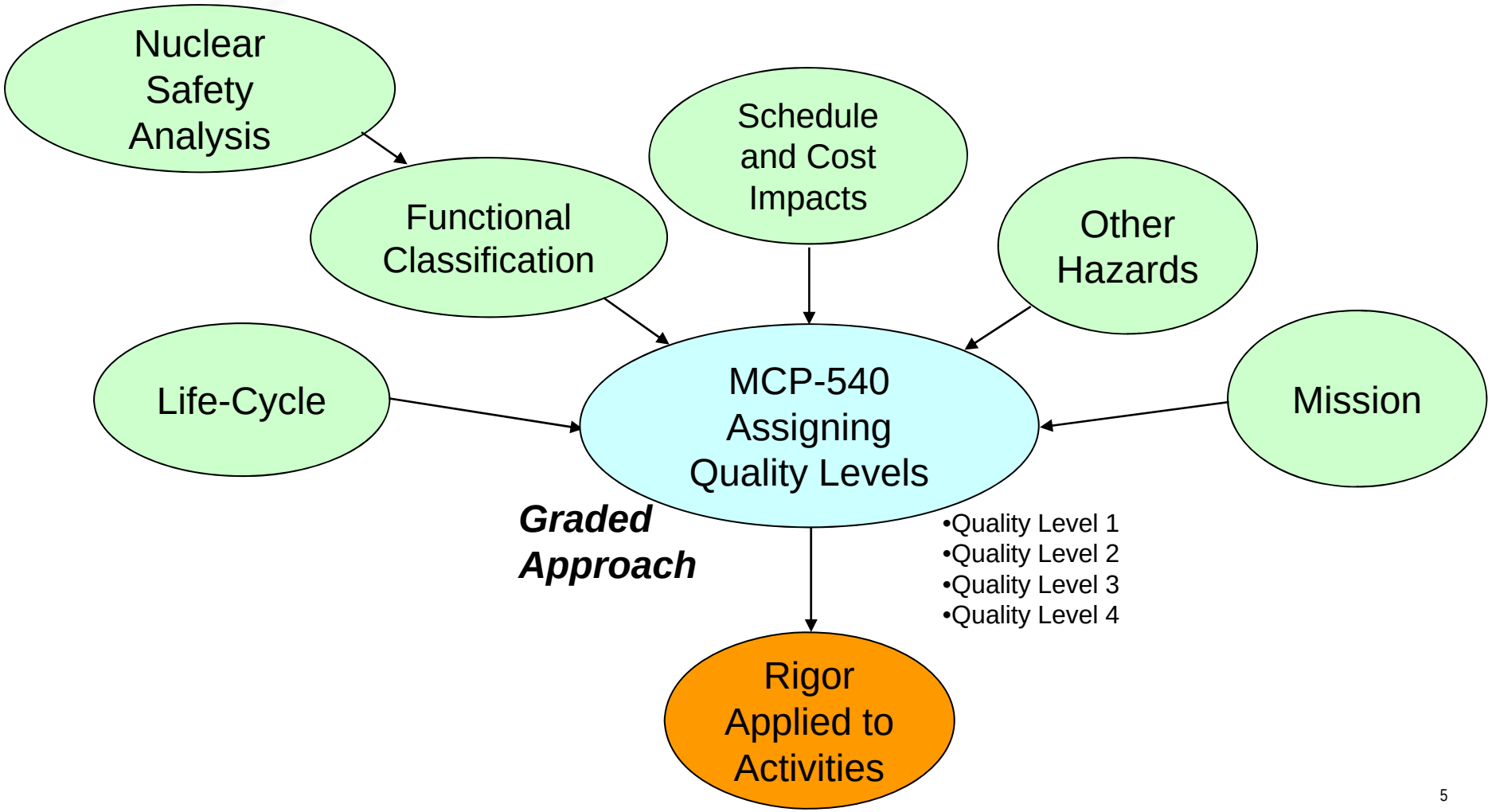
Drivers for a Graded Approach

- 10 CFR 830.7 – "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."
- 10 CFR 830.3 – "…the process of ensuring that the level of analysis, documentation, and actions used to comply with a requirement in this part are commensurate with:
  - The relative importance to safety, safeguards, and security;
  - The magnitude of any hazard involved;
  - The life cycle stage of a facility;
  - The programmatic mission of a facility;
  - The particular characteristics of a facility;
  - The relative importance of radiological and non-radiological hazards"
- DOE G 414.1-2A - "The scope, depth, and rigor of the quality management system's application of requirements should be determined by the use of a grading process before performing the activity"

Attributes of an Effective Process

- Grading does not determine quality verification and documentation requirements; it **enables** the implementation of a graded approach
- Grading cannot be used to "grade to zero" (i.e., eliminate requirements) – even for the lowest graded item or activity, compliance with design and regulatory requirements is mandatory
- Applies to **nuclear and non-nuclear** items and activities
- Grading is applied in a consistent, rigorous process by knowledgeable personnel, typically the **system engineer**
- Various quality implementing processes use the Quality Level to define level of rigor, as appropriate, for the specific process (e.g., design, procurement, change control, testing, and inspections)

Assigning Risk/Quality Levels



Risk Assessment Process for Assigning Quality Levels

- Questionnaire leads system engineer through evaluation
  - Importance to DSA
  - Failure Consequences
  - Failure Potential
  - Mission Critical Determination
- Performed at level of system, structure, or component as determined by Engineering and the Project
- Electronic form facilitates process
  - Simplifies entry of data
  - Provides definitions and help screens for clarity
  - Allows users to enter additional information that supports the determination
  - Automatically routes for electronic signatures
  - Provides for storage and retrieval of Quality Level Determinations (QLD)
- Questions also developed for software Quality Level assignments

Example of Question Set

Failure Consequence Levels

1. Adverse safety impact of my test failure is:
   - ○ a. Safety function of a vital safety system identified in the documented safety analysis is jeopardized
   - ○ b. Function of a safety system identified in a hazards analysis document is degraded
   - ○ c. Potential industrial injuries typically addressed in OSHA regulations
   - ○ d. No impact
2. Mission interruption impact of my test failure is:
   - ○ a. Project impacted by more than six months
   - ○ b. Project impacted by more than 60 days
   - ○ c. Project impacted by less than 60 days
   - ○ d. No impact
3. Environmental damage from my test failure is:
   - ○ a. Permanent damage to the ecology
   - ○ b. Severe, acute, or long-term damage to the ecology
   - ○ c. Recoverable impacts to the local ecology
   - ○ d. No impact
4. Negative government or public perception from my test failure is:
   - ○ a. National or international attention
   - ○ b. State or regional attention
   - ○ c. Local attention
   - ○ d. No impact
5. Adverse cost impact of my test failure is:
   - ○ a. Over $2 million
   - ○ b. Between $0.5 million and $2 million
   - ○ c. Less than $0.5 million
   - ○ d. Minimal impact

Failure Consequence Levels

Submit/Update Failure Consequence Levels | Back To Previous

Supporting Information:

Note: “my test” above would be the SSC entered on form.

Completed Form Example

QLD ID = 2018 **Form 431.67 "Quality Level Determination"**

Site Area Idaho Falls Area	**Building or Structure** Lindsay Blvd Complex-641
SSC Number IF-PU-123456	**SSC Name** Coolant Pump
Applicable Item: Item Or Activity	

Quality Level for this Coolant Pump PU-123456 is: QL-3

This quality level is based on the following identified characteristics:

Items or Activities Credited in a DSA				
1	The Coolant Pump PU-123456 being evaluated is not credited in a documented safety analysis.	a.	b.	c.

Supporting Information

Failure Consequence Levels					
1	Adverse safety impact of Coolant Pump PU-123456 failure is potential industrial injuries typically addressed in OSHA regulations.	a.	b.	c.	d.
2	Mission interruption impact of Coolant Pump PU-123456 is project impacted by less than 60 days.	a.	b.	c.	d.
3	Environmental damage from Coolant Pump PU-123456 is recoverable impacts to the local ecology.	a.	b.	c.	d.
4	Negative public perception from Coolant Pump PU-123456 is no impact	a.	b.	c.	d.
5	Adverse cost impact of Coolant Pump PU-123456 is minimal impact	a.	b.	c.	d.

Supporting Information

otential Levels				
	ant Pump PU-123456 lifecycle is permanent.	a.	b.	c.
2	Design or work complexity is medium.	a.	b.	c.
3	Degree of item standardization is mature.	a.	b.	c.
4	Ease of detecting process failure is probable.	a.	b.	c.
5	Level of personnel qualification and special skills is medium.	a.	b.	c.
6	History of problems or failures is low.	a.	b.	c.

Supporting Information

Mission Critical Equipment										
1	Coolant Pump PU-123456 Involves a mission critical *engineered item.*	a.	b.	c.	d.	e.	f.	g.	h.	

Supporting Information

Comment: (The "Comments" field is used to aid in QLD review, and the information is NOT retained with the approved QLD. Use the "Supporting Information" field for information that will retained with the QLD.)

Submit | Save As Draft | Edit QLD

Existing Comments:

Requester	Pettet, Mark Charles	Submitted	Date
Quality Engineer	Holder, Robert Bradley	Concurrence	Date
Approver	Pettet, Mark Charles	Approval	Date

Unique Identifier

Summary of Responses

Questions put in context for clarity

Electronic Signatures

CWI Additional Selected Attributes for Mission Critical

Mission Critical

The design authority determines if the 'my test' is mission critical (QL-3) by evaluating the level of risk imposed by the following attributes, functions, and implications:

A. Provide a single barrier to probable serious injury or death. These items may include: pressure relief devices, ASME pressure vessels and over-current protective devices (i.e. breakers and fuses) 480V and above.
B. Provide hazard mitigation or control to protect the public, the workers, or the environment.
C. Perform a defense-in-depth or specific administrative control function.
D. Involves an engineered item.
E. Provide credited regulation against regulatory noncompliance or is a requirement of an environmental or other regulatory agreement or permit.
F. Provide for monitoring, surveillance, or data acquisition that is relied upon for regulatory requirement surveillance or reporting.
G. Are permanently installed as active equipment to function as a requirement of PRD-183, "Radiological Control Manual."
H. Perform a load bearing or safety function that is a requirement of DOE-STD-1090-04, "Hoisting and Rigging."

Is the 'my test' mission critical?

○ Yes ◉ No

Submit/Update Mission Critical | Back To Failure Potential Level

Application at Idaho Cleanup Project

- Developed in 2006 with all impacted stakeholders at ICP, co-sponsored by QA and Engineering
- Process improvements and lessons learned have been incorporated several times since initial implementation
- Does not eliminate the potential that someone might “game” the system, but has not been ICP experience
- Grading of software risks has also been adapted to the process
- The procedure lists many items that may be considered QL-4 without applying the determination process
- Quality implementing procedures at ICP use Quality Level to determine appropriate level of rigor for application of a graded approach

Backup Information

- Failure Consequence weighting matrix
- Failure Potential weighting matrix
- Risk/Quality Level assignment matrix

Determination of Failure Consequence Level (Example)

	Adverse Safety Impact	Mission Interruption[1]	Environmental Damage[2]	Public Perception[3]	Cost Impact[4]
HIGH	Direct and immediate failure of parent system's safety function +7	Severe or Greater Than 6 months +2	Severe, acute, long-term or permanent damage to ecology +2	National or International attention +2	Greater Than $2M +2
MEDIUM	Detectible degradation of parent system's safety function +4	Greater Than 60 days +1	Severe, acute, long-term or permanent damage to ecology +1	State or regional attention +1	Between $0.5M And $2 M +1
LOW	No Effect +1	Less Than 60 days 0	Recoverable impacts to the local ecology 0	Local attention 0	Less Than $0.5M 0

Failure Consequence Level (FCL) is equal to the sum of the above factors:

- **FCL-1** *(high)*: If net adjustment is 7 or greater;
- **FCL-2** *(medium)*: If net adjustment is 4, 5, or 6
- **FCL-3** *(low)*: If net adjustment is 3 or less

Determination of Failure Potential Level (Example)

	Life Cycle	Complexity of work process	Standardization of item	Ease of process error failure detection	Extent of personnel qualification and special skills	History of process or item problems or failures
HIGH	Permanent +1	High +1	Untested +1	Not Likely +1	High +1	High +1
MEDIUM	<6 months 0	Medium 0	Demonstrated 0	Probable 0	Medium 0	Medium 0
LOW	<1 month -1	Low -1	Mature -1	Obvious -1	Low -1	Low -1

<u>Failure Potential Level</u> is equal to the sum of the above factors:

- **FPL-1** *(high)*: If net adjustment is + 3 or greater;
- **FPL-2** *(medium)*: If net adjustment is –2, -1, 0, +1 or + 2;
- **FPL-3** *(low)*: If net adjustment is –3 or less

Determining Final Risk/Quality Level

Failure Consequence Level	Failure Potential Level		
	FPL-1	FPL-2	FPL-3
FCL-1	QL-2	QL-2	QL-3
FCL-2	QL-3	QL-3	QL-4
FCL-3	QL-3	QL-4	QL-4

Note: QL-1 is imposed for Safety Class only unless directed by Engineering Manager.

EM Environmental Management

safety ❖ performance ❖ cleanup ❖ closure

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EFCOG

Energy Facility Contractors Group

Project Area #2

Adequate NQA-1 Suppliers

EM QA Corporate Board Meeting
Knoxville, TN
August 27-28, 2009

Team Members

- Bill Rowland — DOE SRS
  DOE Team Lead
- Rich Campbell — Energy*Solutions*
  EFCOG Team Lead
- Lynne Drake — SRNS
- Cathy Nesser — WTS
- Robert Thompson — ICP
- Brenda Hawks — DOE ORO

Background

- Team deliverables completed and presented at EM QA Corporate Board Meeting in August
- Alert System Implemented via EM QA Corporate Board Chair Memo of 6/22/09
- Joint Supplier Evaluation Program concept presented and approved in March EM QA Corporate Board Meeting
  - Basis of Program is the Supplier Evaluation Program (SEP) developed and implemented by EFCOG Supply Chain Quality Task Team (SCQTT)
  - EM and the SCQTT will adapt the SEP to accommodate the suppliers from EM
- Joint Supplier Evaluation Program Implementation Plan requires approval

Implementation Plan Tasks

- Consolidate and integrate EM Suppliers into the current SCQTT Common Commodity and Joint Audit Schedule
- Develop an Electronic Management System to support the consolidated Supplier Evaluation Program
- Upload information into the Electronic Management System
- Develop new NQA-1 Evaluation Documents

Implementation Plan Tasks

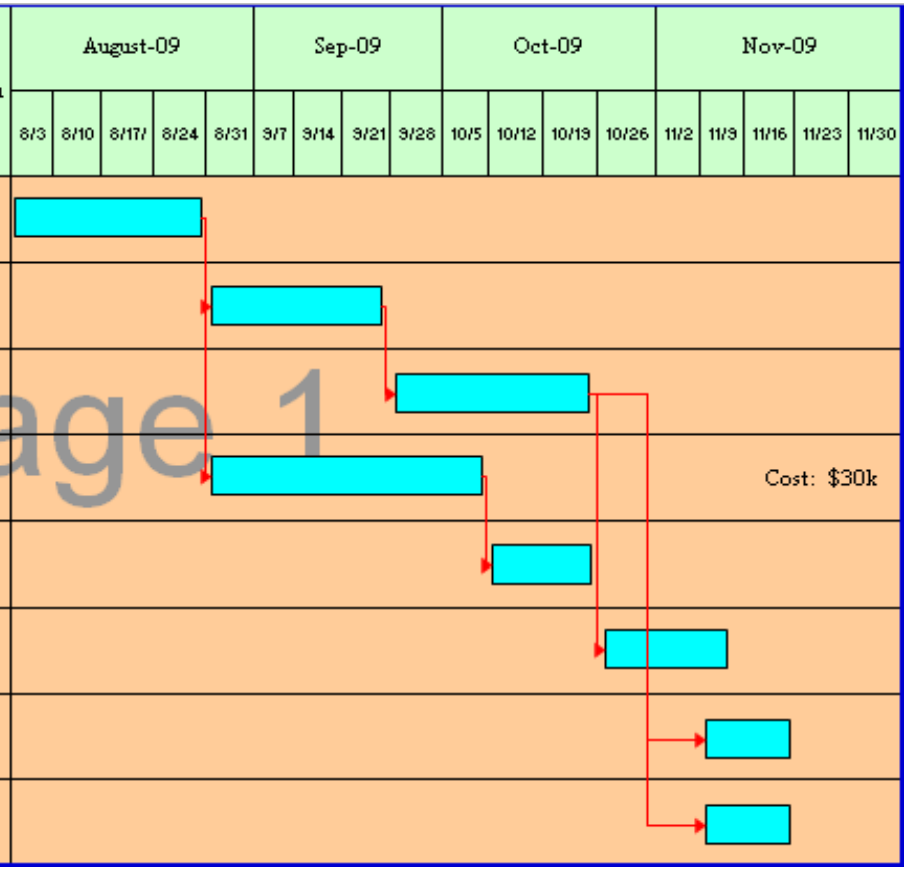
- Establish or revise administrative controls including:
  - Roles and responsibilities
  - Primary Points of Contact at each site
  - Minimum audit reporting requirements
  - Report review and approval process
  - Review and approval of Lead Auditor Qualifications
- EM to coordinate participation on calls, meetings, audits and other support, as needed

Implementation Plan

- Responsibilities
  - Idaho National Lab (INL) Supplier Management Program Lead is the current Team Leader for the SCQTT. This individual will be the point of contact from EFCOG in the effort to integrate EM into the Supplier Evaluation Program.
  - EM Office of Standards and Quality Assurance will serve as the point of contact between the SCQTT Team Leader and the EM sites during the process of integration and consolidation.

Schedule

ID	Task Name	Start	Finish	Duration
1	Authorization	8/3	8/28	4 w
2	Consolidation	8/31	9/25	4 w
3	Develop Evaluation Basis Matrix Documents and Conduct Gap Analysis	9/28	10/23	4 w
4	Electronic Management System	8/31	10/9	6 w
5	Database/ User Interface Validation	10/12	10/23	2 w
6	Electronic System Information Data Entry	10/26	11/6	3 w
7	Database User Test Period	11/6	11/20	2 w
8	Assign Resources and Initiate Audit	11/6	11/20	2 w

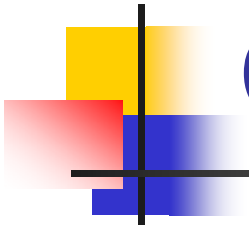


Funding Requirements

- The Electronic Management System initial set-up cost will be between $25-30K with about $100 monthly service fees thereafter.
- The INL Supplier Management Program Lead will be needed full-time for four (4) months to set-up, integrate and consolidate EM into SEP.
- EM and sites will need to contribute support for this four (4) month start-up period.

Follow-Up Actions

- EM will solicit feedback from participants after each audit for the 1st year to gather lessons learned
- The SCQTT will be encouraged to do the same with its participants
- EM HQ will conduct a survey after the 1st year of implementation to determine level of acceptance and to solicit process improvements
- Results of these follow-up actions will be presented at a future EM QA Corporate Board Meeting



Questions & Comments

Environmental Management

safety ❖ performance ❖ cleanup ❖ closure

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Energy Facility Contractors Group

Project Focus Area #3

Commercial Grade Item and Services Dedication Implementation

EM QA Corporate Board Meeting
Knoxville, Tenn
August 28, 2009

Recommendation

- Develop and providing training on application of the Commercial Grade Dedication (CGD) process

Training Scope

- Training presented in six modules
  - Course Overview and Introduction
  - Technical Evaluation
  - Determining Critical Characteristics
  - Dedication Package
  - Supplier Dedication Oversight
  - Implementation and Lessons Learned.

Course Objective

- The intent of the course is to provide federal employees, prime contractors, and vendors who are involved with or oversee the procurement of nuclear material and services an introductory level course on Commercial Grade Dedication
- The course material, without exercises, is designed for one to one and a half days of class room work.

Course Objective, cont.

- Define the terms “commercial grade item” and “commercial grade services”
- Understand the process for commercial grade dedication
- Describe the bases for implementing each element of the generic process and how each element relates to DOE/NQA-1 requirements and EPRI Guidelines
- Describe each element of the process and its purpose
- Understand the acceptance process for items and services
- Discuss the need for detailed documentation of the CGD activity for each item

EM Environmental Management

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Energy Facility Contractors Group

Project Focus Area #5

Line Management Understanding of QA and Oversight

EM QA Corporate Board Meeting
Knoxville, TN
August 27, 2009

Team Members

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

Scope

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

Actions / Status

Task 5.1: Add interim QAP Performance/Risk data to the Quarterly Performance Review (QPR) briefing packages.	Working. Draft QPR Quad Chart was distributed to the Exec. Committee on 10/23/08 for review and comment. The new QPR Quad Chart guidance has not been distributed to the FPDs for use.
Task 5.2: Obtain commitment from all EM site managers on QA qualifications and training for assigned project QA staff.	Complete. Training for the Federal QA Staff is ongoing.
Task 5.3: Develop an EM QA Program (QAP) that will be applicable to all EM sites.	Complete. QAP was approved by EM-2 in November 2008.

Actions / Status

Task 5.4: EM-1 provides direction and guidance to EM field sites to promulgate EM Corporate QAP.	Complete. Memorandum issued in November to HQ and Sites.
Task 5.5: Develop detailed QAP implementation guidance for EM-3.	Complete. Memorandum issued in Dec. 2008 to HQ and Sites.
Task 5.6:Develop Training modules on the value of a strong QA Program	Complete. Training Academy course was given in Oct. 2008 in NM. MOU in place between HQ and EMCBC for QA training initiatives and improvements.
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 Prog	A 4 hour course was developed. Bob Toro gave a shortened version to a limited number of FPD in July. The feedback was the course needs to be shortened to 1 hour and focused on EM-64 initiatives to be more effective. To be completed by 10/1/09.

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.	Complete. Assessment expectations have been developed, reviewed and submitted for posting to the EM QA Portal.
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.	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
- 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

Counterfeit, Suspect, Fraudulent Items (CSFI): Today & Tomorrow

DOE – EM QA Corporate Board Meeting
August 28, 2009 - Knoxville, TN

Daniel Pasquale

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TOPICS

1. Recent CSFI activity
2. Program Strategies
3. The need for a solid community
4. NRC outreach efforts
5. What is the NRC doing in CSFI

RECENT CSFI ACTIVITY ON THE INDUSTRY'S RADAR

1. ABB Capacitors – *U.S.A. (Nuclear Power)*
2. Copper Busmann Fuses – *U.S.A. (Nuclear Power)*
3. Ladish Valves – *U.S.A. (Nuclear Power)*
4. Square-D Breakers – *U.S.A. (Nuclear Power)*
5. Microchip, Handheld Rad Detector - *U.S.A. (Nuclear Power)*
6. Fasteners – *U.S.A (DOE facility)*
7. Moisture Separator Reheater Piping – *Japan (Nuclear Power)*
8. Substandard Steel – *Italy (Nuclear Power)*
9. Seamless Pipe – *China (Fossil Power)*
10. Fasteners – *U.S.A. (Oil Refinery)*
11. ASME Flanges – *U.S.A. (Oil Refinery)*
12. Chrome gas valves 2"-24" - *U.S.A. (Oil Refinery)*
13. Pressure Safety Valves - *U.S.A. (Oil Refinery)*

RECENT CSFI DATA FROM THE DEPARTMENT of COMMERCE

1. **Approx. 500 *participants in the 2008 electronics supplier survey***
   - ***OEM's; OCM's; Authorized Distributors, Independent Distributors, Brokers, Board Assemblers***

2. **No. of counterfeit incidents (2005-2008)**
   - **3,397 < 2005**
   - **5,985 < 2006**
   - **5,747 < 2007**
   - **7,383 < 2008**
   - **22,512 < 2005-2008**

3. **Percentage of counterfeit incidents: Out vs. In production**
   - ***36/64 %*** **< 2005**
   - ***44/56 %*** **< 2006**
   - ***47/53 %*** **< 2007**
   - ***46/54 %*** **< 2008**
   - ***43.25 %*** **< Out of Production (Avg.)**
   - ***56.75 %*** **< In Production (Avg.)**

RECENT CSFI DATA FROM THE DEPARTMENT of COMMERCE

4. **Average percentage of suppliers testing incoming parts (by type)**
   - ***44 %*** ***< OEMs***
   - ***52 %*** ***< OCMs***
   - ***52 %*** ***< Authorized Distributors***
   - ***58 %*** ***< Independent Distributors***
   - ***62 %*** ***< Brokers***
   - ***38 %*** ***< Internet-exclusive sources***

5. **Percentage of companies performing inventory audits for counterfeits**
   - ***52 %*** ***< Distributors***
   - ***17 %*** ***< OCMs***
   - ***13 %*** ***< Board Assemblers***

Program Strategies
The Defense

- Self Assess – and be critical
- Encourage a questioning attitude
- Perform thorough receipt inspections
  - Verify procurement requirements
- Provide CSFI training to QA/QC receipt inspectors
- Make Current CSFI information available
- Maintain a comprehensive CGD program

Program Strategies
The Offense

- Self Assess – and be critical
- Zero tolerance policy for counterfeiting
- Supplier selection
  - Know your suppliers (Upstanding)
  - Assess supplier's return & scrap/disposal policies
- Precise procurement specifications based on engineering input
- IT protection of Intellectual Property
- Community Watch programs
  - Outreach efforts

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WHAT IS THE NRC DOING?

1. Completed a self assessment of the published CSFI guidance
2. Issued IN 2008-04, "Counterfeit Parts Supplied To Nuclear Power Plants" (April 7, 2008)
3. Developing the NRC's CSFI community (June 4, 2009)
4. Continuing to enhance the NRC's Vendor Inspection program
5. Working with NUPIC to enhance their audit process
6. Working with EPRI's Technical Advisory Group (TAG) on CSFI
7. Cooperating with DHS's Anti-Counterfeiting task forces
8. Improving communications and sharing information with the nuclear community
   - Presentations to NUPIC, EPRI, Federal Agencies, etc.

Generic Communication IN 2008-04

"Counterfeit Parts Supplied To Nuclear Power Plants"

The **3 characteristics** of an effective procurement and dedication plan:

1) The involvement of engineering staff in the procurement and product acceptance process;

2) Effective source inspection, receipt inspection, and testing programs;

3) Thorough, engineering-based programs for review, testing, and dedication of commercial-grade products for suitability for use in safety-related applications.

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COMMUNITY WATCH PROGRAMS

A community-based organization working together to combat CSFI activity:

- Take positive steps
- Share current information of new trends in CSFI
- Establish consistent programs for combating CSFI activity
- Awareness of & access to the various related government agencies
- Develop industry standards
- Evaluate CSFI claims
- Training for Inspectors, Purchasers and QA personnel

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EXISTING DATA SOURCES

- 10 CFR Part 21 Reports - NRC
- **OpE**: Operating Experience - NRC
- **OpEx**: Operating Experience - INPO
- **EPIX**: Equipment Performance & Information Exchange-INPO
- **GIDEP:** Government Industry Data Exchange Program
- **SCI:** Suspect & Counterfeit Items – DOE
- **EPLS:** Excluded Parties List System - GAO
- **CPSC:** Consumer Protection Safety Commission
- **TheTrueCosts.org:** U.S. COC
- **STOPFAKES.gov:** Joint Effort hosted by DOC
- **IRS:** Incident Reporting System – IAEA
- **ConE:** Construction Experience - NRC
- **ConX:** Construction Experience - NEA

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Outreach Organizations

- **Department of Defense**
  - **Government Information Data Exchange Program (GIDEP)**
  - **Diminishing Sources and Material Shortages (DMSMS)**
  - **NASA**
  - **Aerospace Standard AS5553, "Counterfeit Electronic Parts; Avoidance, Detection, Mitigation, and Disposition**
- **Department of Energy**
  - **Suspect/Counterfeit or Defective Items Program (S/CDI)**
  - **Occurrence Reporting and Processing of Operations Information (ORPS)**
- **Department of Commerce**
  - **International Trade Administration, Office of Energy and Environment**
  - **Manufacturing & Services**
  - **Bureau of Industry & Security, Office of Technology Evaluation**
- **Nuclear Procurement Issues Committee (NUPIC)**
  - **Commercial Nuclear Power Licensees & Suppliers**
- **Nuclear Energy Institute (NEI)**
- **Electric Power Research Institute (EPRI)**

SUMMARY

- The threat of CFSI is real – and growing
- Industry vulnerabilities are growing also
- Maintain a robust CSFI program
  - Refer to current NRC guidance
  - Protect your Intellectual Property (IP)
  - Incorporate Best Practices
- Build and maintain a solid CSFI community
  - Federal agencies
  - Industry communities
  - Supply chain

QUESTIONS

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Department of Energy/Environmental Management Quality Assurance Corporate Board Meeting

August 2009

Knoxville, TN

NRC Perspectives on Dedication

Paul Prescott
NRR/DE/EQVB

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Commercial-Grade Item (CGI) Dedication Process

Topics

- Commercial Grade Dedication : Achieving Safety Through a Quality Process
  - Attributes of Process
  - Oversight of Process
- Technical Evaluations
  - Critical Characteristics
  - Like-For-Like CGI Replacements
  - Equivalency Evaluations
- Acceptance Methods
  - Method 1 – Special Test & Inspections
  - Method 2 – Commercial- Grade Survey
  - Method 3 – Source Verification
  - Method 4 – Acceptable Supplier/Item Performance

CGD: Achieving Safety Through a Quality Process

- Engineering Involvement
- Documentation
- Established Process

CGD: Achieving Safety Through a Quality Process

- Inspection Procedures
- Inspector Qualification
- NRC Oversight

CGD: Achieving Safety Through a Quality Process

- Generic Communications
  - Endorsement of Industry Guidance
  - Website
- NRC/Stakeholder Interaction
  - Workshops
  - NUPIC (Nuclear Procurement Issues Comm.)
  - EPRI (Electric Power Research Institute)
  - NQA-1 (American Society of Mechanical Engineers (ASME))

CGI Dedication Process

Dedication

- 10 CFR 21.3, “Definitions”
  - Dedication is an acceptance process undertaken to provide reasonable assurance that a commercial grade item to be used as a basic component will perform its intended safety function, and in this respect, is deemed equivalent to an item designed and manufactured under an 10CFR50, Appendix B QA Program.

CGI Dedication Process

- An acceptable dedication program consists of:
  - Technical Evaluation - identifies
    - Technical requirements
    - Quality requirements
  - Acceptance Method - verifies
    - Technical and quality requirements have been met.

Technical Evaluations

- Identify item's safety function, classification, performance requirements, and service conditions.
- Identify **critical characteristics**, including acceptance criteria.
- Identify dedication methods for verification of acceptance criteria.

Critical Characteristics (CCs)

- 10 CFR 21.3, “Definitions”
  - Important design, material, and performance characteristics of a CGI (or service) that, once verified, will provide reasonable assurance that the item (or service) will perform its intended safety function.

Critical Characteristics (CCs)

- Basis for Selection of CCs
  - Design, material, performance characteristics
  - Active/passive safety-related functions.
  - Safety/non-safety interfaces.
  - Changes in design, material, or manufacturing process.
  - Number and nature of CCs are based on safety function, application requirements, FMEA, and performance requirements.
  - Seismic and environmental qualification should be treated as critical characteristics to be verified.

Like-for-Like CGI Replacements

- Like-for-like criteria:
  - Item was purchased at the same time and from the same supplier, **or**
  - User verifies that no changes in the design, materials, or manufacturing process have occurred since procurement of original item.
- If dedicating entity can demonstrate that replacement item is identical, then the safety function, design requirements, and critical characteristics need not be re-established.
- CCs must still be verified.

Equivalency Evaluations

Equivalency evaluation: A technical evaluation performed to confirm that a replacement item (not identical to the original) can satisfactorily perform its intended safety functions.

Equivalency Evaluations

- Equivalency evaluations shall be documented and include the following:
  - Identification of the change(s) in design, material, manufacturing process, configuration, form, fit, or function of the replacement item;
  - Evaluation of the change(s);
  - Confirmation that the change(s) do not adversely affect the current design or safety function of the item.
- Equivalency evaluations are not to be used as the sole basis to accept a commercial-grade item. Selection and verification of the identified critical characteristics by an appropriate dedication method(s) is required to verify the acceptability of the replacement item.

Acceptance Methods

Relation to Appendix B of 10 CFR Part 50

- Criterion VII - Control of Purchased Material, Equipment, and Services

  "Measures shall be established to assure that purchased material, equipment, and services, whether purchased directly or through contractors, conform to the procurement documents. These measures shall include provisions, as appropriate, for source evaluation and selection (Method 2), objective evidence of quality furnished by the contractor or subcontractor (Method 4), inspection at the contractor or subcontractor source (Method 3), and examination of products upon delivery (Method 1)."

Acceptance Methods

Method 1 - Tests/Inspections

Inspections*

- Receipt
- Installation
- Post Installation
- Document Review

Tests*

- Pre-Installation
  - Bench
  - Aging
  - Destructive
  - Non-Destructive
- Post Installation
  - Post Maintenance Test
  - Surveillance/Test Procedure

*Critical Characteristics (CCs)

Acceptance Methods

Method 2 - Survey

- Should be used in combination with one or more of the other acceptance methods to collect objective evidence necessary to ensure acceptable historical item performance
- Acceptance based on merits of commercial vendor's quality controls
  - Documented quality program
  - Procedures
  - Practices
- Purchase orders (POs) invoke the acceptable vendor controls

Acceptance Methods

Method 2 - Survey

- Surveys should be CC specific and item specific
- Survey documentation should include identification of:
  - Item the surveyed vendor is supplying
  - Item's CCs the vendor is expected to control
  - Programmatic controls to be applied
  - Description of activities performed
  - Survey results/conclusion

Acceptance Methods

Method 3 – Source Verification

- Source verification involves direct observation to confirm the item's CCs are satisfactorily controlled by the CV
- Involves witnessing quality-related activities before releasing the item from the vendor or test facility
- Verifies supplier controls when those controls are not documented in a commercial quality program or procedures

Acceptance Methods

Method 3 – Source Verification

- Source verification should be conducted and controlled using a source verification plan that identifies:
  - A process of interest that may be associated with a manufacturing phase
  - Method of verification
  - Appropriate verification points
  - Document results, including the CCs for acceptance
  - Deficiencies observed should be corrected by the vendor before shipping
  - Final item acceptance should be completed by receipt inspection

Acceptance Methods

Method 4 – Acceptable Supplier/ Item Performance Record

- Acceptance of one or more CCs based upon a confidence in the supplied item's performance
- Item performance could be based on historical verification, acceptable quality control of CCs (as confirmed periodically by survey) or other acceptance methods

Acceptance Methods

Method 4 – Acceptable Supplier/ Item Performance Record

- Performance record should provide data that is directly applicable to the item's CCs for acceptance and its plant-specific, safety-related application

- This method should be used in combination with one or more of the other acceptance methods to collect objective evidence necessary to ensure acceptable historical performance

Questions or Comments?

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Suspect/Counterfeit and Defective Items

EM Corporate Board Meeting

Oak Ridge, TN

August 28, 2009

Contents

- Definitions
- Program Purpose
- S/C-DI Process Flow Chart
- HSS Responsibilities
- Data Sources
- Notification Methods
- Resources

S/CI-DI Definitions

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Some quick definitions for this session:

- **Counterfeit Items** – *Hard evidence* to support an intent to misrepresent or to defraud
- **Suspect Items** – *Indications* of an intent to misrepresent or to defraud
- **Defective Items** – *Failure* to perform as expected

Hunt Valves

- In 2004, the IG found that the QA manager for Hunt Valves had been charged with conspiring to defraud the US Government
- This company sold hundreds of valves to DOE over time
- Suspect Valves were found at Portsmouth, Paducah, and ETTP
- The Criminal Investigation revealed that they had been manufactured using improper techniques, and documentation and certifications were falsified

Wright Industries, Inc.

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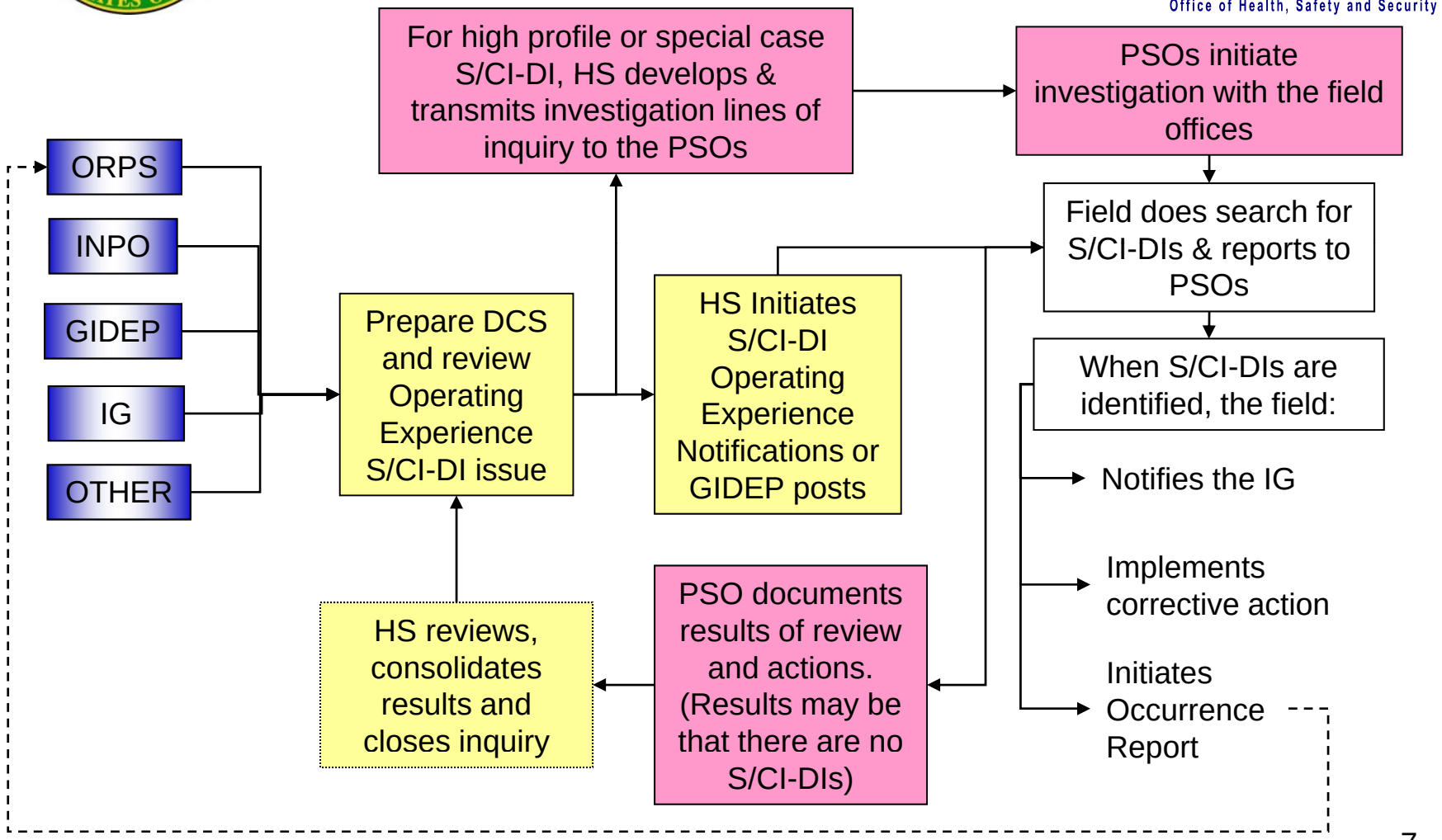
- in 2008, DOE Savannah River Site and Washington Savannah River Company LLC had concerns about a supplier's QA program, so they conducted a QA audit on Wright Industries, Inc
  - The audit resulted in 18 findings covering program weaknesses such as not flowing down NQA-1 requirements to subcontractors, lack of program documentation, lack of internal audits, using non-qualified suppliers, and QA program under-staffing
  - Wright's product line includes many specialized items including glove boxes, hot cells, double door sealed transfer systems, process instrumentation, and numerous stainless steel fabrication items
  - Wright Industries was known to supply safety-related components to at least 3 DOE projects
  - This case is documented in Safety Bulletin 2008-02

Why do we track these items?

- DOE O 414.1C Quality Assurance outlines the S/CI-DI program requirements
- Suspect/counterfeit and defective items are frequently identified throughout the DOE complex—they reduce safety margins and are sometimes points of failure
- Globally, counterfeiting increased **3000%+** from 1994 to 2006
  - $20 Billion in 1994
  - $600+ Billion in 2006 (worldwide)
    - » *World Customs Organization*

HSS S/CI-DI Process Flow Chart



HSS Responsibilities for the S/CI-DI Process

- Screen data sources
- Develop Data Collection Sheets
- Develop lines of inquiry (if needed)
- Request PSOs direct field element investigations
- Evaluate field investigation results
- Post notifications to website, distribute operating experience notices, or post notices to GIDEP (if warranted)
- Analyze and trend S/C-DI's

Finding Candidate S/CI-DI Items

Office of Health, Safety and Security

- Suspect/Counterfeit items are identified throughout the complex and reported in ORPS (searched daily)
  - In calendar year 2008, there were 77 reports
  - There were 40 defective item reports in 2008
- GIDEP – explained further on the next slide (searched weekly)
- INPO maintains a database with items member utilities find (searched weekly)
- Other sources – including underwriter's laboratory, CPSC, and the media (searched on a continuing basis)

GIDEP

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- Government-Industry Data Exchange Program (GIDEP)
  - "A cooperative activity between government and industry participants, seeking to reduce or eliminate expenditures of resources by sharing technical information essential during research, design, development, production and operational phases of the life cycle of systems, facilities and equipment." (GIDEP website)
- Federal Acquisition Regulations (FAR Part 46) require the reporting of non-conforming items in GIDEP.
- OFPP Presidential Policy Letter 91-3, April 1991 mandates agency participation in GIDEP

S/CI-DI Notification Methods

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- Operating Experience Summaries
  - Wide applicability, long-term issue
- Safety Alerts, Bulletins, and Advisories
  - DOE wide-applicability
  - Depending on the speed and importance of the particular issue
- Suspect Counterfeit Item website
  - Normal location for posting DCS information

S/CI-DI Resources

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- All relevant resources, including the database, training manuals and S/CI-DI points of contact are found at the following website:
  http://www.hss.energy.gov/csa/csp/sci/
  - Much of the website content is password protected
- The Quality Assurance Order and the *Suspect/Counterfeit Items Guide for Use with 10 CFR 830 Subpart A, Quality Assurance Requirements, and DOE O 414.1B, Quality Assurance* can be found at this website:
  http://www.hss.energy.gov/nuclearsafety/qa/policy_directives.html
- GIDEP Contact Information:
  P.O. Box 8000
  Corona, CA 92878-8000
  Phone (951)898-3207 Fax (951)898-3250
  http://www.gidep.org/

Thank You

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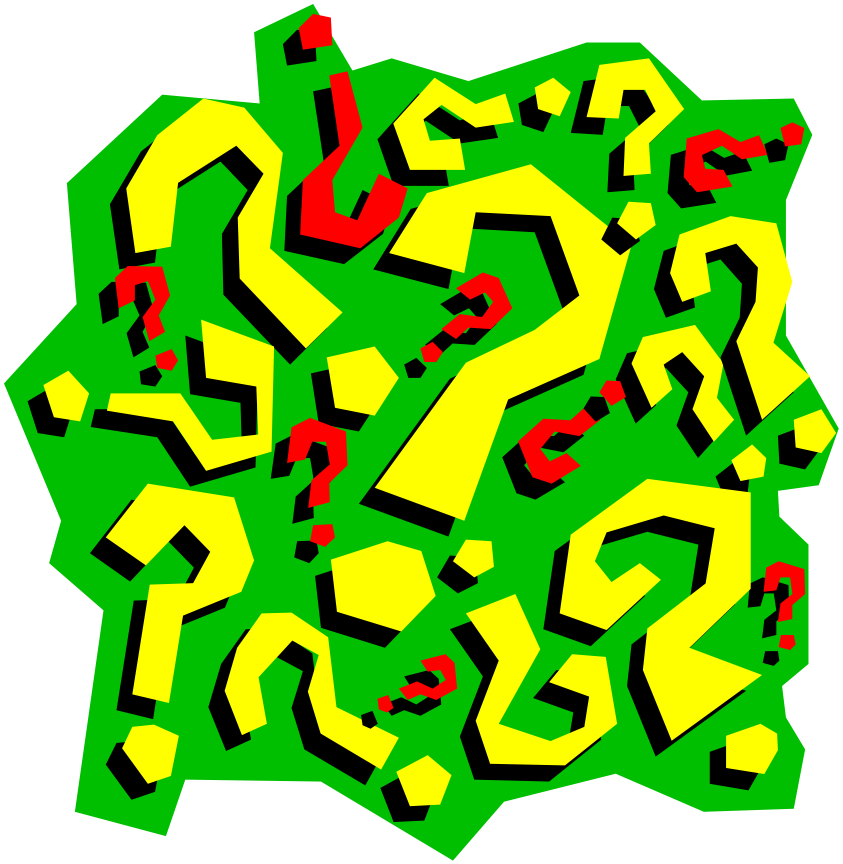

Counterfeiting in Perspective

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Athletic equipment

Clothes, shoes and accessories

Music and movies

Antique furniture

Computer software

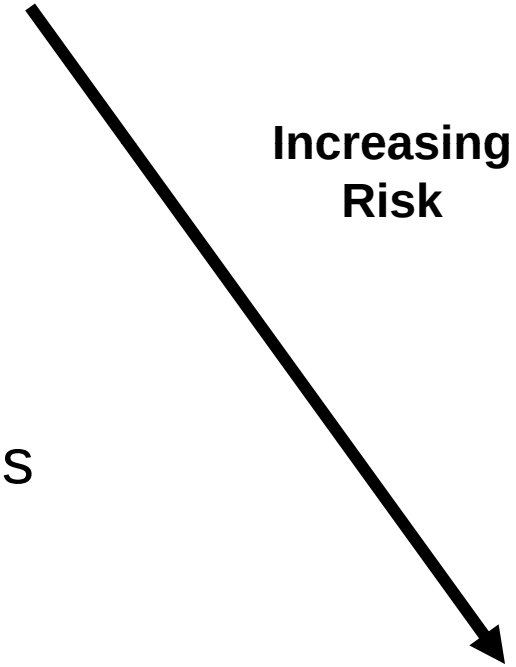
Cat food

Auto brakes, steering assemblies

Aircraft engines, landing gear

Medicines

Nuclear facility parts and components



Counterfeiting in Perspective

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- Negatively impacts safety
- Damages the economy
- Victimizes legitimate manufacturers and suppliers
- Causes loss of customer confidence
- Compounds the product liability issue

Common Indicators of S/CIs in General

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- Item configuration is inconsistent
- Poor fit of assembled items
- Metallic items pitted or corroded
- Hand tool marks
- Dissimilar parts evident
- Wear marks or scratches on external surfaces
- Hand painting (touch up)
- Recent polishing of non-ferrous metals
- Handmade parts
- Casting markings ground off & re-stamped
- Not factory authorized supplier
- Inconsistent dimensions with purchase order

Role of the PSOs

- Provide guidance to the field on S/CI-DIs
- Document results of field investigations
- Verify the field's S/CI-DI corrective actions are appropriate

Role of DOE Field Management

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- Take actions required by Alerts & Bulletins
- Investigate/report to PSO on special S/CI-DI
- Ensure S/CI-DI requirements flow down to contractor
- Notify the local IG – as per local arrangement
- Ensure contractor reports corrective actions

Role of the Operating Contractor Management

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- Assure :
  - Personnel are trained & competent
  - Use of qualified vendors (procurement)
  - "Use as is" or "repair determinations are appropriately evaluated "
  - S/CI-DIs are identified before they enter operations
  - S/CI-DI requirements flow down to the subcontractors
- Document identified S/CI-DIs via ORPS
- Notify the local IG – as per local arrangement
- Take corrective action(s)

Role of the Crafts in S/CI-DI

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Handling parts that don't look right?

- Item not packaged as usual from supplier
- Parts are not new
- Different type parts in same batch
- Painting, grinding, polishing not normal

STOP and notify your supervisor

INPO

- INPO stands for “Institute of Nuclear Power Operators.”
- It is an organization formed in 1979 by the nuclear power plant operators;
- Operational experience is shared through the INPO database.

Criminal Sanctions

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- People have actually faced criminal charges related to defrauding DOE.

M&M Aerospace Contract with Honeywell

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- M&M Aerospace sold specialty metals to the Aerospace community. It was owned by a licensed beautician named Tina Muldoon and her husband, Timothy Muldoon.
- In 2003, the Kansas City Plant awarded a contract to M&M Aerospace, to provide metal bars to Honeywell Manufacturing that would have gone into Peacekeeper missile components.

Documentation Problems

- Honeywell employees discovered that documentation provided by M&M Aerospace fraudulently claimed that the metals conformed to purchase order requirements.
- A number of falsifications were ultimately identified, such as altered heat-treat certifications and altered hardness test results.

Investigation & Indictments

- This resulted in an investigation by the FBI, as well as the DOE IG.
- The Muldoons were indicted for fraud and entered guilty pleas.

Environmental Management

safety ❖ performance ❖ cleanup ❖ closure

www.em.doe.gov

Energy Facility Contractors Group

Project Focus Area #3

Commercial Grade Item and Services Dedication Implementation – Lessons Learned

EM QA Corporate Board Meeting
Knoxville, Tenn
August 28, 2009

Background

- Commercial Grade Dedication (CGD) issues dealing with CGD performed by Prime Contractors and their vendors currently being addressed by ORP Prime Contractors (Tank Farms and Waste Treatment Plant) had their roots in the 2002-2003 time frame.
- CGD program implementation for the site and for suppliers were not in accordance with NQA-1 requirements and industry guidance. Program weaknesses were not identified by prime contractors nor by DOE.
- The country's nuclear material supply chain supported by NQA-1 vendors experienced in nuclear material fabrication and commercial material upgrade activities is very weak compared to 20 years ago
- Currently there is very little nuclear fabrication work available making it cost prohibitive for vendor shops to stand up an NQA-1 based program

WTP Issues

- Initially, WTP did not intend to use CGD as part of its procurement strategy, opting to use NQA-1 qualified vendors to supply all safety related components.
- Once it was determined that the pool of NQA-1 qualified supplies was not sufficient to meet the procurement demands of the WTP, CGD was initiated. However, these procurements did not fully implement CGD as part of the overall procurement strategy.
- The process was not reviewed by ORP prior to implementation nor during the early years of procurement. This is viewed as a missed opportunity.

WTP Issues, cont.

- During the period 2004 to 2006, ORP and BNI identified through assessment, that BNI's CGD program was not adequate to meet NQA-1requirements and supporting guidance documents
- As part of PAAA NTS corrective actions, BNI implemented extensive program improvements including
  - Adoption of NQA-1-2004 requirements and guidance
  - Establishment of a dedicated group of industry experienced procurement engineers to perform CGD activities
  - Revision of their Quality Assurance Manual and CGD implementing procedures

WTP Issues, cont.

- In response to identified issues, BNI documented the need for additional corrective actions in their corrective action management system.
- Actions were established to insure vendors supporting procurements already in place were implementing BNI's expectations for performing CGD
- These actions were not effectively verified because only the sub-vendors procedures were reviewed
  - By not evaluating the effectiveness of the sub-vendor's implementation of their procedure, assurance was not established to close out the action

WTP Issues, cont.

- In Dec 2008, ORP's WTP vendor inspection program identified issues with how CGD acceptance criteria had been established by BNI and implemented at the vendor level. CA's from the NTS report were expected to address these issues for future dedications
- In May 2009, ORP's WTP vendor inspection program determined that the continuation and significance of issues being identified during ORP vendor inspections indicated a negative trend and that corrective actions taken to address CGD implementation at the vendor level supporting WTP were not effectively implemented
- In August 2009, BNI issued an NTS report on less than effective implementation of its vendor CGD program

Tank Farm Issues

- In September 2008, ORP's assessment activity identified an instance in which a procured item that was designated as safety significance was not procured from an NQA-1 qualified vendor or through CGD as required
- In January 2009, ORP identified that the CGD packages for two components with multiple items did not have sufficient technical evaluation, critical characteristics nor validation methods to determine that they met design requirements to perform their intended safety function.
- Compounding the Tank Farm issue is that many of the spare parts procured to support tank farm operation and single shell tank retrieval by the previous prime contractor did not have adequate CGD when procured

Tank Farm Issues, cont.

- CGD after the fact does not lend itself to all available methods for validation of CC for design acceptance during the procurement process
- WRPS has continued to perform CGD activities while addressing issues and establishing corrective actions to include training and program improvements.
- While some improvement is noted, this approach has resulted in additional issues being identified during follow-on ORP surveillance and auditing
- WRPS has documented this programmatic issue in NTS.

Common Issues

- There was a lack of program and implementing documents that provide the frame work and working level guidance based on experience of CGD performers
  - Identified at prime contractor and vendor level programs
- CGD is not being managed as a procurement strategy
- The lack of proper training
  - individuals performing technical evaluations
  - individuals establishing critical characteristics, and development of methods and actions for acceptance
  - individuals performing self assessment of prime contractor and vendor performance

Common Issues, cont.

- Generally, CGD packages did not document adequate technical evaluation to determine design criteria that supports the safety function on which to base dedication activities
- Weakness in the selection of critical characteristics
  - CC were not always based on the safety basis for the facility or item
  - Lack of understanding of what constitutes a design characteristic of the item and than a critical characteristic supporting the safety function
  - Need to be identifiable and measurable attributes or variables appropriate for the safety function

Common Issues, cont.

- Weakness in the performance of validation activities
  - Lack of understanding of what constitutes a CGD vendor survey including review plan, documentation, and knowledge of the review team
  - Use of validation methods such as PMI that do not validate material characteristics nor all chemical compositions for some material types when that information is required
  - Failure to provide an adequate quality package of all documentation of the validation such that it would be self supporting during a future review or investigation of a failed component

Common Issues, cont.

- Lack of understanding of the upgrading process for commercial raw material from an ASME certificate holder
  - Differences between upgrading raw material for an ASME pressure boundary verses CGD of other safety related equipment

Benchmarking Lessons Learned

- During benchmarking reviews performed by ORP in support of development of the EM training for CGD several key points were identified
  - Early communication and integration of Engineering and QA supporting CGD
  - Safety basis and design work completed before procurement
  - Detailed technical evaluation by Engineering to determine the specific design elements that address the safety function of the item

Benchmarking Lessons Learned, cont.

- Use of EPRI Joint Utility Task Group (JUTG) database to assist in development of CGD CC, acceptance methods, and acceptance criteria to supplement the technical evaluation
- Investigate establishing test laboratory capabilities to support DOE complex wide CGD needs.
  - This effort could be in line with 3rd party dedication activities
  - Should be to established CC, acceptance methods and actions established by the prime contractor
  - Should be established as part of the procurement strategy for the item to be dedicated

Benchmarking Lessons Learned, cont.

- Establish and Maintain Engineering and QA Training Programs
- Effective use of NQA-1-2004 Method 2 and 3-Commercial Grade Supplier Survey and Source Inspections for CGD of item.
- Method 4 should be used with caution, be used with full knowledge of requirements in NQA-1-2004, Part 1 and 3, and used in conjunction with one or more of the other three methods

Commercial Grade Dedication

2009 DOE Integrated Safety Management

Quality Assurance Track
August 24-27, 2009

Eric Rozek
Member of the Technical Staff
Defense Nuclear Facilities Safety Board

Commercial Grade Dedication

Topics included in the Presentation

- DOE Directives that support commercial grade dedication
- Definitions
- How is Dedication Achieved
- Critical Characteristics
- Selection of Appropriate Critical Characteristics
- Acceptance Methods of Dedication
- Documentation
- Complex Issues
- References

Commercial Grade Dedication

Why is Commercial Grade Dedication (CGD) a "HOT" topic?

Year	Component		Material		Total
	Domestic	International	Domestic	International	
1982	386	49	95	54	584
2005	78	50	23	16	167

- This data represents the number of nuclear companies with ASME certificates.
- With the decrease in nuclear vendors, nuclear facilities are having to purchase increasing numbers of commercial grade items and services.

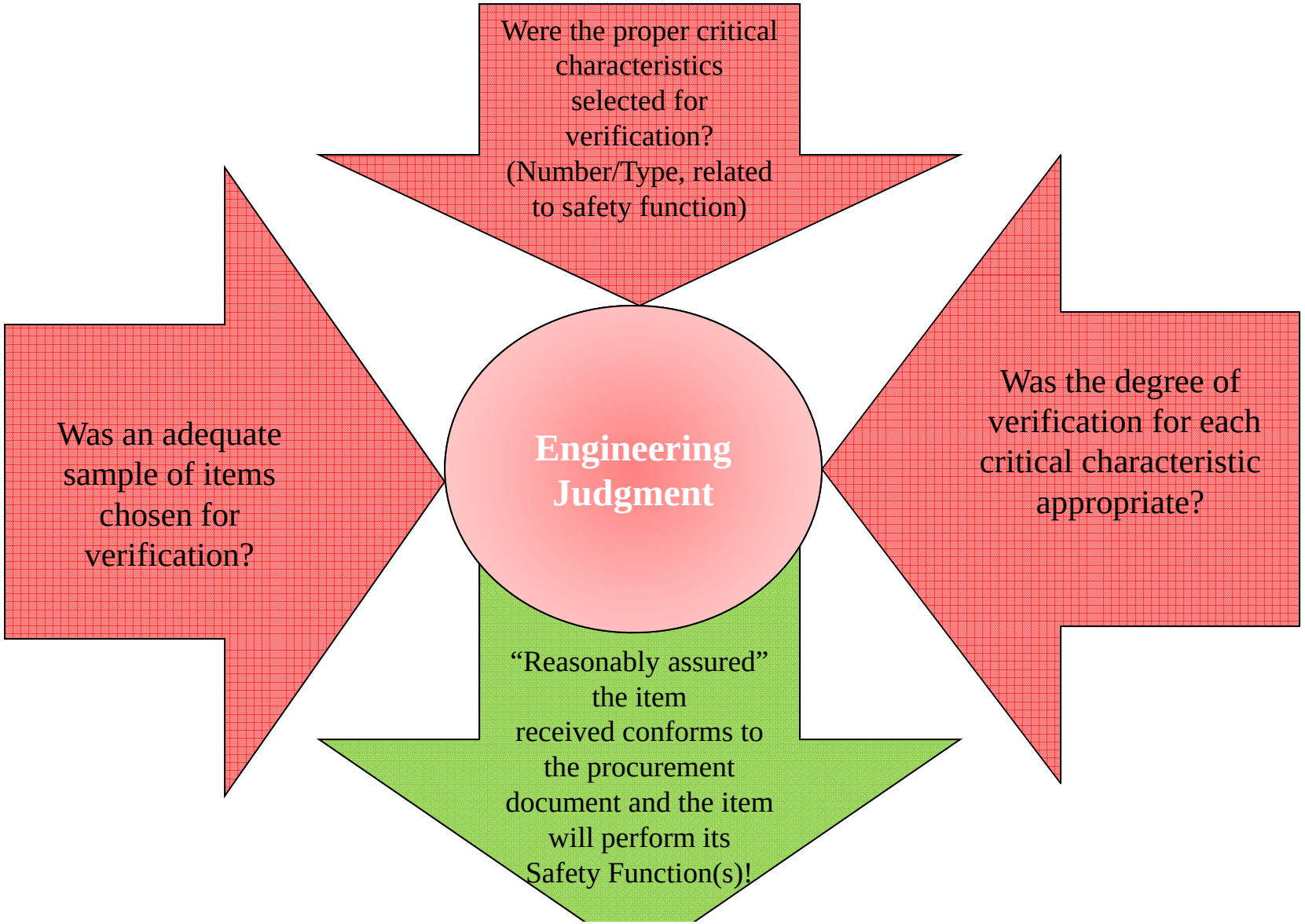
Commercial Grade Dedication

How do DOE Orders and Guides support CGD?

10CFR830 Subpart A, Quality Assurance Requirements	10CFR830 Subpart A Criterion 7, Performance/Procurement, requires : (1) procurement of items and services that meet established requirements and perform as specified., (2) Evaluate and select prospective suppliers on the basis of specified criteria, and (3) Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.
DOE O 414.1-C, Quality Assurance	DOE Order 414.1C states that a QAP uses a national or international consensus standards where practicable and consistent with contractual or regulatory requirements.
DOE G 414.1-2A, Quality Assurance Management Guide	DOE G 414.1-2A Quality Management System Guide (for use with 10 CFR 830.120 and DOE O 414.1) – Commercial Grade Items intended for use in nuclear safety applications should be procured in accordance with documented processes using recognized consensus standards.
DOE G 414.1-3, Suspect/Counterfeit Items Guide	DOE G 414.1-3 Suspect/Counterfeit Items Guide (for use with 10 CFR 830.120 and DOE O 414.1) – Provides definitions for: (1) commercial grade item, (2) dedication. The methods of the acceptance process to provide sufficient confidence in items is defined.
ASME NQA-1	NQA-1 Quality Assurance Requirements for Nuclear Facilities Applications – Establishes requirements for the establishment and execution of quality assurance programs for nuclear facilities. CGD process is defined in Part 1, Requirement 7, Control of Purchased Items and Services. Depending on the version of NQA-1 additional guidance is found in Part 2 and Part 3.
Recognized Industry Standards	EPRI NP-5652 and EPRI TR-102260 – EPRI NP-5652, Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications and EPRI TR-102260, Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial Grade Items are recognized in the nuclear industry as the standard documents regarding the purchase of commercial grade items for use in nuclear safety related applications. DOE G 414.1-2A and DOE G 414.1-3 references these documents.

Commercial Grade Dedication

Reasonable Assurance



Commercial Grade Dedication

Definitions

- Commercial Grade Item (CGI)*: an item satisfying the following:
  (a) Not subject to design or specification requirements that are unique to those facilities or activities
  (b) Used in applications other than those facilities or activities
  (c) To be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (e.g., a catalog)

- 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 (NQA-1).

Commercial Grade Dedication

Definitions

- Commercial Grade Service *-**: a service that was not provided in accordance with the requirements of this Standard (NQA-1).

* This definition is applicable to facilities and activities other than nuclear power plants licensed pursuant to 10 CFR Part 50.

** These definitions are for nuclear power plants pursuant to 10 CFR Part 50 and also provides sufficient quality criteria for facilities identifies in Part I, Introduction

Commercial Grade Dedication

Definitions

- DEDICATION: An acceptance process performed IAW NQA-1 to provide REASONABLE ASSURANCE that a commercial grade item or commercial grade service will successfully perform its intended safety function and, in this respect, is deemed equivalent to an item or service provided under the requirements of NQA -1.

- The action taken to utilize a commercial grade item in a safety-related application.

Commercial Grade Dedication

Definitions

- DEDICATION: An acceptance process undertaken to provide REASONABLE ASSURANCE that a CGI to be used in a safety system or mission essential facility meets specified requirements. This assurance is achieved by identifying the critical characteristics of the item and verifying their acceptability by inspections, tests, or analysis performed by the purchaser or third party dedication entity after delivery, supplemented as necessary by one or more of the following: CG surveys; product inspections or witness at hold points at the manufacturer's facility, and analysis of historical records for acceptable performance.

Commercial Grade Dedication

How is Dedication Achieved

- Confirmation that the item/service meets the definition criteria
- Technical evaluation to determine the Safety Function
- Technical evaluation of the modes of failure of the item. (during normal and accident conditions and includes seismic or environmental applications)
- Identification of the Critical Characteristics, including acceptance criteria.
- Selection, performance, and documentation of the dedication methods(s) for determining compliance with acceptance criteria

Commercial Grade Dedication

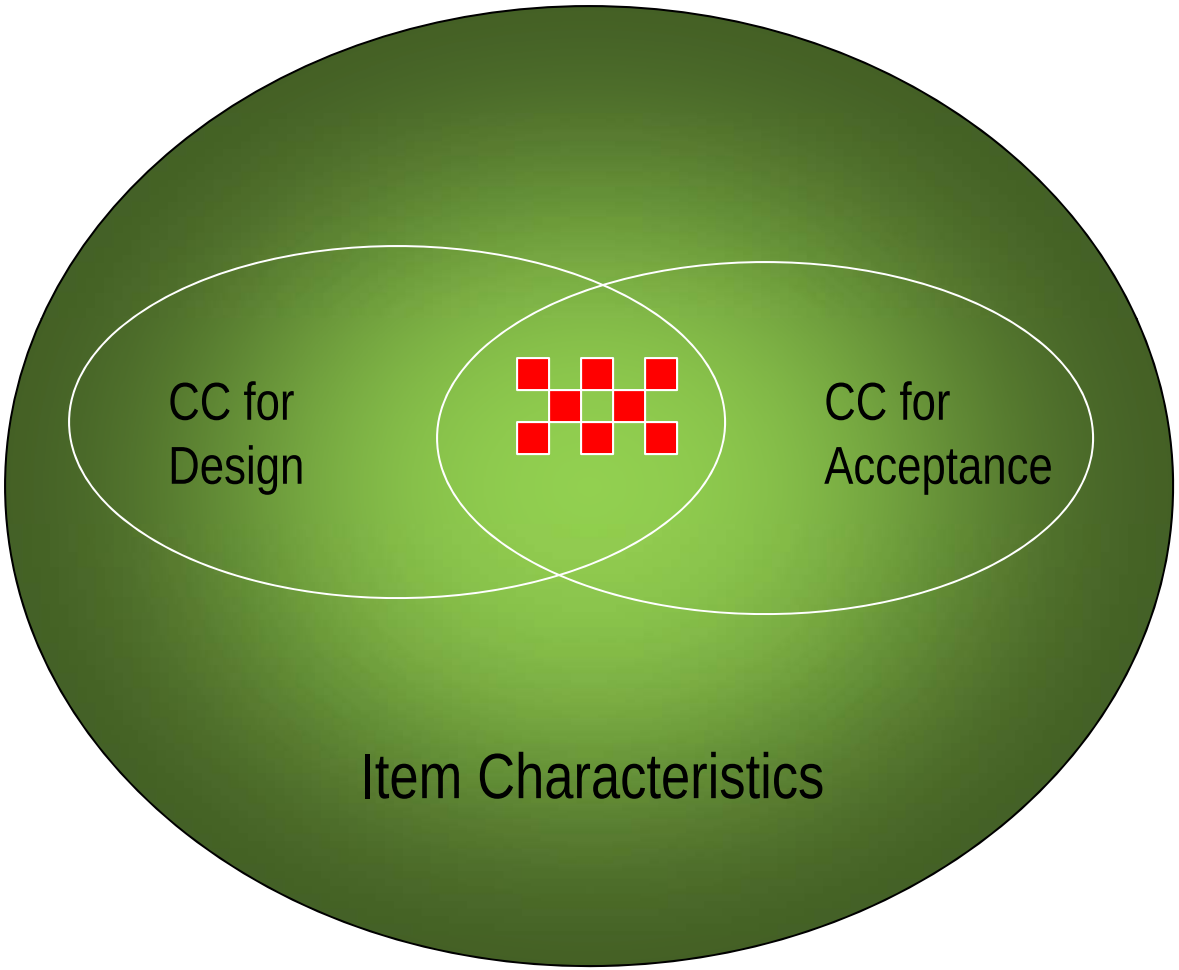
Critical Characteristics

- Important design, material, and performance characteristics of a commercial grade item or service that, once verified, will provide reasonable assurance that the item or service will perform its intended safety function.
- General types
  - Product Identification
  - Physical Characteristics
  - Performance Characteristics
  - Dependability

- When one or more Critical Characteristics cannot be verified by the dedication method, the item/service cannot be dedicated.

Commercial Grade Dedication

Selection of Appropriate Critical Characteristics



Commercial Grade Dedication

Acceptance Methods of Dedication

- Method 1 – Special Tests and Inspections
- Method 2 – Commercial Grade Survey
- Method 3 – Source Verification
- Method 4 – Acceptable Supplier/Item Performance Record

Commercial Grade Dedication

Method 1 – Special Tests and Inspections

- Inspection: Receipt, Installation, Post Installation
- Tests: Pre-Installation (Bench, Aging, Destruction, Non-destructive), Post-Installation (Post Maintenance Test, Surveillance/Test Procedure)

- The Inspections and Tests will adequately verify the CC. Vendors should be approved through a survey.

- Sampling: Provides technical basis considering lot traceability, homogeneity, complexity of item.

Commercial Grade Dedication

Method 2 – Commercial Grade Survey

- Ensure CCs to be verified are documented including following processes (Design Control, Procurement Control, Calibration, Inspection, Material Control, Fabrication, Assembly)
- Acceptance is based on merits of vendor's quality controls
- Surveys should be CC specific and item specific
- A Certificate of Conformance or a Certified Material Test Report may be accepted if (verified traceability to original vendor, verification of vendor's implementation of adequate quality controls, vendors compliance to procurement order requirements, if a distributor in supply chain, survey their activities.

Commercial Grade Dedication

Method 3 – Source Verification

- Involves direct observation to confirm the item's CCs are satisfactory controlled by the vendor.

- Witnessing quality related activities before the item is released from the vendor.

- Verifies supplier controls when those controls are not documented in a commercial quality program or procedures

Commercial Grade Dedication

Method 4 – Acceptable Supplier/Item Performance Record

- Acceptance of one or more CCs based upon a confidence in the supplied item's performance
- Item performance could be based on historical verification, acceptance quality control of CCs (confirmed periodically by survey)
- Performance data should include: Historical Performance (Operational performance, Test Data), Historical Verification (use methods 1,2,3)
- Use this method in combination with one or more of the other methods to ensure acceptable historical performance.

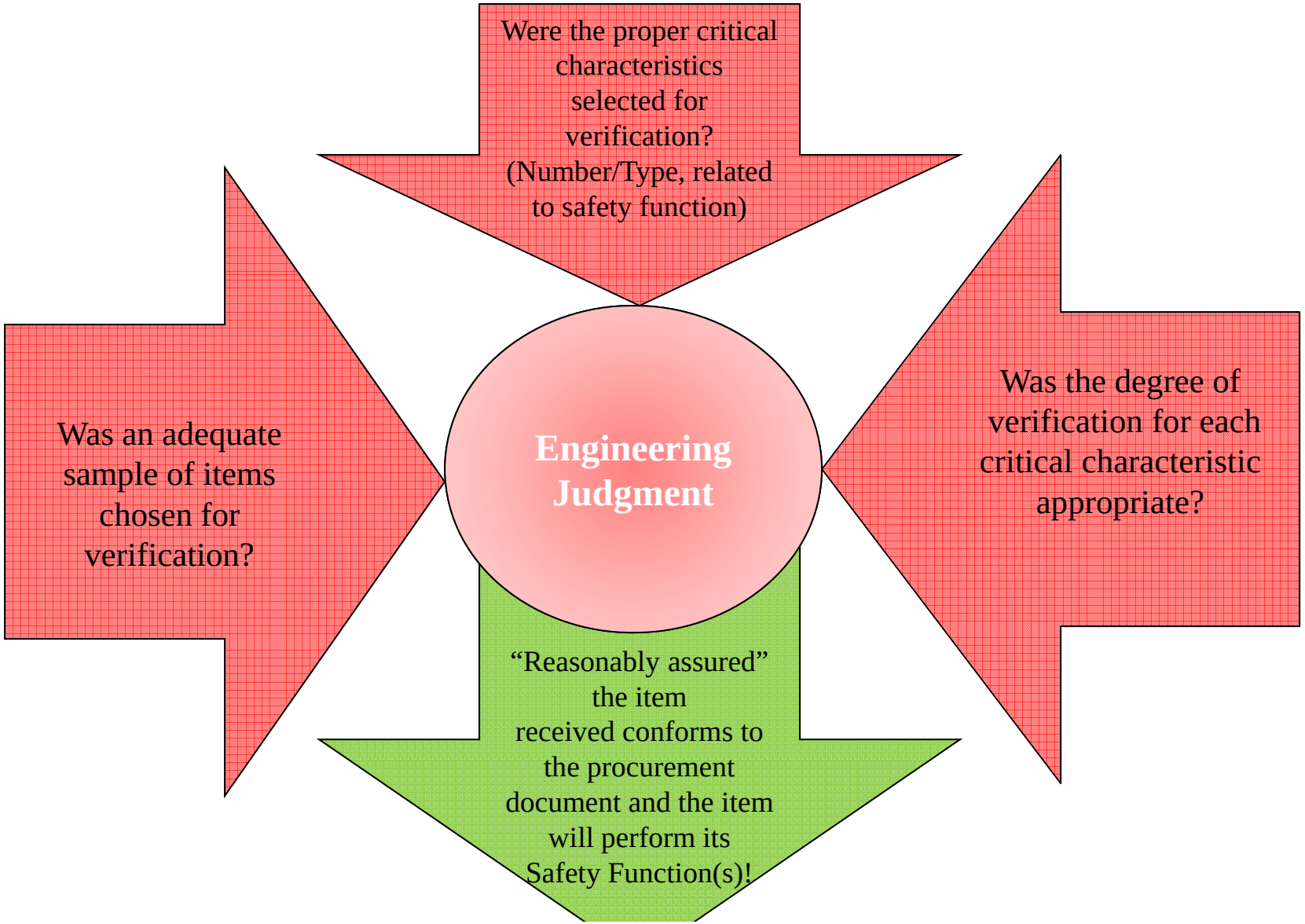
Commercial Grade Dedication

Documentation

- Dedication plans or procedures
- CGI or CGS Procurement Documents
- Technical evaluation of Safety Function
- CC identification and acceptance criteria
- Test reports or results, inspection reports
- Survey reports
- Source verification report
- Historical performance information
- Dedication report containing sufficient data to accept the item

Commercial Grade Dedication

Reasonable Assurance



Commercial Grade Dedication

Complex issues

1. What definition will be used, (is there a qualified NQA-1 vendor for that engineered item – if not what is the plan)?

2. Will services be dedicated?

3. Involvement of Design and Engineering in the process.

4. Who is the dedicating entity? Are you sure!

5. Proper identification of safety function and failure modes

6. Proper selection of critical characteristics

Commercial Grade Dedication

Complex issues

7. Does the Prime's definition of reasonable assurance = sub-vendor's = DOE site = DOE HQ = outside regulators?

8. Post installation testing – (do you have an administrative procedure to track prior to requiring the item to perform then intended safety function)?

9. Flowdown of the proper technical specifications

10. Documenting critical characteristics, maintaining the commercial grade dedication package

11. Having a Technical Sampling Basis for conducting Method 1.

Commercial Grade Dedication

Commercial Grade Dedication References

- Department of Energy:

- DOE Guide 414.1-2A Quality Assurance Management System Guide. Discusses using a recognized international consensus standard for conducting Commercial Grade Dedication

- DOE Guide 414.1-3, Suspect/Counterfeit Item Guide. Defines the methods of acceptance process to provide sufficient confidence in the items (the four methods are consistent with the EPRI guidelines.) Defines a commercial grade item, and dedication.

- US Nuclear Regulatory Commission:

- NRC Generic Letter 89-02: Conditionally endorses EPRI NP-5652, *Guideline for the Utilization of Commercial-Grade Items in Nuclear Safety-Related Applications (NCIG-07)*. Promotes the use of method one, test and inspection, and if method two or four are used they must be used in conjunction with additional methods.

- NRC Generic Letter 91-05: Defined critical characteristics. Stated that NRC staff would not conduct procurement inspections to allow licensees time to fully understand and implement guidance developed by industry to improve procurement and commercial-grade dedication programs. The Enclosure provided characteristics of effective commercial-grade procurement and dedication programs.

- NRC Inspection procedure 38703, *Commercial Grade Dedication*

- NRC Inspection Procedure 43004, *Inspection of Commercial-Grade Dedication Programs*

Commercial Grade Dedication

Commercial Grade Dedication References

- ASME Quality Assurance Requirements for Nuclear Facility Applications

- NQA-1-2000-addendum 2002:
- Part I, Introduction (defines commercial grade item (one definition))
- Part I, Requirement 7, *Control of Purchased Items and Services*
- Part III, Appendix 7A-2, *NonMandatory Guidance on Commercial-Grade Items*
-
- NQA-1-2004
- Part I, Introduction (defines commercial grade item (two definitions), commercial grade service, critical characteristics, dedication, and dedicating entity
- Part I, Requirement 7, *Control of Purchased Items and Services*
- Part III, NonMandatory Appendix 7A-2, *Guidance on Commercial Grade Items and Services*
-
- NQA-1-2008
- Part I, Introduction (defines commercial grade item (two definitions), commercial grade service, critical characteristics, dedication, and dedicating entity
- Part I, Requirement 7, *Control of Purchased Items and Services*
- Part II, SubPart 2.14, *Quality Assurance Requirements for Commercial Grade Items and Services*
-
- Addendum 09 –

Commercial Grade Dedication

Commercial Grade Dedication References

- Electric Power Research Institute: Documents requiring purchase:
  - JUTG Commercial Grade Item Technical Evaluations, 1008034
  - Information for Use in Conducting Audits of Supplier Commercial Grade Item Dedication Programs, 1016157
  - Generic Qualification and Dedication of Digital Components: Project Status and Lessons Learned, 1009659
  - Generic Qualification/Dedication of Digital Components: Summary of 2004 Generic Qualification Activities , 1011383

- Electric Power Research Institute: Documents free of charge:

http://my.epri.com/portal/server.pt?space=CommunityPage&cached=true&parentname=ObjMgr&parentid=2&control=SetCommunity&CommunityID=221&PageIDqueryComId=0

Generic Topic of Commercial Grade Dedication:

- NP-5652, Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications (NCIG-07)
- TR-102260, Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial Grade Items

Technical Evaluation and procurement:

- NP-6406, Guideline for the Technical Evaluation of Replacement Items in Nucelar Power Plants (NCIG-11)
- NP-6629, Guideline for the Procurement and Receipt of Items for Nuclear Power Plants

Critical Characteristics

- TR-112579, Critical Characteristics for Acceptance of Seismically Sensitive Items (CCASSI)

Commercial Grade Dedication

Commercial Grade Dedication References

- Electric Power Research Institute: Documents free of charge:

http://my.epri.com/portal/server.pt?space=CommunityPage&cached=true&parentname=ObjMgr&parentid=2&control=SetCommunity&CommunityID=221&PageIDqueryComId=0

Sampling Guidance

- TR-017218-R1, Guideline for Sampling in the Commercial-Grade Item Acceptance Process

Digital Equipment Commercial Grade Dedication

- TR-106439, Guideline on Evaluation and Acceptance of Commercial-Grade Digital Equipment for Nuclear Safety Applications
- TR-107339, Evaluating Commercial Digital Equipment for High-Integrity Applications: A Supplement to EPRI Report TR-106439
- 1001452, Generic Qualification of Commercial Grade Digital Devices: Lessons Learned from Initial Pilots
- 1003585, Generic Qualification/Dedication of Digital Components: Lessons Learned Beyond Initial Pilots
- 1011710, Handbook for Evaluating Critical Digital Equipment and Systems
- TR-107330, Generic Requirements Specification for Qualifying a Commercially Available PLC for Safety-Related Applications in Nuclear Power Plants
- 1006842, Generic Qualification / Dedication of Digital Components

ISO 9000 Suppliers

- 1003105, Dedicating Commercial Grade Items Procured from ISO 9000 Suppliers
- TR-1002976, An In-Depth Review of Licensee Procurement Options for Use with ISO 9000 Suppliers
- 1003104, Assessment of the ISO 9000 Quality Management System (QMS) Registrar Accreditation and Supplier Certification Processes

Commercial Grade Dedication

QUESTIONS?

EM Environmental Management

safety ❖ performance ❖ cleanup ❖ closure

www.em.doe.gov

EFCOG

Energy Facility Contractors Group

Project Area #2

Adequate NQA-1 Suppliers

EM QA Corporate Board Meeting
Knoxville, TN
August 27-28, 2009

Team Members

- Bill Rowland — DOE SRS
  DOE Team Lead
- Rich Campbell — Energy*Solutions*
  EFCOG Team Lead
- Lynne Drake — SRNS
- Cathy Nesser — WTS
- Robert Thompson — ICP
- Brenda Hawks — DOE ORO

Background

- Team deliverables completed and presented at EM QA Corporate Board Meeting in August
- Alert System Implemented via EM QA Corporate Board Chair Memo of 6/22/09
- Joint Supplier Evaluation Program concept presented and approved in March EM QA Board Meeting
  - Basis of Program is the Supplier Evaluation Program (SEP) developed and implemented by EFCOG Supply Chain Quality Task Team (SCQTT)
  - EM and the SCQTT will adapt the SEP to accommodate the suppliers from EM
- Joint Supplier Evaluation Program Implementation Plan requires approval

Implementation Plan Tasks

- Consolidate and integrate EM Suppliers into the current SCQTT Common Commodity and Joint Audit Schedule
- Develop an Electronic Management System to support the consolidated Supplier Evaluation Program
- Upload information into the Electronic Management System
- Develop new NQA-1 Evaluation Documents

Implementation Plan Tasks

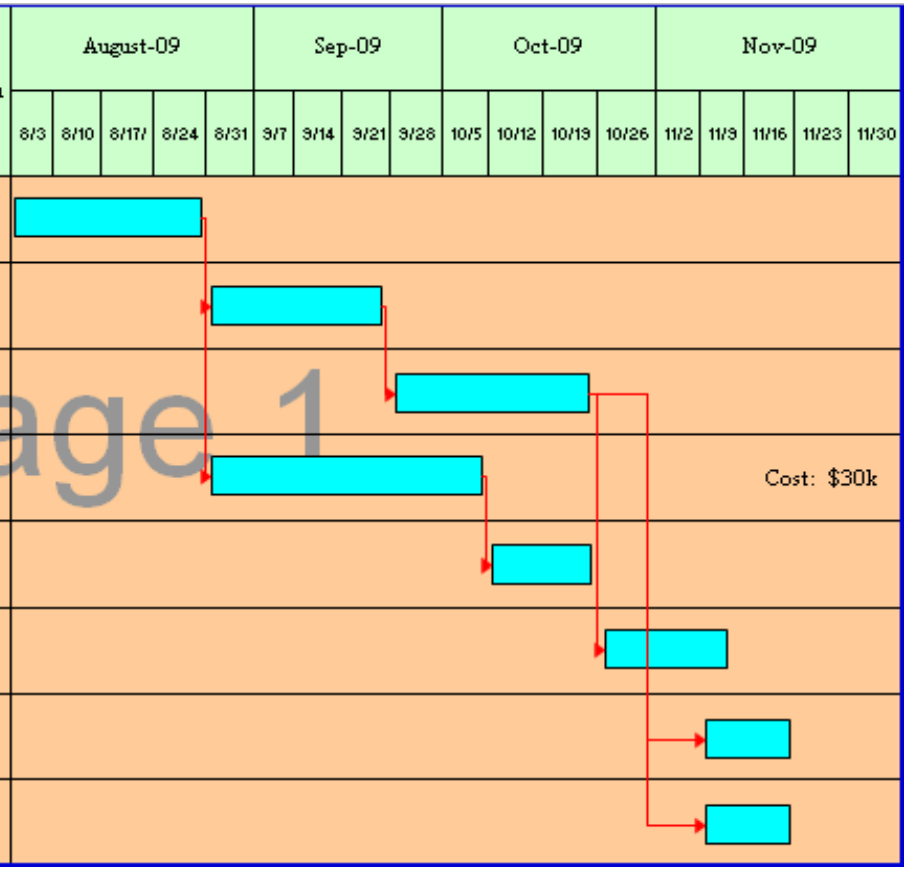
- Establish or revise administrative controls including:
  - Roles and responsibilities
  - Primary Points of Contacts at each site
  - Minimum audit reporting requirements
  - Report review and approval process
  - Review and approval of Lead Auditor Qualifications
- EM coordination of participation on calls, meetings, audits and other support, as needed.

Implementation Plan

- Responsibilities
  - Idaho National Lab (INL) Supplier Management Program Lead is the current Team Leader for the SCQTT. This individual will be the point of contact from EFCOG in the effort to integrate EM into the Supplier Evaluation Program
  - EM Office of Standards and Quality Assurance will serve as the point of contact between the INL Supplier Management Lead and the EM sites during the process of integration and consolidated

Schedule

ID	Task Name	Start	Finish	Duration
1	Authorization	8/3	8/28	4 w
2	Consolidation	8/31	9/25	4 w
3	Develop Evaluation Basis Matrix Documents and Conduct Gap Analysis	9/28	10/23	4 w
4	Electronic Management System	8/31	10/9	6 w
5	Database/ User Interface Validation	10/12	10/23	2 w
6	Electronic System Information Data Entry	10/26	11/6	3 w
7	Database User Test Period	11/6	11/20	2 w
8	Assign Resources and Initiate Audit	11/6	11/20	2 w

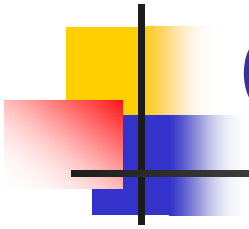


Funding Requirements

- The Electronic Management System initial set-up cost will be between $25-30K with about $100 monthly service fees thereafter.
- The INL Supplier Management Program Lead will be needed full-time for four (4) months to set-up, integrate and consolidate EM into SEP
- EM and sites will need to contribute support for this four (4) month start-up period.

Follow-Up Actions

- EM will solicit feedback from EM participants after each audit for the 1st year to gather lessons learned
- The SCQTT will be encouraged to do the same with its participants
- EM HQ will conduct a survey after the 1st year of implementation to determine level of acceptance and to solicit process improvements.
- Results of these follow-up actions will be presented at a future EM Corporate QA Board Meeting



Questions & Comments

Attachment 1

By-Laws
Office of Environmental Management
Quality Assurance Corporate Board

Article 1 Name

The name shall be the Environmental Management (EM) Quality Assurance Corporate Board (hereafter referred to as the Board).

Article 2 Mission

The Board will serve a leadership role within EM for overseeing the effectiveness of implementing policies or requirements, and disseminating lessons learned and best practices such that a consistent and effective approach to quality is obtained through independently managed federal and contractor Quality Assurance Programs. The Board will serve as a consensus-building body to facilitate institutionalization of a Quality Assurance (QA) Management System across the EM-Complex. The desired result or overarching mission is to instill a quality culture in EM so that sites perform work safely and correctly and to ensure a stable and qualified QA workforce.

Article 3 Goals and Objectives

The Board will ensure that major QA program decisions and recommendations incorporate and promote the use of the best practices and commonly accepted standards in nuclear industry, including:

- Standardization and consistency in establishment and implementation of QA programs, including Software Quality (SQA) programs, in the EM complex;
- Institutionalization of a QA implementation verification process and proper integration of QA, including SQA, and ISMS;
- Validation of site and contractor compliance to applicable requirements (e.g., 10 CFR 830, DOE O 414.1C, ASME NQA-1);
- Assurance that adequate levels of competent qualified QA and SQA personnel and other resources are available to be able to achieve QA objectives in the EM complex;
- Effective collection, communication, and application of lessons learned throughout the EM complex; and

- Continuous improvement of the overall EM cleanup performance by sustaining a quality culture in the EM complex.

Article 4 Membership

Membership in the Board shall consist of senior EM and contractor representatives. Board membership will consist of a Chair and voting and non-voting members as follows:

Chair:

- Deputy Assistant Secretary for Safety Management and Operations (voting member).

Voting Members:

- Board Chair
- Director, Office of Standards and Quality Assurance (Headquarters QA Manager & Deputy Chair).
- Site Managers or designated alternate (Deputy Manager)[1]: Savannah River; Oak Ridge; Portsmouth and Paducah; Idaho; Carlsbad; River Protection; Richland; Consolidated Business Center.
- Chief Nuclear Safety (CNS), Office of the Under Secretary of Energy

Advisors (Non Voting Members):

- Site QA Managers/ES&H Managers.
- Senior Site Contractor Representatives.
- Board Secretary, appointed by the Board and approved by the Chair.
- CNS Staff Representatives

Article 5 Process for Membership Selection

Chair may add or remove non voting members on the Board as program activities warrant. Voting members can only be removed by the Chair through consensus recommendation of the voting Board members. Article 4 will be changed to reflect such changes.

1. Resignation:
   No Board member or Officer shall resign without providing written notice to the Board Secretary of their resignation. The resignation of a Board member shall take effect upon receipt by the members of a resignation notice or at such later time as shall be specified in the notice.

[1] Site managers should send an official memorandum to Board Chair identifying their alternate who will have voting rights in their absence at any Board meeting. Further, if a Site Manager can not attend a planned Board meeting, he/she should notify the Board Chair and Deputy Chair by email prior to the meeting.

2. Filling Vacancies:
   Voting members will recommend a replacement member of the Board to the Chair. Upon agreement, the new member of the Board will be seated.

Article 6 Duties

1. Chair
   a. Establishes, implements, and maintains the EM Quality Assurance Program vision, mission, goals, and objectives.
   b. Has the final approval on all actions the Board undertakes.
   c. Monitors the work of the Board to ensure that operations of the Board are consistent with the needs and requirements of EM and the Department.
   d. Serves as Board spokesperson.

2. Deputy Chair (HQ QA Manager)
   a. Monitors performance of Board actions in order to make appropriate recommendations to the Board.
   b. Initial point of contact for recommending and obtaining a status of Board actions.
   c. Ensures that actions of the Board, upon approval of the Chair are implemented.
   d. Serves as Chairperson of the Board in the absence of the Chair.

3. Board Secretary
   a. Prepares/Distributes Board meeting agendas for approval by the Chair.
   b. Notifies participants of Board meetings.
   c. Tracks issues and work of Board and Board Committees.
   d. Provides facilitation and logistic support for the Board.
   e. Serves as liaison to all standing committees of the Board.
   f. Manages and facilitates the Board's meetings.
   g. Prepares and issues Board Meeting minutes.
   h. Maintains Board records.

Article 7 Board Member Roles and Responsibilities

1. Provides solutions, ideas, and suggestions to meet and remove challenges or barriers, respectively, that affect the vision, mission and goals of the EM QA Management System.

2. Actively participates in Board activities.

3. Regularly attends Board meetings.

4. Provides recommendations and prioritization for Board business initiatives.

5. Brings knowledge of and is prepared to discuss perspectives and plans to manage and implement QA programs.

6. Monitors, reviews, and recommends appropriate performance metrics that arise from implementation of Board recommendations.

7. Champions and communicates Board recommendations, and shares lessons learned and best practices at their individual sites and across the DOE-Complex.

8. Ensures adequate DOE staff and contractors are trained in QA principles and procedures and that the DOE staff and contractors are qualified, as appropriate, to Departmental QA and Software Quality Assurance (SQA) guidelines.

Article 8 Advisors

Technical Advisors to the Board may be nominated by voting members from time to time to provide assistance to the Board in the resolution of issues. Technical advisors will only be approved by the Board Chair. These individuals may include: DOE and contractor QA managers at the various sites as well as individuals whose specific areas of expertise will assist the Board

a. Technical advisors will:
    i. Serve a temporary assignment on the Board.
    ii. Not have voting rights to Board recommendations.
    iii. Obtain support for their assignment from their duty station of record.
    iv. Provide technical advice to the Chair and other voting members.
    v. Attend meetings at the request of the Chair or other voting members.

Article 9 Interfaces

The Board will interface with other DOE and contractor QA committees, groups, and organizations as appropriate. The Chair or his designee(s) will be the liaison with the interface groups. Interface groups will include at a minimum:

- Energy Facilities Contractors Group (EFCOG)
- EM/Nuclear Energy/Science SQA Support Group
- DOE/Health, Safety, and Security (HSS) QA Council

Article 10 Committees

The Board Chair will approve or disapprove committees when recommended by the Board. Committees will be established by the Board on a temporary basis to address specific issues of interest by the Board. Committees will:

1. Collect information from all sources within DOE-Complex affecting QA issues of concern.
2. Assign individual investigative teams and actively intervene across all EM for disposition of issues.
3. Assess and determine compliance with recommendations.
4. Assist sites with implementation and monitoring of recommendations.
5. Draw resources from their sites of record.
6. Interact with the EM QA Manager.
7. Provide their recommendations to the Board for review and approval prior to submittal to the Chair.

Article 11 Quorum

The attendance or participation of the Voting Board Members shall constitute a quorum of the Board. Notwithstanding the foregoing, if a member fails to attend a meeting for which proper notice has been given and the absence is not reasonably excused due to emergency or other critical situations, then any five voting Board members and the Chair or Deputy Chair shall constitute a quorum.

Article 12 Meetings

1. The Board meets in person two times a year for regular meetings to review general status of EM QA issues and the status of committee activities. Supplemental meetings may be scheduled as needed to fulfill the Board's responsibilities as determined by the Board Chair, by any appropriate means (e.g., videoconferences, teleconferences, and other electronic means).

2. Written notice of Regular meetings, listing those invited to attend and stating the place, day, and hour of the meeting and the purpose(s) for which the meeting is called, shall be delivered by the Board Secretary no fewer than 30 days before the date of the meeting by electronic or regular mail. The Board Secretary shall issue the agenda for regular meetings no later than 15 days prior to the meeting. Agendas for supplemental meetings shall be issued prior to the meeting, as early as possible.

Article 13 Issue Resolution and Change Process

1. Issues are primarily brought before the Board by the Deputy Chair. However, an issue may be brought before the Board by any voting or

nonvoting member as a representative for any DOE or DOE contractor employee.

2. A request for the Board to consider an issue is submitted to the Board Deputy Chair who will coordinate the request with the Board voting members and the Board Chair. Upon approval of the Board Chair, issues are placed on the Board agenda.

3. As required, the Board will prioritize all issues under its consideration and submit any changes to the Deputy Chair.

4. The Board will review an issue and may recommend to the Deputy Chair:
   a. Further study,
   b. Ask for more information,
   c. To form a sub-committee to prepare advice for the Board,
   d. To establish a point of contact from the Board for the formation of a committee, and/or
   e. Deletion from the Board issues.

5. Upon Chair approval of the change, the Deputy Chair changes priorities and schedules.

6. Board members are responsible for ensuring implementation of the change in their individual organizations.

Article 14 Board Consensus Recommendations and Dispute Resolution Process

The Board will make consensus recommendations to the Chair. Consensus is defined as general agreement or accord and includes agreement to implement the decision for DOE operations within their control. Simply, this means that each Board member is comfortable with the recommendation even if it may not be his or her first choice. For Board purposes, consensus will mean substantive agreement among Board voting members on recommendations. However, from time to time, the Board may not be able to reach consensus. On those rare occasions, the Board will direct the Deputy Chair to prepare a majority and minority report summarizing the Boards concerns and issues for submittal to the Board Chair. The Board Chair will then make a determination on the resolution of the issue.

Article 15 Amendments to the By-laws

Amendments to the By-laws may be submitted annually or as necessary to the Board for consideration. The Board will make a consensus recommendation to the Chair for changes to the By-laws, which upon approval the changes will be incorporated.

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

Quality Assurance Improvement Project Plan Rev. 5 DRAFT F

Approved by:

James Owendoff, DOE/EM _____
Chief Operations Officer

Steve Krahn, DOE/EM _____
Deputy Assistant Secretary
Office of Safety Management and Operations

Dave Amerine, Parsons _____
EFCOG Board of Directors

Joe Yanek, Fluor _____
EFCOG Board of Directors

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

EM Quality Assurance Corporate Board (8/28/09)

Office of Environmental Management and Energy Facility Contractors Group Quality Assurance Improvement Project Plan

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.

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.

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, **Energy*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 (ISM)/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.

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.

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.

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)

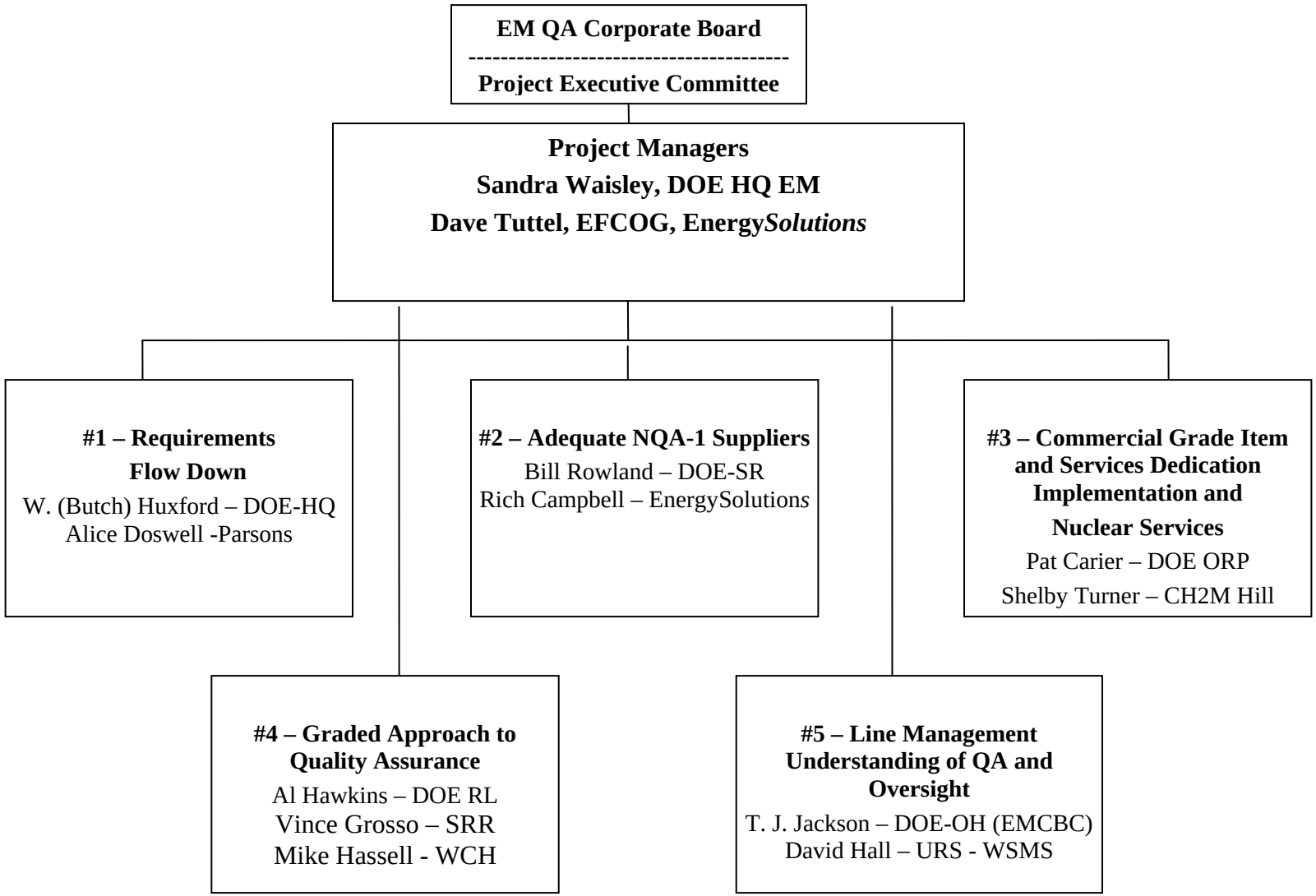
Communications:

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.

Project Termination:

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

Figure 1. Quality Assurance Program Improvement Project



Quality Assurance Project Focus Areas

Project Area 1 – Requirements Flow Down
Target Completion Date: February 28, 2008

Background:

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

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

Scope:

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

DOE Lead: Wm. (Butch) Huxford, EM-HQ

EFCOG Lead: Alice Doswell, Parsons

Support Team: Telak Verma, Energy*Solutions*
Juan Hernandez, Energy*Solutions*

Project Milestones:

Task #	Estimated Due Date	Task Description	Deliverable
1.1	6/16/08	Develop a brief questionnaire to send out to both commercial and EM contractors to describe their current approach for identifying the applicable QA requirements for subcontractors, tailoring the requirements based upon risk, process for working with procurement to ensure QA requirements are incorporated into subcontracts, and implementing verification of requirement flow-down by their suppliers, subcontractors, and sub-tiers.	Completed: Questionnaire
1.2	7/07/08	Request targeted EM contractors to respond to questionnaire	Completed: Questionnaires
1.3	8/01/08	Solicit similar input from a few commercial nuclear contractors to compare with the DOE processes.	Completed: Questionnaires
1.4	8/15/08	Select contractors will be asked to provide a briefing of their approach for flow-down of QA program requirements and quality-related requirements (i.e., NQA-1, ISO, etc.) to their suppliers, subcontractors, and sub-tiers. Briefing should address the basis for flow-down and extent of requirements addressed	Completed Briefing from Select Contractors
1.5	8/15/08	Complete an analysis of the DOE and commercial processes used.	Completed: Summary of Analysis of Commercial & DOE Contractor Processes
1.6	8/30/08	Develop a composite flow-down process including best practices from both DOE and the commercial sector, and provide recommendations to EM for its action.	Completed: Decision Tree Flow Diagram
1.7	9/15/08	Work closely with Project Focus Area #4 – *Graded Approach to Quality Assurance Implementation* - to amend the Decision Tree Flow Diagram with implementation guidance notes. This will ensure that the Decision Tree has considerations for contractor oversight and vendor submittals, ensuring requirements are evidenced in the products delivered for use, and that there are adequate oversight functions to address all of the above issues.	Completed: Amended Decision Tree Flow Diagram

1.8	12/20/08	Resolve path forward with Projected Focus Area #4. White Paper will include section consistent with Project Focus Area #4	Completed: Clarify Roles and Responsibilities between Project Focus Areas #1 and #4 Following Re-direction from 3rd Corporate Board Meeting (11/08)
1.9	2/20/09	Complete White Paper covering procurement QA process flow diagram (will combine eventually with Project Focus Area #4 Task #4.2.	Completed: White paper and Amended Flow Diagram
1.10	3/09/09	Incorporate comments from EFCOG QA Committee	Completed: Final Project Focus Area #1 Deliverables- Flow Diagram and White Paper have been incorporated into Focus Area 4 deliverable.

Project Area 2 – Adequate NQA-1 Suppliers
Target Completion Date: 2/27/09

Background:

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

Scope:

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

DOE Lead: Bill Rowland, EM - SR

EFCOG Lead: Rich Campbell, Energy*Solutions*

Support Team: Lynne Drake, SRNS
Cathy Nesser, WIPP
Robert Thompson, ICP
Brenda Hawks, ORO

Project Milestones:

Task #	Estimated Due Date	Task Description	Deliverable	Deliverable To Be Submitted to Project Managers
2.1	6/09/08	Request a current list of commodities/ items/ services from major EM contractors	Commodity List for use in Task 2.9	No Informational Complete
2.2	6/09/08	Request a list of the current points of contact for Supplier Quality Assurance from each of the major EM contractors	List of Contacts	No Informational Complete
2.3	6/13/08	Attend the NEI Manufacturing Outreach Workshop to gain insight into NEI efforts to attract nuclear suppliers	Trip Report	No Informational Complete
2.4	6/23/08	Request the names of current suppliers that are providing nuclear grade (Safety Class, Safety Significant, and Important to Safety) materials, equipment, items and services from each major EM contractor	List of Suppliers for use in Tasks 2.10 and 2.11	No Informational Complete
2.5	6/23/08	Request the procedures used for qualifying nuclear grade suppliers from each major EM contractor	Procedures for use in Task 2.6	No Informational Complete
2.6	7/18/08	Evaluate procedures being used by major EM contractors for consistency	Evaluation Report	Yes Complete – Evaluation Report Submitted
2.7	7/31/08	Hold a one day Nuclear Vendor Day, possibly in conjunction with other groups, EFCOG, NEI, etc.	Completed Vendor Day	No Complete
2.8	11/3/08	Evaluate impact of “Buy American” clause on efforts to expand the supplier base within EM.	Evaluation Report	Yes Complete – Evaluation Report Submitted
2.9	8/29/08	Evaluate the applicability and completeness of the listing of common commodities/items/ services provided by the major EM contractors.	Final List	Yes Complete – Final List Submitted
2.10	12/31/08	Determine the feasibility of EM contractors performing joint audits of common suppliers. If feasible, recommend procedure and checklist requirements that would be needed to implement.	Report of Recommendations	Yes Complete- Report Submitted
2.11	10/31/08	Evaluate inputs to determine if there are common suppliers being used for nuclear grade procurements within EM. Identify redundant supplier audits being performed by major EM contractors	Evaluation Report	Yes Complete – Evaluation Report Submitted

Task #	Estimated Due Date	Task Description	Deliverable	Deliverable To Be Submitted to Project Managers
2.12	12/31/08	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	Report of Recommendations	Yes Completed – Report Submitted
2.13	12/31/08	Evaluate the possibility of integrating EM procurement activities with other supplier initiatives such as NEI, NIAC, NASA, etc.	Evaluation Report	Yes Complete- Evaluation Report Submitted
2.14	1/16/09	Develop a formal process or "alert" system for documenting and notifying the EM-complex and other DOE offices of nuclear suppliers not meeting QA requirements.	Draft Process Description Document	Yes Complete – Alert System Implemented
2.15	1/23/09	Provide deliverables and recommendations to Project Managers and Project Focus Area Leads for review and comment.	Draft Report	Yes Complete – Report Submitted
2.16	1/30/09	Receive comments from Project Managers and Project Focus Area Leads.	Written Comments	N/A Complete – Comments received
2.17	2/06/09	Resolve comments from Project Managers and Project Focus Area Leads	Revised Draft Report	No Complete
2.18	2/11/09	Provide revised draft report to Project Executive Committee for review and comment	Revised Draft Report	Yes Complete
2.19	2/19/09	Receive comments from Project Executive Committee	Written Comments	No Complete
2.20	2/25/09	Resolve comments from Project Executive Committee	Revised Report	No Complete
2.21	2/27/09	Submit Final Report to Project Managers	Final Report	Yes Complete except for presenting Implementation Plan to EM QA Board in August
2.22	08/27/09	Submit plan for implementing EM and EFCOG Joint Supplier Evaluation Program.	Implementation Plan	Yes

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

Background:

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

Scope:

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

DOE Lead: Pat Carier, EM-ORP

EFCOG Lead: Shelby Turner, CH2M Hill

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

Project Milestones:

Task #	Estimated Due Date	Task Description	Deliverable
3.1	8/31/08	Complete a survey of selected EM contractors requesting them to identify the process and basis for their CGI dedication program including safety classification of items being dedicated for nuclear applications within their facilities.	Completed Survey
3.2	8/31/08	Complete a survey of selected EM contractors requesting them to identify the process and basis for the process used to accept nuclear services.	Completed Survey
3.3	12/15/08	Conduct benchmarking activities of operating reactor plants to review CGI dedication and acceptance of nuclear services processes.	Completed Benchmarking Report
3.4	1/15/09	Provide EM for review and concurrence recommended baseline requirements/guidance actions considered necessary for implementation of an effective CGI/Services dedication process within EM nuclear facilities.	Recommendation to EM
3.5	1/15/09	Combined w/ #3.4	
3.6	2/20/09	Issue final baseline requirements/guidance actions considered necessary for implementation of an effective CGI/Services dedication process within EM nuclear facilities.	Baseline Requirements Issued to EM Complex
3.7	2/20/09	Combined w/ #3.6	
3.8	3/15/09	Establish training for EM Projects on CGI/Services dedication process based on requirements/guidance baseline approved by EM.	CGD Training Module Completed 8/7/2009
3.9	3/27/09	Provide CGI/Services dedication training to site personnel (i.e., “Train the Trainer”)	DOE/Contractor Training Scheduled for Fall 2009

Project Area 4 – Graded Approach to Quality Assurance
Target Completion Date: June 1, 2010

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:

Phase 1 of the Project Focus Area #4 team will provide EM with a model process for application of a graded approach for use in the procurement process for both contractor and federal QA programs. This includes framing the graded approach process, considering its multiple uses and interfaces, developing/adapting a software grading tool and providing examples of successful application from across the complex.

DOE Lead: **Al Hawkins, EM -RL**

EFCOG Lead: **Steve Piccolo – URS/WGI**

Contractor Leads: **Vince Grosso – SRR**
Mike Hassell - WCH

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

Project Milestones:

Task #	Estimated Due Date	Task Description	Deliverable
4.1	6/27/08	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	9/26/08	Draft an EM Position Paper describing the application of the graded approach in federal QA programs.	Completed Submission of Draft EM Position Paper to Reviewers on Application of Graded Approach to EM Federal QA Activities
4.3	11/13/08	Present draft EM Position Paper to the EM QA Corporate Board for review and discussion.	Completed EM Position Paper on Graded Approach Issued to Corporate Board Members
4.4	6/18/09	In coordination with Project Focus Area #1, provide an EM Standard for application of the graded approach to procurement. The standard will include: • A consistent process for assessing risk and assigning Quality Levels (QLs) • Standard QLs and terminology • Description of procurement variables as function of QL • Expectations for implementation and approval • Training proposal Ensure consistency with Project Focus Area #5. Transmit to EM HQ for EM QA Corporate Board review at the August 2009 Corporate Board Meeting.	EM Graded Approach Procedure for Procurement
4.5	8/27/2009	Present Graded Approach Position Paper at August EM Corporate Board meeting for vote on proceeding.	Presentation to Board For Decision to Proceed
4.6	TBD	Further action as determined by the QA Corporate Board (specific actions and milestones to be developed) If accepted actions to include: • Training package • EM HQ finalization, central control, and distribution of risk assessment tool	

Project Area #5 - Line Management Understanding of QA and Oversight
Target Completion Date: June 30, 2009

Background:

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

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

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

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

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

Scope:

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

DOE Lead: T. J. Jackson, DOE EMCBC

EFCOG Lead: Dave Hall, URS-WGI

Support Team: Brian Anderson, DOE-ID
Kriss Grisham, EM/HQ
Al Hawkins, RL
Bob Toro, EM/HQ
Jack Zimmerman, PPPO
Ken Armstrong, DOE EMCBC

Project Milestones:

Task #	Estimated Due Date	Task Description	Deliverable
5.1	7/15/08	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	7/30/08	Obtain commitment of all EM site managers on QA qualifications/training for assigned project QA staff and development of a schedule to achieve qualifications for any areas that are incomplete. Analyze EM sites responses to EM-2 memorandum (issued May 13, 2008), and identify gaps in implementation in qualifying and training staff.	Completed List of QA Points of Contact for All Organizations, Commitment, and Schedule for Development of Qualifications
5.3	9/30/08	Develop EM QA Program (QAP) applicable to all EM sites (contractor/federal staff) to ensure consistency and to instill a strong QA culture. Draft QAP discussed at 2nd Corporate Board Mtg.	Completed Final Draft QAP
5.4	10/31/08	EM-1 provides direction and guidance to EM field sites to promulgate EM Corporate QAP.	Completed EM-1 Memorandum (11/5/08)
5.5	11/30/08	More detailed QAP implementation (QIP) - next steps and guidance - will be issued by Office of Safety Management and Operations (EM-60 Deputy Assistant Secretary) following the EM-1 Memorandum. Draft presented to Corporate Board for review and discussion.	Completed EM-60 Memo to Field Sites on Path Forward (12/2/08)
5.6	10/31/08	Develop Indoctrination/Training modules on the value of a strong QA Program: 1) Establish 1st EM Centralized Training Platform or Academy: 40-hour training course for federal staff; and 2) Focus on line management (contractor and federal), FPDs, and the IPTs: develop a half-day training program using Training Platform and SRP modules.	Training Academy Modules & Course Held in 10/08. Development of ½ day training program for IPTs and FPDs is complete. The EM HQ/EMCBC MOU and EM Centralized Training Platform Project Plan
5.7	3/31/09	Complete QA training for FPDs/IPT participants to reinforce consistent performance expectations. Initial FPD/IPT training session scheduled for July 2009.	Training Records to EM HQ or Approval Authority
5.8	3/31/09	Establish assessment expectations for FPDs and IPTs (e.g., Phase I, Phase II, annual reviews, performance measures, lessons learned). Include QA capabilities at all CD phases of a project. Complete IPT/FPD assessments before Annual Declarations are submitted to HQ end fiscal year.	Assessment Expectations Document with Common Checklists (for consistency) to be issued during FPD/IPT QA training session in July.
5.9	6/30/09 - 9/30/09	Following EM QA Program promulgation, associated Project Execution Plans, procedures, implementation plans, and charters will be developed to ensure adequate and consistent implementation of the QAP.	Sites to Deliver Procedure/Plan Set to Their Approval Authority

Glossary:

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

EM QUALITY ASSURANCE CORPORATE BOARD DELIVERABLES STATUS REPORT
Holiday Inn Convention Center, Knoxville, TN
August 27, 2009

Project Focus Area Group	Deliverables	Board Vote Needed	Final Board Approval Obtained?	Implementation Approach
#1 Flow Down of Requirements	Task #1.9: White Paper (EM Standard) and Flow Diagram	**N (rework w/ #4)**	**NA**	**TBD- White Paper w/ Table 6.1 reworked – ready for vote.**
#2 Adequate Nuclear Suppliers	Task #2.11: Evaluation Results of EM Common Suppliers	**NA**	**NA**	**NA**
	Tasks #2.10/2.11/2..12: Joint Supplier Audits Evaluation Summary and Recommendations	**Y**	**Y (concept only 3/19/09)**	**Discuss implementation approach w/ EMCBC and EFCOG.**
	Task #2.14: EM QA ALERT System Process (Flow Diagram, ALERT Template) & Recommendation	**Y**	**Y**	**EM-60 DAS (Chair of EM QA Corporate Board) issued memo on 6/24/09 with COO concurrence to field offices with example attached (ALERT Template). EM-64 OD will distribute ALERTS by email to EM Site QA Managers, FPDs, HSS, and NNSA.**
#3 Commercial Grade Item/Services Dedication Implementation	Tasks #3.4/3.6: Recommendations for Baseline Requirements and Path Forward	**Y**	**Y**	**Issue with revised EM Corporate QAP in Fall 2009.**
	Task #3.8: CGD Training Module Course Content	**Y**	**Y (concept only 3/19/09)**	**Schedule training courses (Hanford, SRS, OR) in CY 2009; post training modules on EM website and EM Portal.**
#4 Graded Approach Implementation	Task #4.4: - EM Graded Approach Procedure for Procurements	**Y**	**Y (reworked after 3/19/09)**	**Reworked (see Focus Area #1) in June 2009. Ready for Board vote.** **<u>Proposed Implementation</u> : (If Board Approves)** **Short-Term – EM-60 DAS issues memo to site managers and recommends use at sites and review/comment.** **Long-Term – issue with revised EM Corporate QAP as guidance/best practices.**
	- Standardized Risk Assessment Process	**Y**	**TBD**	

Project Focus Area Group	Deliverables	Board Vote Needed	Final Board Approval	Implementation Approach
#5 Line Management Understanding of QA and Oversight	Task #5.6: QA Training Course for Integrated Project Teams and Federal Project Directors	**Y**	**Y**	**Provide QA Awareness training at EM-50 FPD workshops (1st course offered in July 2009 in Las Vegas, NV at EM-50 AM/PM Workshop).**
	Task #5.8: Assessment Expectations Document w/ Common Checklists	**N (FPD Review Completed)**	**NA**	**Develop as Standard Review Plan (SRP) Review Module; post on EM website and EM Portal; and pilot test during Construction Project Review and/or EM audit. Ongoing w/ Due Date of 9/01/09.**
Standard QA Contract Language	Language for EM-Complex Request For Solicitations (RFPs)	**Y**	**Y**	**Jack Surash, DAS Acquisition and Project Management, issued language to all site managers and procurement officers on August 14, 2009. EM-64 will send language out to all site QA managers and include language as an appendix to the revised EM Corporate QAP in Fall 2009.**

Comments on CGD Course Modules.

Module 1

Slide 5: The words with the last block do not mention WTP but it WTP is in the block. Suggest adding WTP to the words. (DA)

Accepted: Removed reference to WTP from the last block.

Slide 6: This slide is titled Major Steps in the Dedication Process. There is no reference or mention of the dedication package that must be approved prior to placing the procurement. (DF)

Accepted. Bullet #7 was added to state "Document approval that the item/service will, with reasonable assurance perform its safety function".

Slide 7 & 8: Pictorials of process do not address preparation of the dedication package or show the breaks between pre- and post-procurement activities. (DF)

These slides are intended to be a high level depiction of CGD with slide #7 a repeat of Figure 1-1 from EPRI NP 5652. The point of this slide is to introduce the students to the two aspects of CGD, Technical Evaluation and Acceptance Process. Slide #8 is only to show a little more detail of each process as opposed to all the facets of each. The elements from Slide 6 are flushed out within the appropriate modules.

Slide 9: Safety functions may also found in the Preliminary Hazards Analysis, Hazards Analysis, Preliminary Documented Safety Analysis (PDSA), Documented Safety Analysis (DSA), and in DOE Safety Evaluation Reports. (DF)

Accepted. Bullet #2 was updated.

Slide 10 - typo in last dash: "1" should be "in". (DA)

Accepted: Corrected

Slide 11 - should this be worded "designed and/or manufactured"? (DA)

While it may be more correct, since it is a quote of the NQA-1-2004 definition, we cannot improve on it.

Slide 14: Does not address Method 4 as detailed in NQA-1a-2009. (DF) Additional broader question regarding evaluation of NQA-1a-2009 for the training. (JY)

An attempt was not made to implement NQA-1a-2009 since it has not been accepted by DOE as the standard for Contractor implementation. The training is based on NQA-1-2004, however, a formal evaluation will be performed as EM looks to endorse 1a-2009.

Slide 16: Does not address the CRITICAL need to ensure that dedication plans and records from 3rd party suppliers be obtained as part of the record set when the 3rd party supplier/dedicator is the Dedicating Entity. Without these records the item cannot be used. (DF)

Accepted: Bullet #3 was added.

Module 2

Slides 5 & 6: Need to ensure that all of these are captured in addition to the ones you have listed - Safety functions may also found in the Preliminary Hazards Analysis, Preliminary Documented Safety Analysis (PDSA), and in DOE Safety Evaluation Reports (DF)

The team agreed with your comment and considers that with the detailed discussion in module one of what forms the suite of documents that constitute the "safety basis" and the reference to the "safety basis" in these slides covers your issue.

Slide 6: In bullet 2 there is an acronym "CD" that is not defined. (DF)

Accepted: Fixed "CGD"

Slide 13: It states that some failure mechanisms are not "credible" and implies that these failure mechanisms do not need further consideration. This is NOT a correct position. The potential failure mechanisms are a component of the hazards analysis (HA) and must be evaluated to ensure the assumptions from the HA are preserved. You cannot just disregard them as not credible – they were identified as a failure mechanism because they ARE credible. They may be very low probability (and in some cases may allow them to be disregarded) but you must evaluate where you are. (DF)

Slide 13 - failure mechanisms are limited to mechanical features; what about electrical, chemical, et.al.? (DA)

Accepted: Fixed slide. Added reference to electrical.

Accepted: Fixed slide. Provided updated words to DF and DA by separate correspondence.

Module 3

Slide 19: Makes specific reference to “Procurement Engineer” - The important thing here is that this is an engineering function. Some smaller orgs will not have separate Systems and Procurement Engineering groups. (DF)

Accepted: Removed reference to “procurement”.

Slide 20: Titled “Key Elements of CCFA” What is CCFA? (DF)

Accepted: Heading now states “Critical Characteristics for Acceptance”

Slide 23: 4th bullet – states “When acceptance criteria are known . . . “ If you do not know the acceptance criteria you are not allowed to pursue CGI. This bullet implies that if you do not know the acceptance criteria one of the other methods should be used and that is a real problem. (DF)

Accepted: 4th bullet deleted.

Module 4

Slide 6: Acceptance criteria may or may not be in ENGINEERING DOCUMENTS. They may be contained in the Technical evaluation prepared to support CGI which may be part of the dedication package and not a stand-alone engineering document. (DF)

Since the technical evaluation is performed by engineering and is based on engineering documents, it would also be considered an engineering document. The slide also states “generally” so there is room for something else but we couldn’t come up with a document with acceptance criteria that was not an engineering type document.

Slides 12 & 18: CCFA again. What is this? (DF)

Accepted: All reference to CCFA has been removed. Where appropriate critical characteristics to be verified or critical characteristics for acceptance have been added.

Slide 22: 3rd bullet/ Word “If” in the middle of the statement should not be title cased (it should be “if”) (DF)

Accepted: Fixed word.

Slides 30 – 33: Not consistent with NQA-1a-2009 regarding Method 4. For example: the use of a single source of information is not sufficient to allow the use of Method 4. (DF)

Agree with your example. NQA-1-2004 and the slide also establish the expectation that there has to be an “industry wide” evaluation of performance directly related to the CC that is being considered for the design element supporting the safety function being

reviewed. The industry wide evaluation is discussed on two slides. With that said, the training will be updated to 1a-2009 when approved and endorsed by EM.

Module 5

General Comments

1. Purchaser (and end user if different) always retains overall accountability for the adequacy of any 3rd party CGI dedication including the adequacy of dedication records.
2. Allowing a supplier to select critical characteristics can be problematic and result in missing critical characteristics or safety functions. Please note, #1 above always applies. (DF)

The team agrees with your position and ORP has pointed out to both prime contractors the trap of expecting a supplier to perform the technical evaluation without all the needed safety base documents on which to base the evaluation. It should also be noted that NRC in their recent Q & A stated that a vendor should not be expected to perform the technical evaluation unless they are also responsible for the design work. Even in this case, the contractor/owner is still responsible.

DOE TRAINING

Commercial Grade Dedication Training

MODULE 1

Overview of CGD Process

U.S. DEPARTMENT OF ENERGY

Office of River Protection

Course Objectives

- Define the terms “commercial grade item” and “commercial grade services”
- Understand the process for commercial grade dedication
- Describe the bases for implementing each element of the generic process and how they relate to requirements and EPRI Guidelines
- Describe each element of the process and its purpose
- Understand the acceptance process for items and services

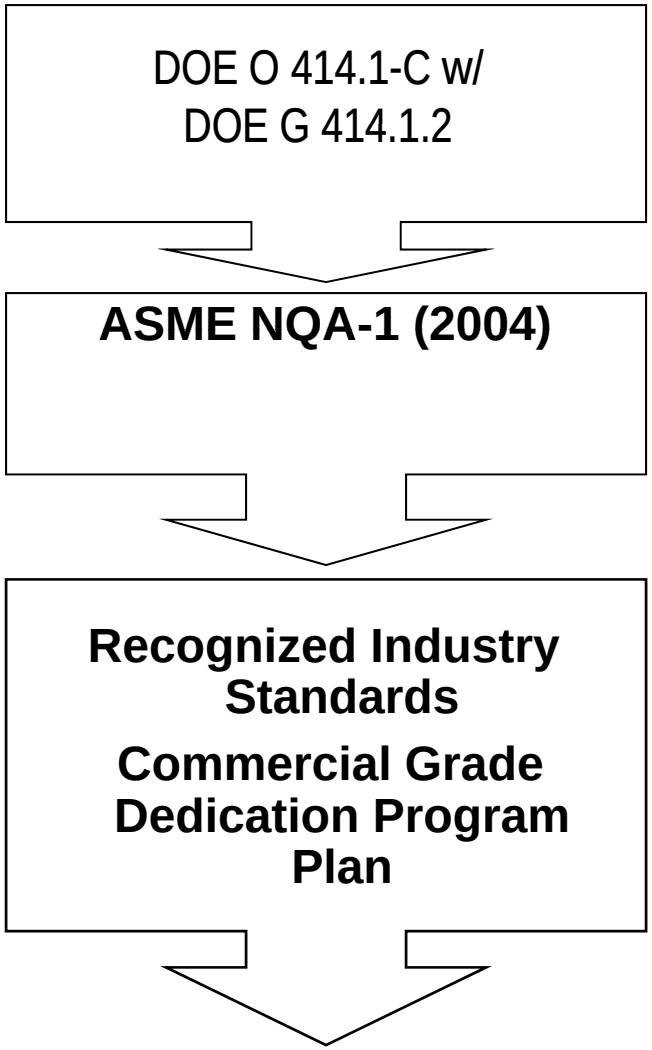
Course Content and Structure

- Module 1 – Overview of CGD Process
- Module 2 – Technical Evaluation
- Module 3 – Acceptance Planning
- Module 4 – Dedication Package
- Module 5 – Supplier Dedication Oversight
- Module 6 – CGD Implementation and Lessons Learned

Introduction

- What is the purpose of dedication?
  - Dedication is performed to establish the acceptability of an item to perform its safety function.
- How is dedication performed?
  - Dedication consists of a technical evaluation of an item followed by establishment of acceptance methods.
- What is needed to start the dedication process?
  - The design must be completed to the point that the suitability of the item for its intended application has been established.
- How much is enough?
  - The extent of technical evaluation and the rigor applied to the acceptance process are both commensurate with the significance of the safety function of the item. This decision is based on engineering judgment. It is important to document this basis.

How does the CGD process meet the requirements of DOE O 414.1C?



DOE Order 414.1C states that a national/consensus standard(s) must be chosen for implementation. NQA-1 2004 Part 1 and Part 3 provide requirements and supporting guidance respectively implementing EPRI guidance for CGD. DOE G 414.1.2 Quality Management System Guide (for use with 10 CFR 830.120 and DOE O 414.1) – Commercial Grade Items intended for use in nuclear safety applications should be procured in accordance with documented processes using recognized consensus standards.

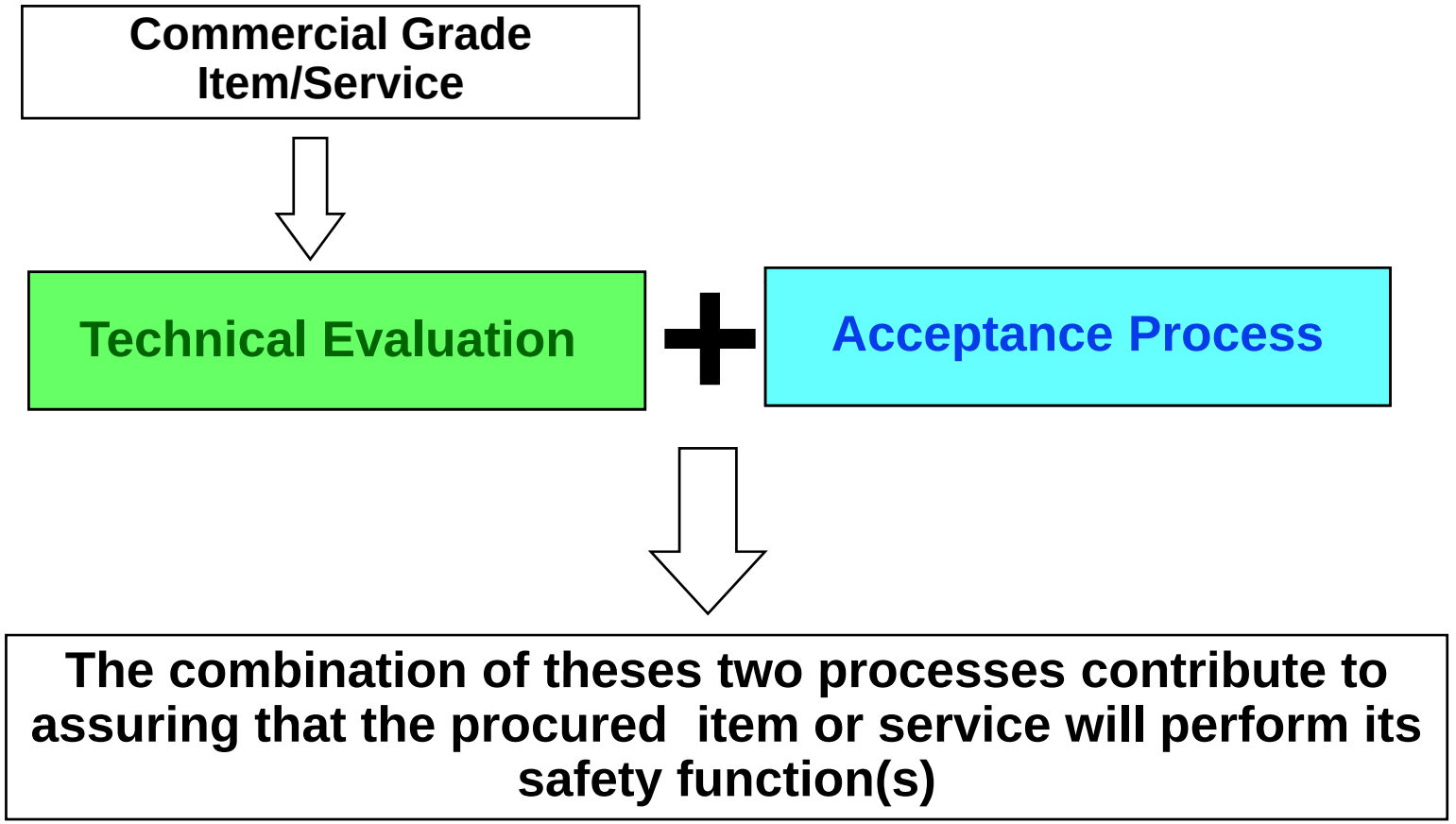
NQA-1 Quality Assurance Requirements for Nuclear Facilities Applications – Establishes Quality Assurance requirements for items and services that provide a safety function. CGD process is used when items or services that provide a safety function are not provided by NQA-1 qualified suppliers.

EPRI NP-5652, EPRI TR-106439 and EPRI TR-102260 – EPRI NP-5652, Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications; EPRI TR-106439, Guideline on Evaluation and Acceptance of Commercial Grade Digital Equipment for Nuclear Safety Application; and EPRI TR-102260, Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial Grade Items are recognized in the nuclear industry as the standard documents regarding the purchase of commercial grade items for use in nuclear related applications.

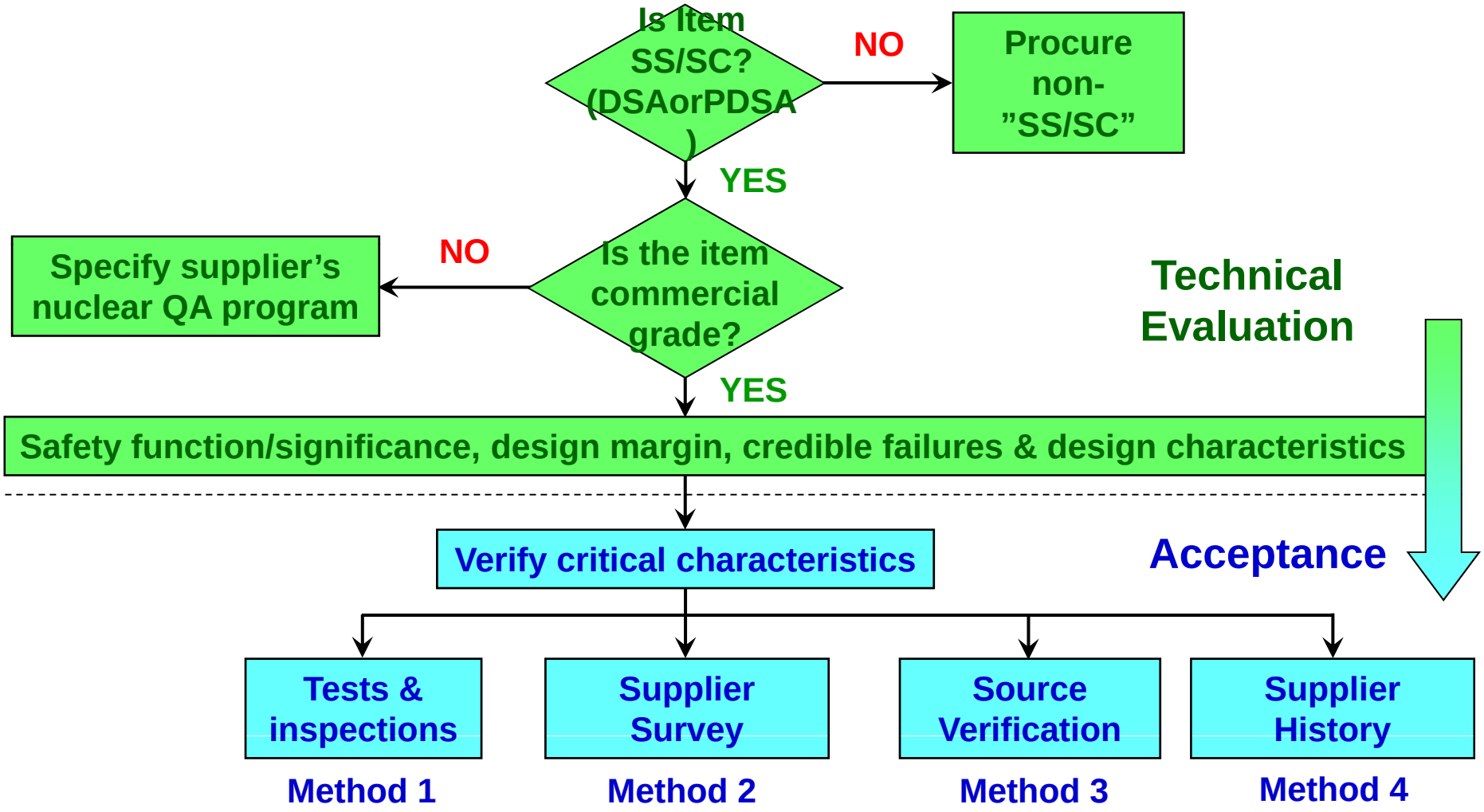
Major Steps In The Dedication Process

- Clearly identify the item
- Bound the application
- Research the design to identify the safety functions, the service conditions and the design margin
- Determine the safety significance of the item considering the consequences and likelihood of failure
- Determine the characteristics of the item that are critical to performance of the safety function
- Select acceptance methods, acceptance values and sample plans commensurate with the items significance
- Document approval that the item/service will, with reasonable assurance perform its safety function
- Document the basis

Commercial Grade Procurement Fundamentals



Overview of the Generic Process



Quality Level Determination

- Determination of item safety function is part of the design process
- Safety functions are reflected in specifications, drawings, data sheets, procurement packages, Preliminary Hazards Analysis, Hazards Analysis, Preliminary Documented Safety Analysis (PDSA), Documented Safety Analysis (DSA), and in DOE Safety Evaluation Reports.
- Technical justification should be documented for items classified differently than their host system/component
- Quality level of a service is equivalent to the quality level of the items associated with the service

Determine if the Item or Service Meets the "Commercial Grade" Definition

- NQA-1-2004 provides two definitions for a commercial grade item depending on the application of the item.
  - Definitions were modified from NQA-1-2000 to recognize that the availability of NQA-1 qualified suppliers who were fabricating one-of-a-kind and/or new technology to support construction activities was less than in previous years.
- Definition 1, a commercial grade item meets all of the following:
  - Not subject to design or specification requirements that are unique to nuclear facilities;
  - Used in applications other than nuclear facilities;
  - 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)

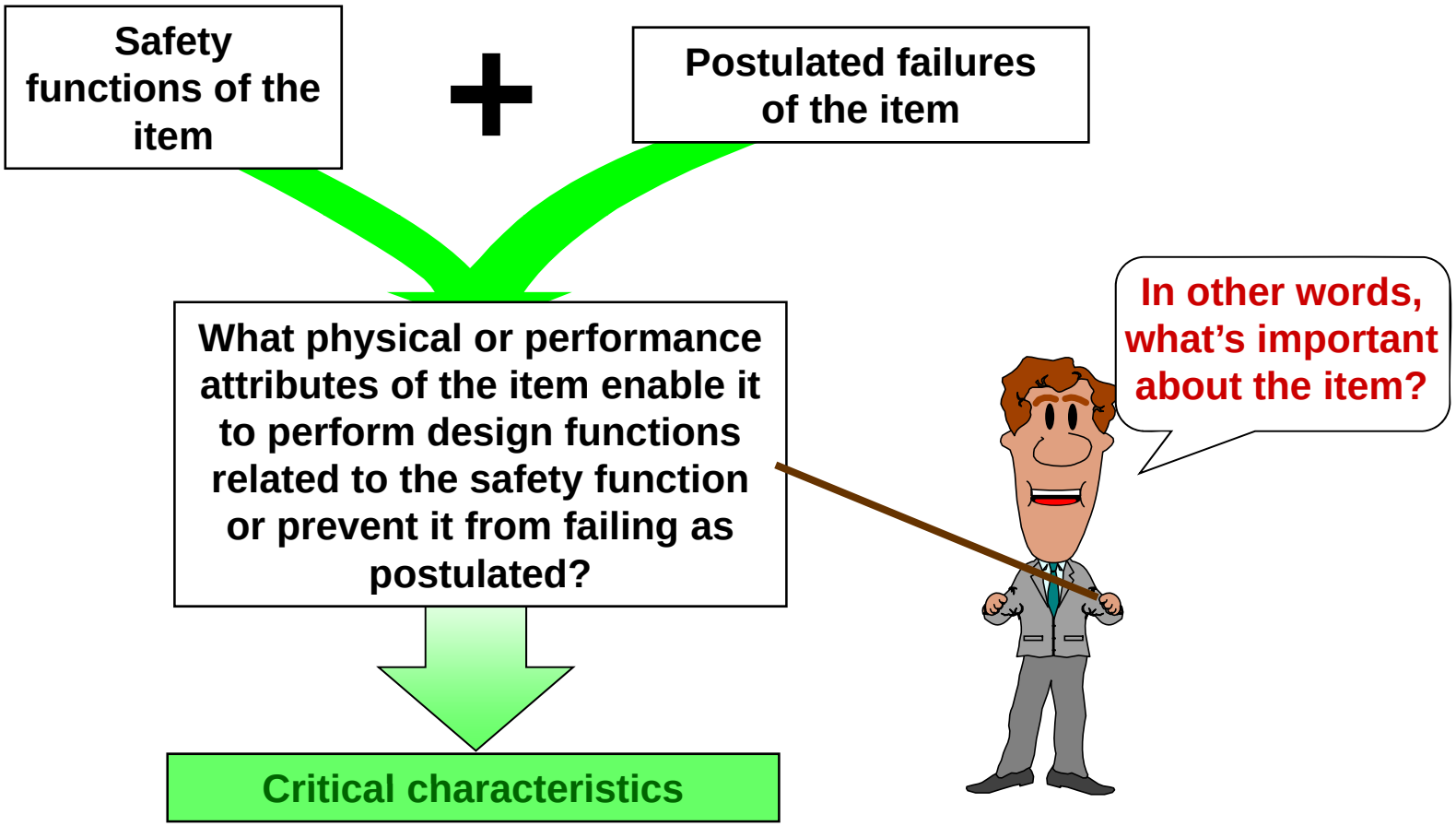
Determine if the Item or Service Meets the "Commercial Grade" Definition – cont.

- Definition 2:
  - Commercial Grade Item (CGI) is a structure, system or component (safety-class/safety-significant), or part thereof, that affects its safety function, that was not designed and manufactured by an NQA-1 qualified supplier
    - The DRAFT NQA-1a-2009 clarifies in Note 4 that this definition is applicable to Department of Energy nuclear facilities and activities regulated under 10 CFR 830, Nuclear Safety Management
  - Commercial Grade Service (CGS) is a service that is not provided by an NQA-1 qualified supplier

Utilization of the CGD Process

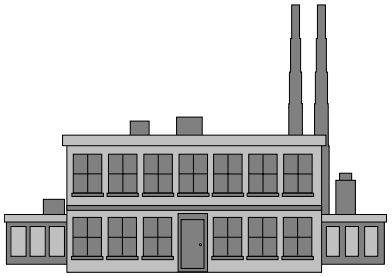
- Utilization of the CGD process for procuring items or services include the following:
  - Technical evaluation to determine that the item or service performs a safety function
  - Confirmation that the item or service meets the commercial grade definition criteria
  - Identification of the critical characteristics, acceptance criteria, and methods of acceptance
  - Documentation of the basis for the acceptance requirements
- When one or more critical characteristics for acceptance cannot be verified, then the CGD procedure is not used to procure or accept the CGI/CGS

Identify Critical Characteristics



When Critical Characteristics Are Verified

During Manufacturing at Supplier/Sub-Supplier



In-process and final product testing

(Method 1)

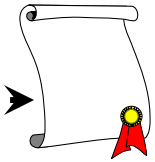
Source Survey/Source Surveillance

(Method 2 and 3)

During Receiving

Inspection of the item

(Method 1)



Review of supplier documentation

(Method 2)

Testing of the item

(Method 1)

After Installation

Post installation testing of the item

(Method 1)

Commercial Grade Dedication

- Commercial grade dedication (CGD) is an acceptance process performed in accordance with procedures to provide reasonable assurance that a CGI or CGS will successfully perform its intended safety function and is deemed equivalent to an item or service provided from a qualified NQA-1 supplier
- Commercial grade dedication consists of two processes: (1) technical evaluation – assures that the requirements for an item/service are specified in procurement documents, and (2) acceptance process – provides methods to reasonably assure that the item/service received is what was specified

Commercial Grade Dedication

- Dedication can be performed by the Contractor, a qualified NQA-1 supplier, or a qualified third-party dedicating entity
- Dedication performed by a qualified NQA-1 supplier or a third-party dedicator must be performed in accordance with the supplier's QA program
- Dedication plans and records from 3rd party suppliers be obtained as part of the record set when the 3rd party supplier/dedicator is the Dedicating Entity.
- Dedication is complete when the organization verifying the critical characteristics completes the acceptance activities

DOE TRAINING

Commercial Grade Dedication Training

MODULE 2

Technical Evaluation

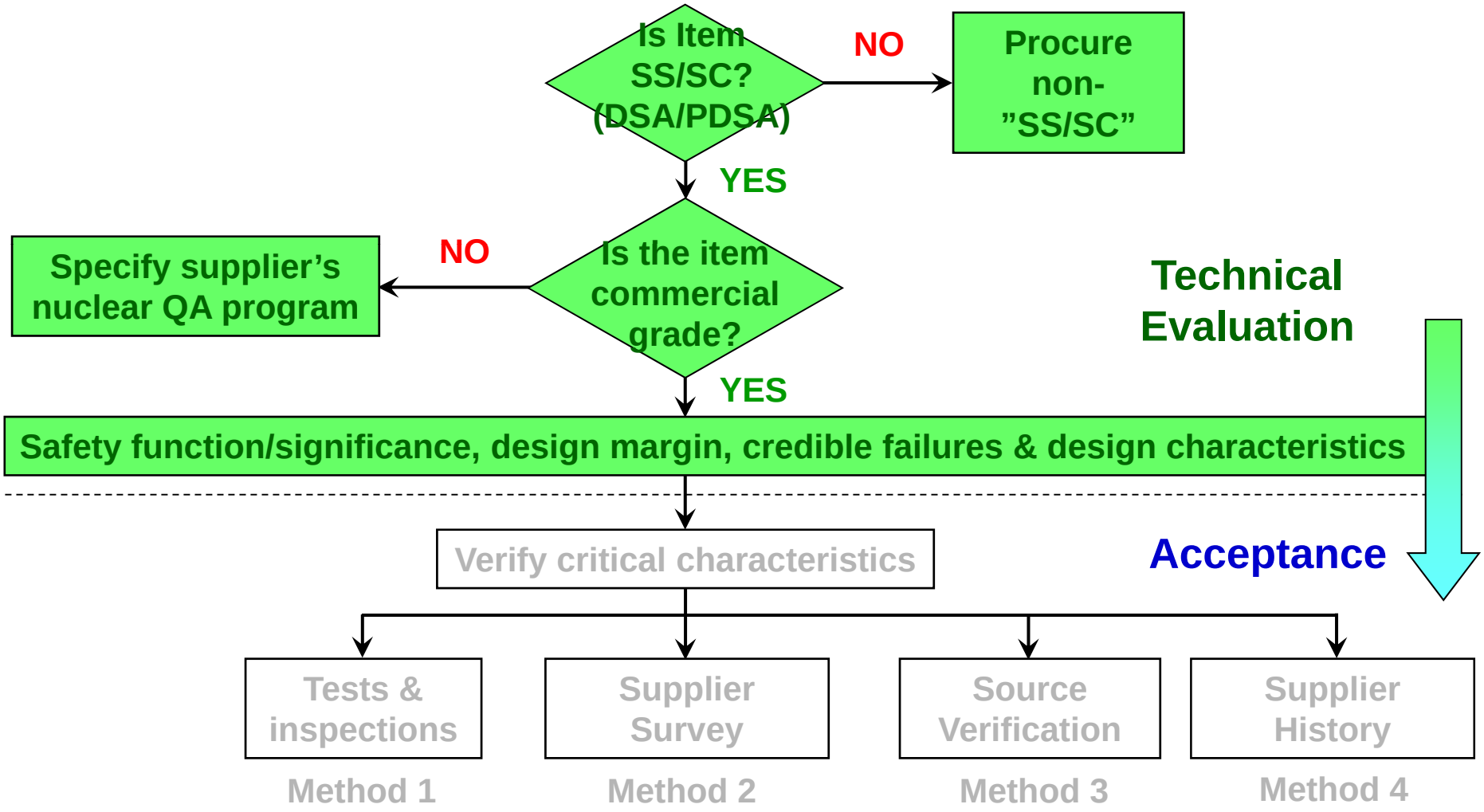
U.S. DEPARTMENT OF ENERGY

Office of River Protection

Enabling Objectives

- Describe the purpose of the technical evaluation
- Describe the steps in performing the Technical Evaluation
- Describe the thought process for determining critical characteristics of design for items and services

Overview of the Technical Evaluation



Purpose of the Technical Evaluation

- Enable the item to be *specified correctly in a procurement document and to establish acceptance requirements*
- For this to happen, the following is required:
  - Identification of the item being procured
  - Knowledge of end-use application(s) including the most severe location of the item or the item impacted by the service
  - Safety function of the item
  - Procurement category (quality level)

Safety Function and Safety Classification

- The need for CGI dedication is not solely a result of safety designation, but also may be a result of OCRWM waste affecting items designation and Air Permit functions that are part of an emission unit that meets the requirements of Stated Codes.
- Safety function of item determined during hazard and accident analysis during the development of the safety basis.
- Safety function assigned by the approved safety basis based on DOE-mandated requirements and guidelines to prevent/mitigate release of radiological/chemical materials.

Safety Function and Safety Classification (cont.)

- Output of the development of the safety basis is a set of Safety Class and Safety Significant structures, systems, and components designed to protect the facility workers and public from excess radiation and chemical hazard doses.
- Engineering evaluates CGI dedication services to determine if the service could adversely affect the safety function of an item

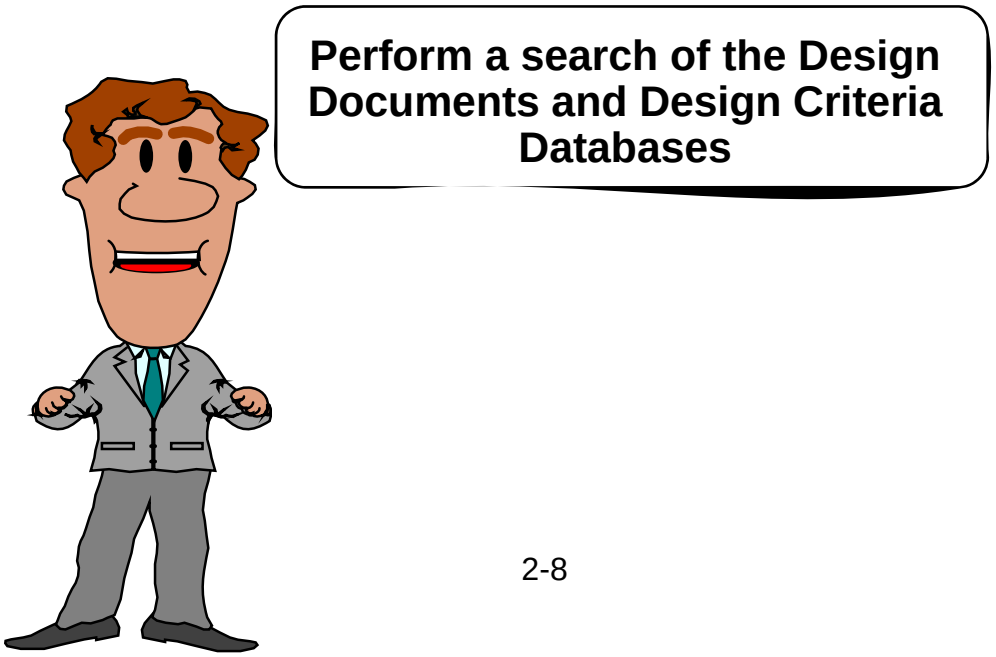
Critical Characteristics

- ASME NQA-1-2004, Part 1, Section 400, defines a critical characteristic as,
  - "important design, material, and performance characteristics of a commercial grade item or service that, once verified, will provide reasonable assurance that the item or service will perform its intended safety function"

Recommended Process for Identifying Safety Function and Determining Critical Characteristics

Thought Process

Research design documents and databases to determine system and component level safety function. Part level function must be deduced from this information



Typical Mechanical Functions

- Maintain pressure integrity
- To open
- To remain open
- To close/isolate
- To actuate/modulate flow

Typical Electrical Functions

- Electrical isolation
- Provide signal or power

Recommended Process for Identifying Safety Functions and Determining Critical Characteristics

Thought Process

What are the safety function(s) of the item/service?

↓

What are the facility design function(s) (including known safety functions and seismic/environmental conditions) of the item/service?

This information should be obtained from the appropriate design documents!

Recommended Process for Identifying Safety Functions and Determining Critical Characteristics

Thought Process

What are the safety function(s) of the item/service?

↓

What are the facility design function(s) (including known safety functions and seismic/environmental conditions) of the item/service?

↓

What are the postulated, credible failure mechanisms of the item/service?

Credible Failure Mechanisms

- Once the safety functions are determined, the selection of critical characteristics begins with the understanding that failure of some important design features of an item may not be credible, and therefore do not need to be verified. The below listed features should be considered in mechanical and electrical applications.
  - Fracture
  - Corrosion
  - Erosion
  - Loss of properties
  - Excess strain
  - Mechanical creep
  - Ductile fracture
- The basis for determining that specific failure mechanisms are not credible should be documented

Potential Failures in the Performance of Services

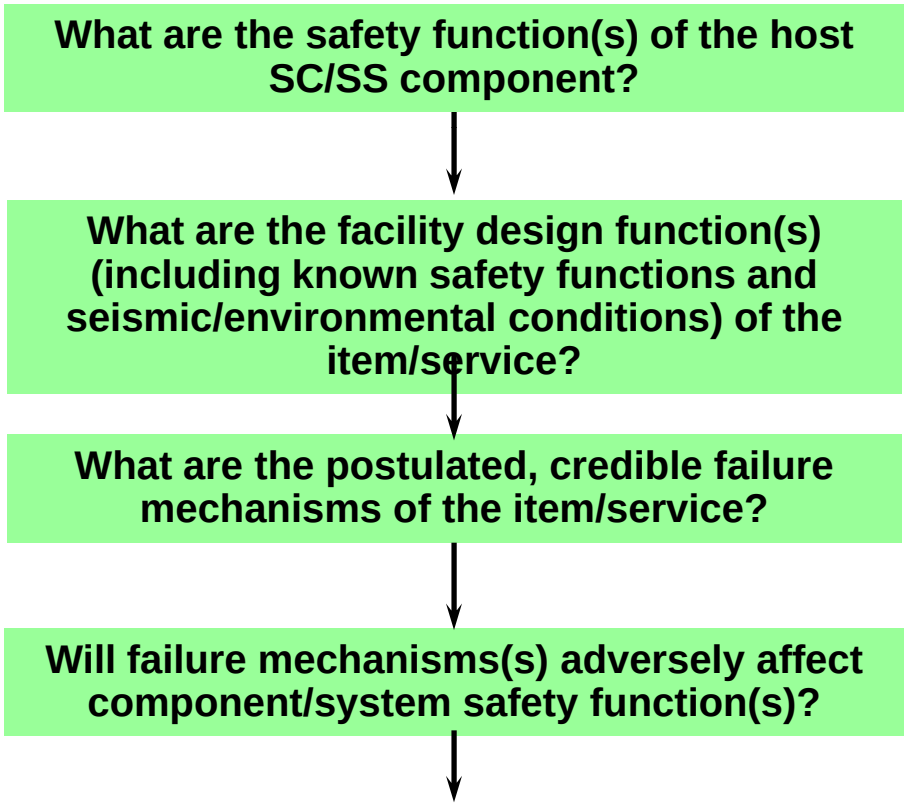
- Repair Services – use of unacceptable parts, improper welding or soldering, improper assembly, component requirements not met after repair
- Testing – use of uncalibrated equipment, technical inadequacies in performing the test, improper specimen preparation, improper calculation of test results
- Fabrication/Machining/Cleaning/Unique Manufacturing Processes – failure to meet dimensional requirements, material contamination, special process controls
- Training – errors in instructional materials used
- Engineering/Technical Services – calculation errors, unconfirmed assumptions, unconfirmed/unverified computer codes to perform analyses/calculations
- Calibration – equipment out of calibration causing failure to accurately measure or actuate at the proper time, incorrect equipment calibration

Postulating Failures

- Consider single-failure analysis
  - Redundancy in design should not be considered as a means to mitigate a failure
- Postulate failures based upon the safety functions of the host component, considering normal and accident design bases.
- Do ***not*** consider the following as credible failures of an item:
  - Normal wear-out (over a long period of time)
  - Failure due to improper maintenance
  - Failure due to improper installation
  - Failure caused by failure of adjacent items

Recommended Process for Identifying Safety Function and Determining Critical Characteristics

Thought Process



Recommended Process for Determining Design Characteristics

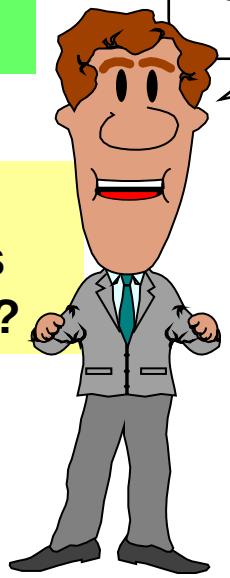
What are the safety function(s) of the item system/component?

What are the facility design function(s) (including known safety functions and seismic/environmental conditions) of the item?

What are the postulated, credible failure mechanisms of the item?

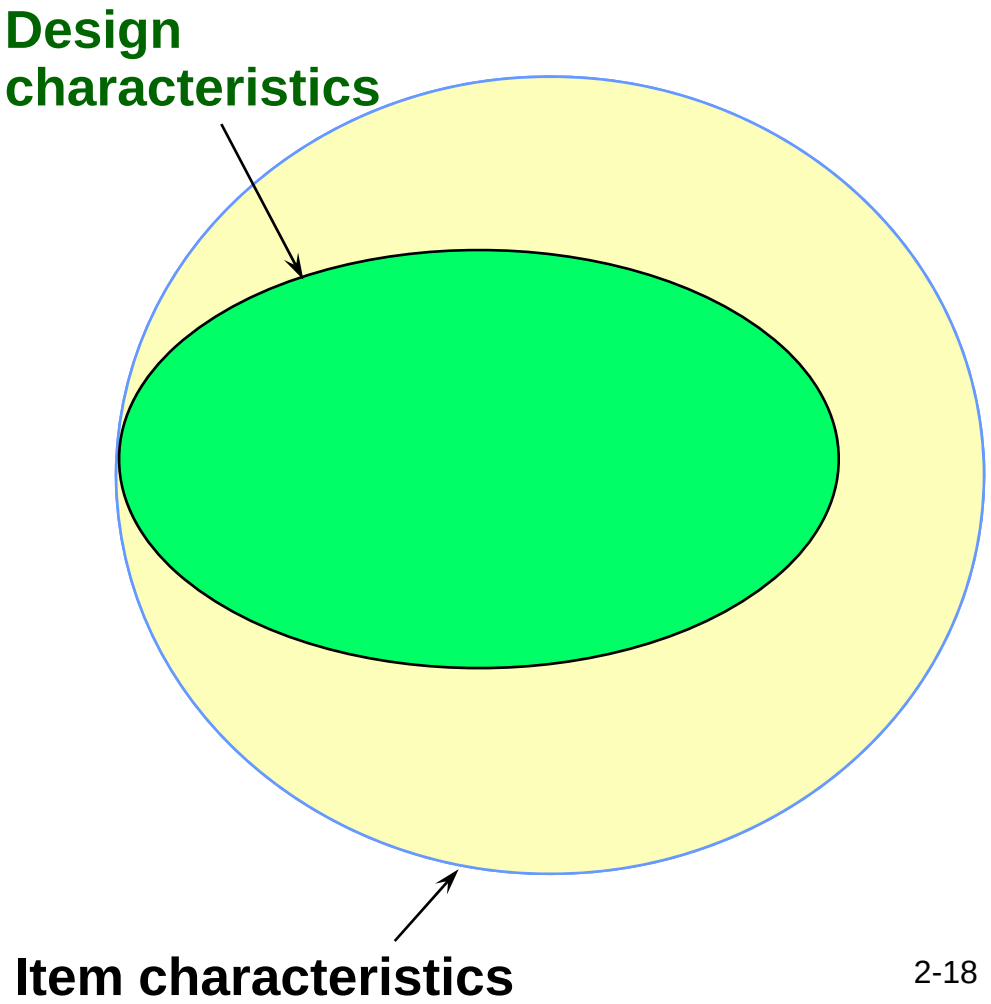
What identifiable and measurable attributes are essential for the item's form, fit, and functional performance?

Design Characteristics



In other words, what about the item enables it to perform design functions or prevents it from failing as postulated?

Design Characteristics



- Dependent on the facility-specific application
- Are a subset of the entire population of attributes describing an item
- Are based on the item's safety functions and operability requirements
- Include design, material and performance attributes of the item

DOE TRAINING

Commercial Grade Dedication Training

MODULE 3

Acceptance Planning

U.S. DEPARTMENT OF ENERGY

Office of River Protection

Enabling Objectives

- Describe the thought process for determining critical characteristics for items and services
- Understand the concept of “reasonable assurance” commensurate with the significance of the safety function
- Describe the different types of critical characteristics
- Describe the critical processes for acceptance of services
- Describe how to achieve reasonable assurance in the context of commercial grade item dedication

Enabling Objectives (continued)

- Describe the purpose of the acceptance methods
- Describe the process for implementing each of the acceptance methods
- Describe how performance history of the item and the supplier can affect the selection and implementation of the acceptance methods

Critical Characteristics of an Item or Service

- Critical Characteristics (CC) defined in NQA-1-2004
  - Important design, material, and performance characteristics of a commercial grade item or service that, once verified, will provide reasonable assurance that the item or service will perform its intended safety function.

Recommended Process for Determining Critical Characteristics

What are the safety function(s) of the host component?

↓

What are the facility-specific safety function(s) of the item?

↓

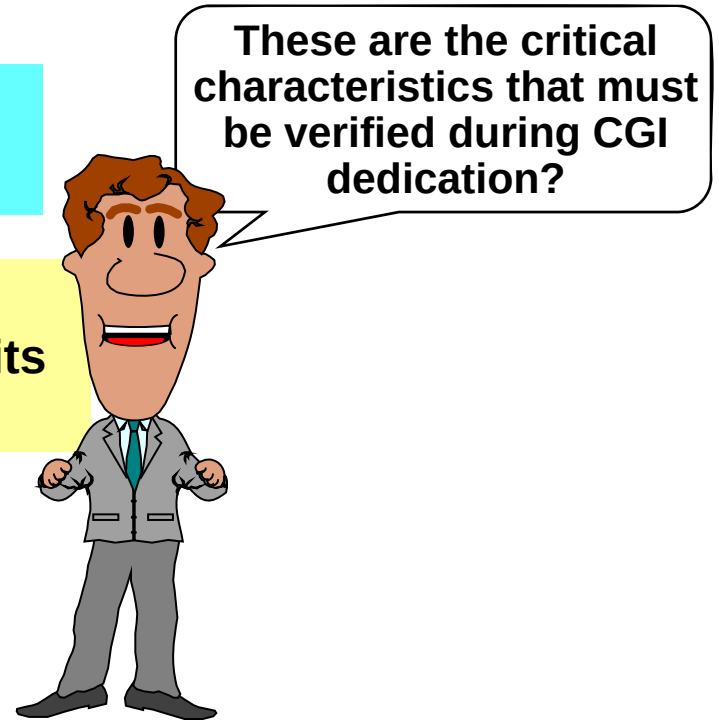
What are the postulated, credible failure mechanisms of the item that potentially affect the safety function?

↓

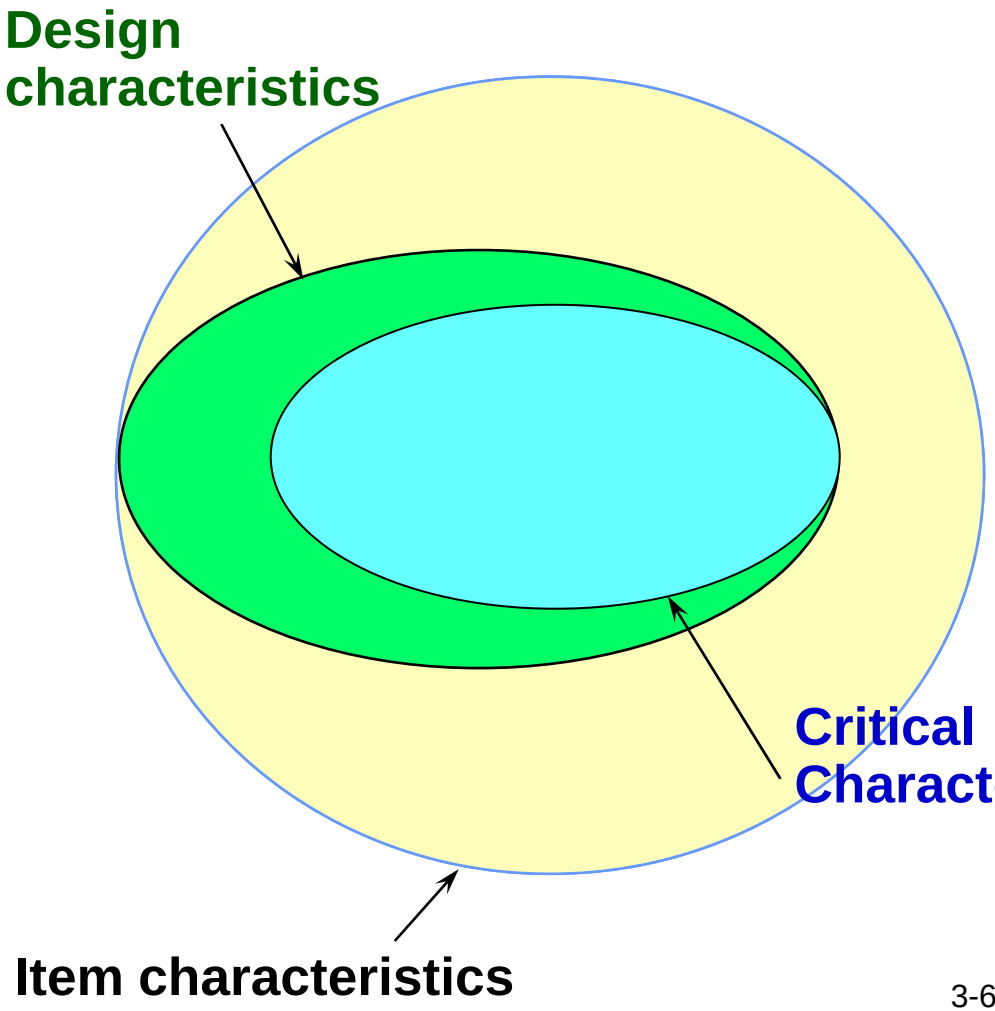
What identifiable and measurable attributes enable the item to perform its safety function(s)?

↓

Critical Characteristics



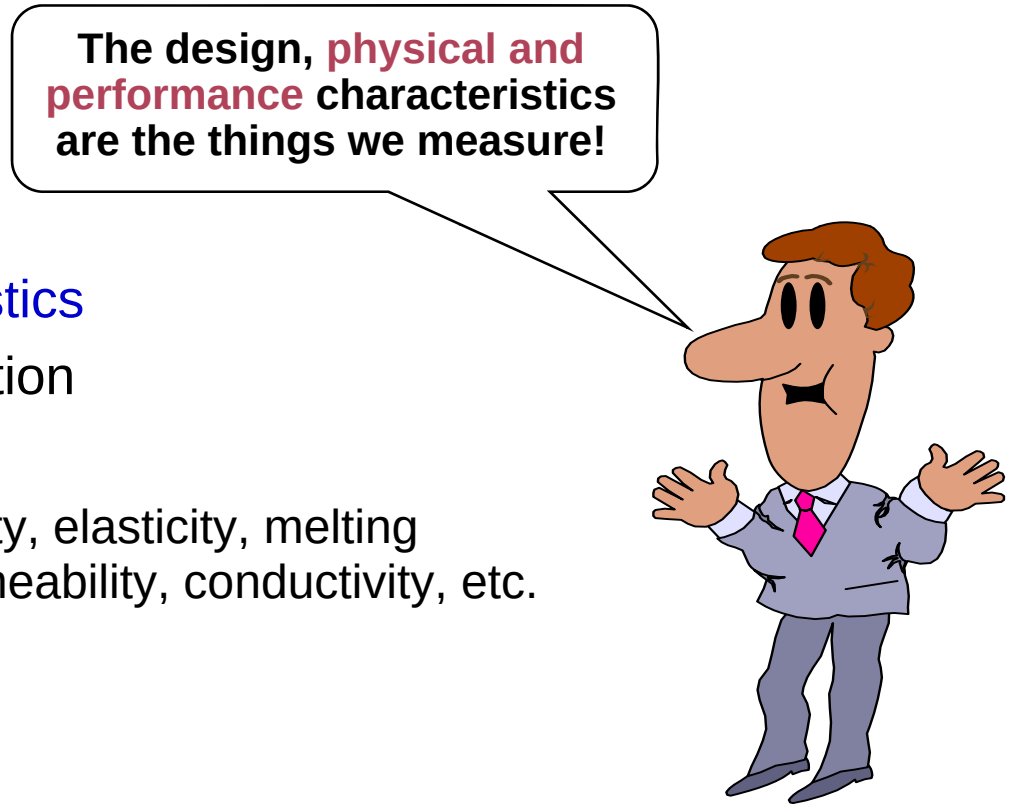
Critical Characteristics



- Are based on the item's *safety* functions
- Are design, material and performance attributes of the item
- Are measurable and verified

Representative Types of Critical Characteristics

- *Design (Configuration)* Characteristics
  - Dimensions
  - Electrical resistance
  - Durometer hardness
  - Part number if assigned
- *Material (Physical)* Characteristics
  - Material chemical composition
  - Material properties
    - Strength, hardness, ductility, elasticity, melting temperature, density, permeability, conductivity, etc.
- *Performance* Characteristics
  - Pick-up/drop-out voltage
  - Open/close time
  - Input/output voltage



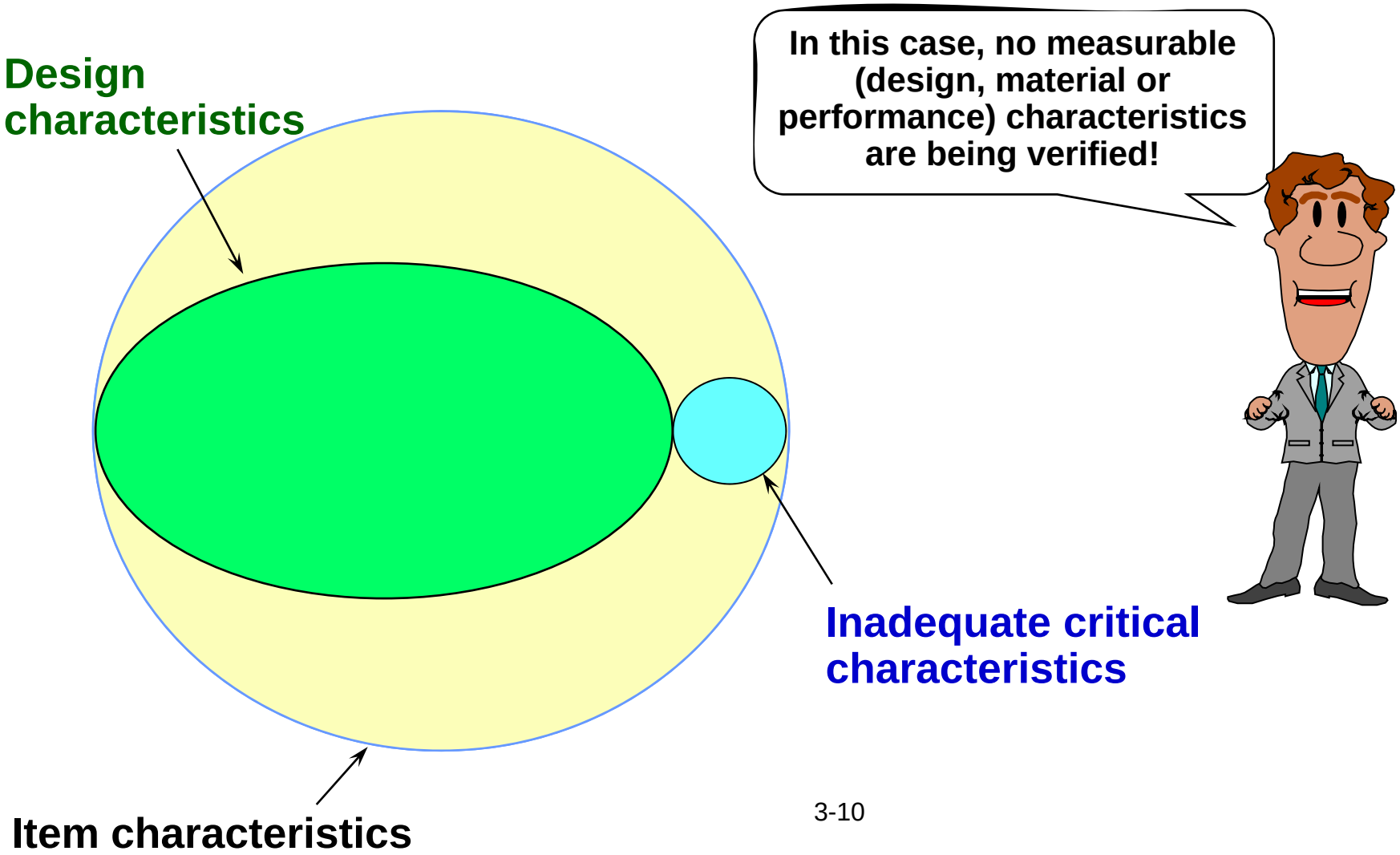
Representative Types of Critical Characteristics, Cont.

- *Dependability Characteristics – Digital Equipment and Software*
  - Typically cannot be verified by inspection and testing alone
  - Are generally affected by the process used to produce the device.
  - Includes reliability, safety, availability, maintainability, and built-in quality

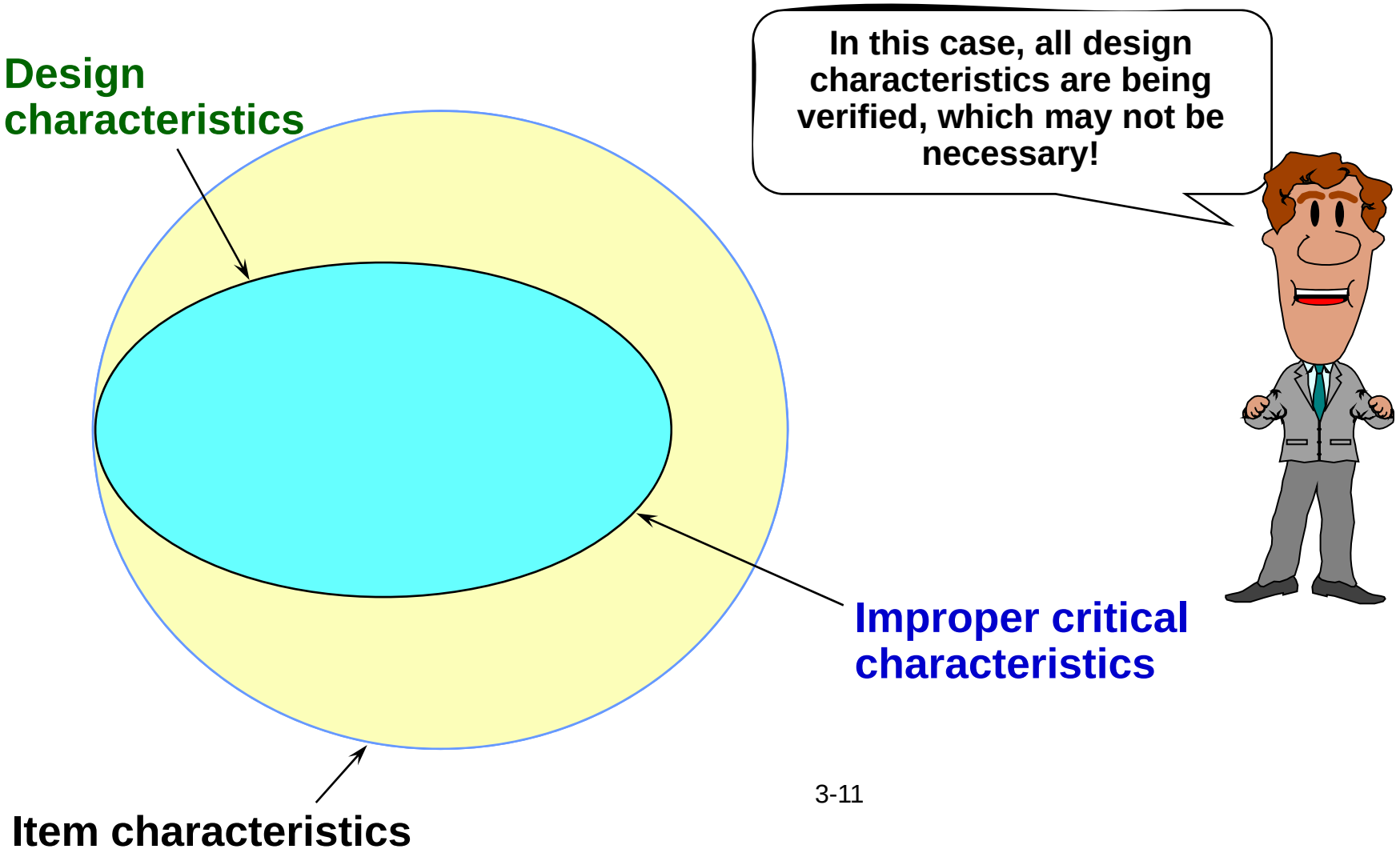
Understanding What Does Not Constitute a Critical Characteristic

- Form, fit and function
- Seismic
- Certificate of conformance
- Hydrostatic test
- Receipt inspection
- Lot homogeneity
- Commercial grade survey
- Maintenance instruction
- Environmental test report
- Vendor manual

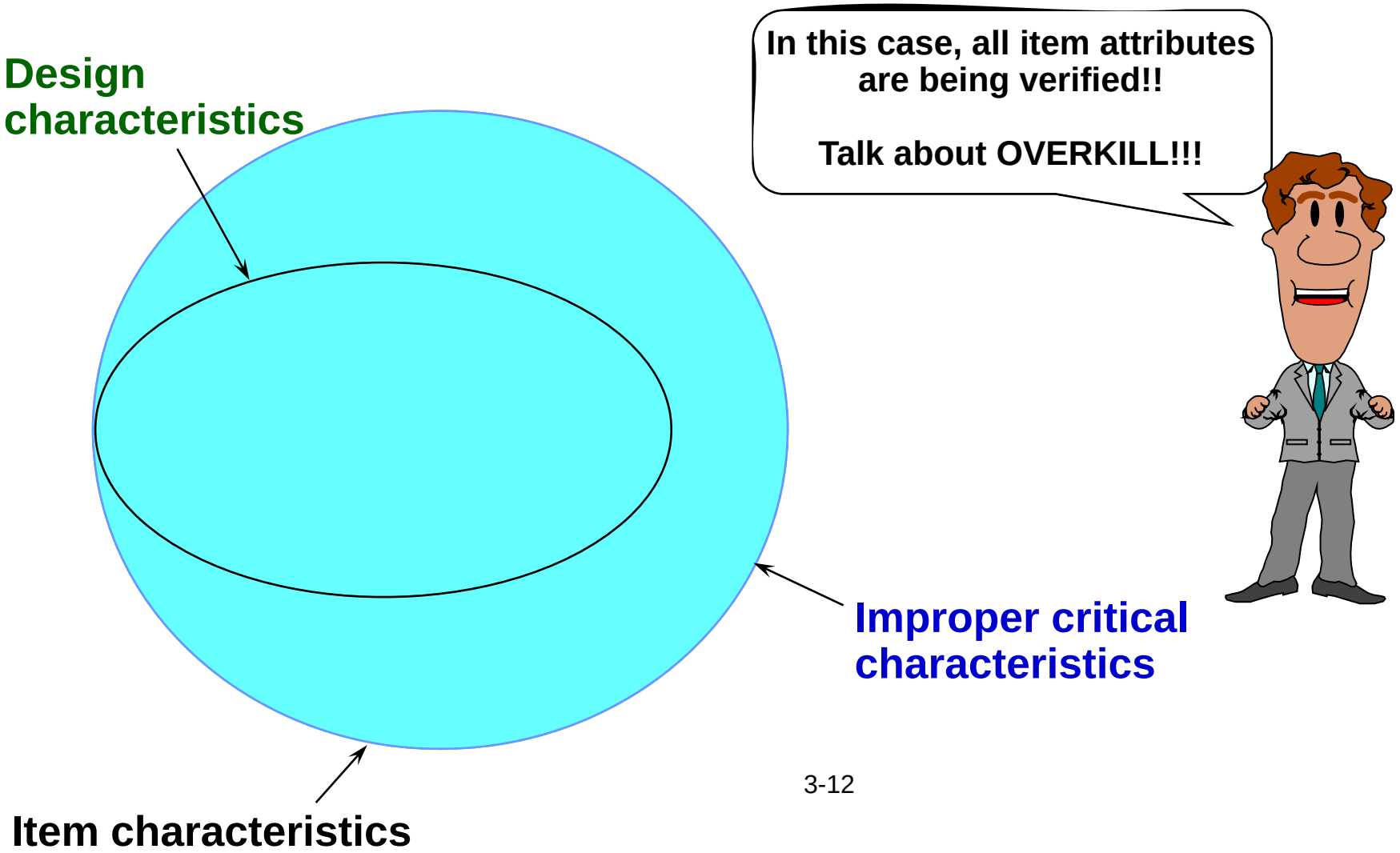
Inadequate Selection of Critical Characteristics



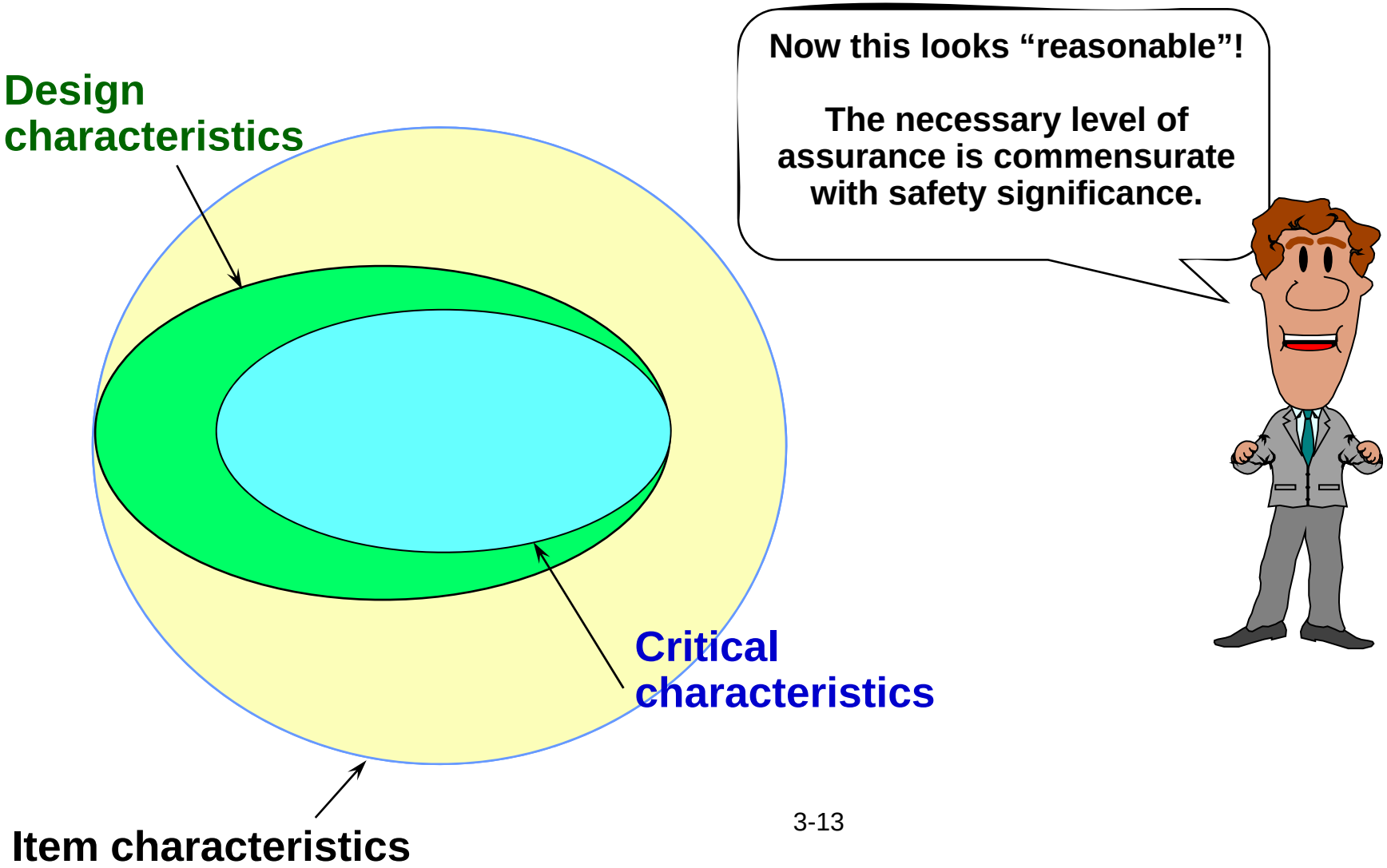
Inadequate Selection of Critical Characteristics



Inadequate Selection of Critical Characteristics



Critical Characteristics



Critical Characteristics for Services

- Process for CGD evaluation for services similar to that for items
- Selection considerations for CC for services are:
  - Identify measurable attributes of the impacted item that are affected by the service AND are critical to the item to perform its safety function
  - Identify in-process controls that are critical for the item impacted by the service to perform its safety function
  - Select a set of CC, that once verified, provide reasonable assurance that the service was performed properly, and the items impacted by the service perform their intended safety functions

Note: Another option is the performance of the service under the dedicating entity's quality program

Critical Characteristics for Design Services

- Those process controls that must be applied to ensure that the design of the item, once translated into the delivered items through manufacturing processes, will meet the requirements of the safety application in which it is to be used
- Items to be verified include:
  - Control of design inputs
  - Control of methods of analysis and design
  - Control of development, review and approval of design outputs
  - Design verification and integrated system design review

Critical Characteristics for Digital Equipment and Software

- Detailed information in EPRI TR-106439, *Guideline on Evaluation and Acceptance of Commercial Grade Digital Equipment for Nuclear Safety Applications. (Oct 1996)*
- Documented operating history of the equipment can be an important factor in providing confidence in the product
- Experience may be gained through applications in industries other than nuclear power
- Experience must be shown to be relevant to the planned nuclear applications
- Additional activities such as testing will be required by the dedicator to reach an adequate level of assurance
- Additional reviews, analysis, and documentation may also be required

Reasonable Assurance

- EPRI TR-102260, *Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial Grade Items, defines reasonable assurance as;*
  - A justifiable level of confidence based on objective and measurable facts, actions, or observations which infer adequacy.

- NQA-1-2004 states,
  - The dedication activities are intended to provide reasonable assurance that the item or service will perform its intended safety function.

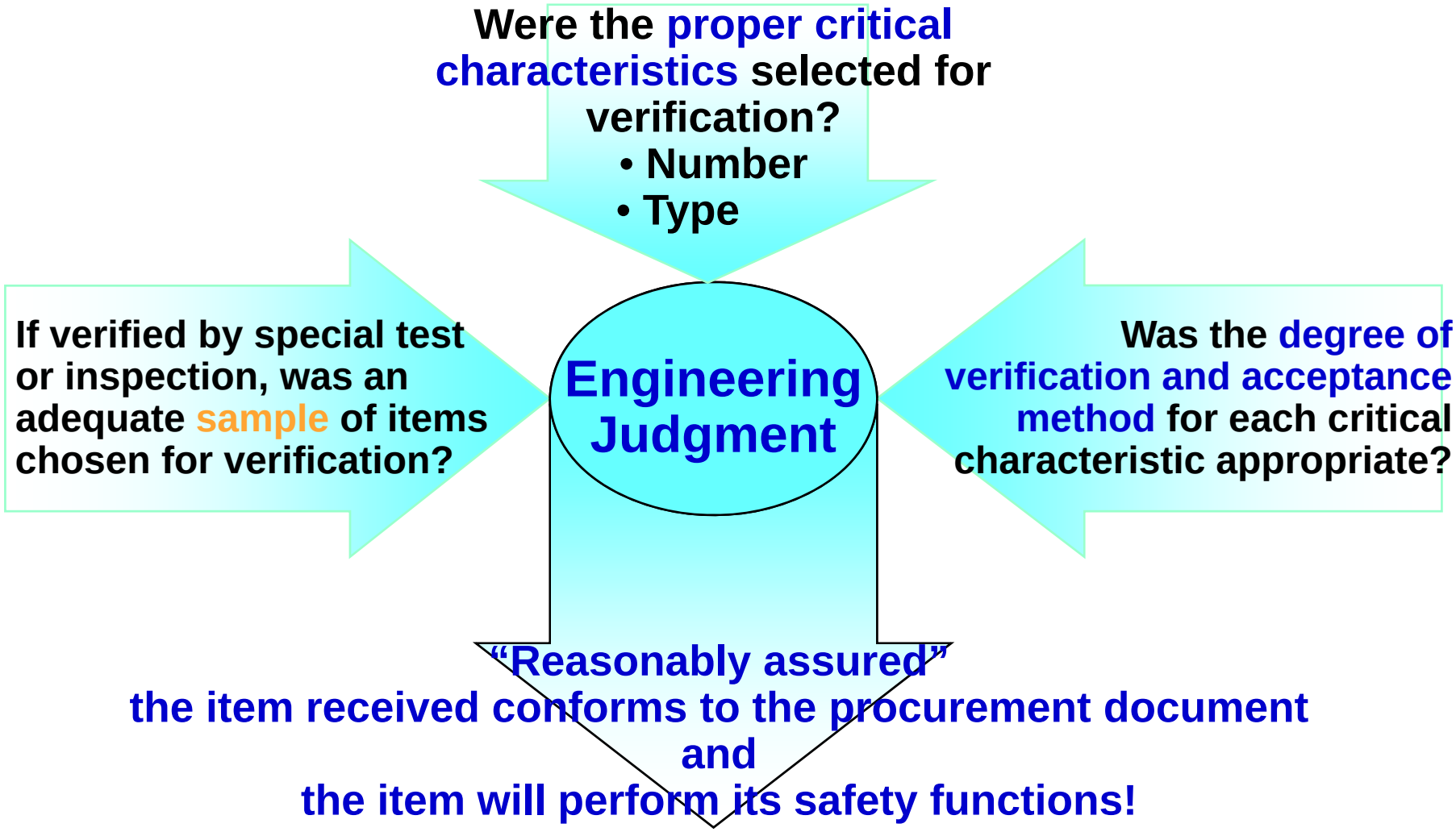
Selection of Critical Characteristics

- CGI's intended for installation in seismically or environmentally qualified applications, require CCs necessary to assure that the original qualification of the parent component is maintained.
- CGI's intended for generic safety-related applications instead of specific applications should be selected based on the most severe conditions encountered unless controls for item use are in place.

Methods for Acceptance

- Engineering selects the acceptance method
- Four methods used to accept commercial grade items/services are:
  - Method 1 – Special Tests, Inspections, or Analysis
  - Method 2 – Commercial Grade Survey of Supplier
  - Method 3 – Source Verification
  - Method 4 – History of Performance
- Methods provide individually or in combination a means to reasonably assure:
  - Commercial grade item received meets specified requirements
  - Services provided are services ordered and the safety items affected by the service will perform their safety functions

Achieving Reasonable Assurance in the Context of CGI Dedication



Key Elements of Critical Characteristics For Acceptance

1) A listing of the selected critical characteristics
2) Which method will be used to verify each critical characteristic

- The method(s) chosen:
  - Should be the most cost-effective means for verifying the selected critical characteristics
  - Determine when and how the critical characteristics will be verified
  - Determine what organizations will be involved in the dedication

Acceptance Methods

- Think of the acceptance methods as four different ways to establish CCFA for the selected critical characteristics
- The acceptance methods can be used individually or in combination
- They can vary from one item to another based on a number of factors:
  - Purchase price of the item
  - Lead times and plant schedule demands
  - Supplier capabilities and quality controls
  - Owner accessibility to item design information
  - Testing/inspection costs
  - Lot size

Acceptance Method 1 (Special Tests & Inspections) Guidance on Utilization

- When the item is simple in design
- Commodity items
- When critical characteristics are able to be verified with tests/inspections
- Data may be available in existing documents such as specifications, drawings, instruction manuals, bills of material and catalogs.
- Multiple suppliers of the item
- Items purchased in small quantities or larger homogeneous lots where sampling can be applied
- Items on which post-installation tests can be conducted

Acceptance Method 2 (Supplier Documentation) Guidance on Utilization

- When the sub-supplier/manufacturer has implemented appropriate, documented quality controls over the critical characteristics (as verified by the commercial grade survey)
- When multiple items are being procured from the same supplier/manufacturing facility
- When those items are procured relatively frequently
- When critical characteristics are not easily verified with tests/inspections

Acceptance Method 3 (Source Verification) Guidance on Utilization

- When in-process verification of one or more critical characteristics is needed
- When non-conformances have been detected during prior receipt inspections
- When problems/deficiencies exist with the manufacturer's quality assurance program/procedures
- Owner schedule demands
- Single supplier of the item
- Item purchased infrequently

Commercial Grade Design Services – Method 3, Source Verification

- Used where CC's cannot be easily verified following completion of the design or manufacturing processes
- Used where supplier controls are insufficient for use of Method 2
- Personnel would observe key activities in the design process such as:
  - Verification of design inputs
  - Use of appropriate calculation methods
  - Performance of independent verification and design review activities

Acceptance Method 4 (Item/Supplier Performance Record) Guidance on Utilization

- Care should be applied to assure that the performance history data is relevant and valid
- Data should be quantifiable information or a summary of quantifiable information from reliable sources
- Conclusions drawn should be directly related to the safety functions
- Contributors of performance history to the overall assurance obtained for the item should be commensurate with the safety significant of the item or service
- Caution - Method 4 should normally be used with one of the other methods

Dedication of Commercial Grade Services

- CGD process can be applied to services such as:
  - Design services
  - Repair and testing services
  - Fabrication/Machining/Cleaning
  - Training
  - Calibration services
- CC for services:
  - Measurable attributes of the impacted item(s) affected by the service and critical for the item to perform its safety function
  - In-process controls of the service critical for the item(s) impacted by the service to perform its safety function

Commercial Grade Services, cont.

- Once verified, provide reasonable assurance that the service was performed properly and items impacted by the service perform their safety functions

DOE TRAINING

Commercial Grade Dedication Training

MODULE 4

Dedication Methods and Support Documentation

U.S. DEPARTMENT OF ENERGY

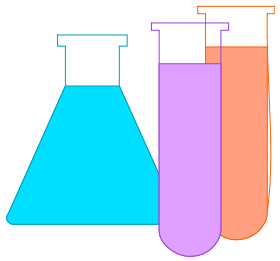
Office of River Protection

Enabling Objectives

- Describe the key elements of the CGI dedication package
- Describe the purpose of acceptance methods 1-4
- Describe the process for implementing acceptance methods 1-4
- Describe documentation associated with implementing acceptance methods 1-4

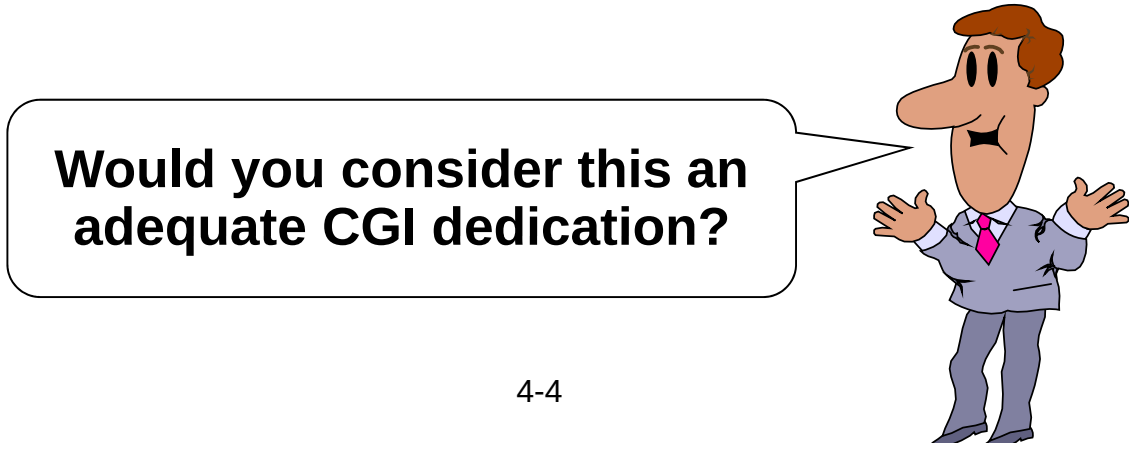
Purpose and Implementation of Acceptance Method 1 (Special Tests & Inspections)

- Purpose
  - To dedicate a CGI for safety-related use by verifying one or more critical characteristics after receipt
- Special tests/inspections can occur:
  - During receipt of raw material or a manufactured item
  - During and after fabrication of individual piece-parts
  - During and after assembly of the final product
  - Post installation testing (PIT)
- Sampling is permitted when testing/inspecting a batch/lot of items



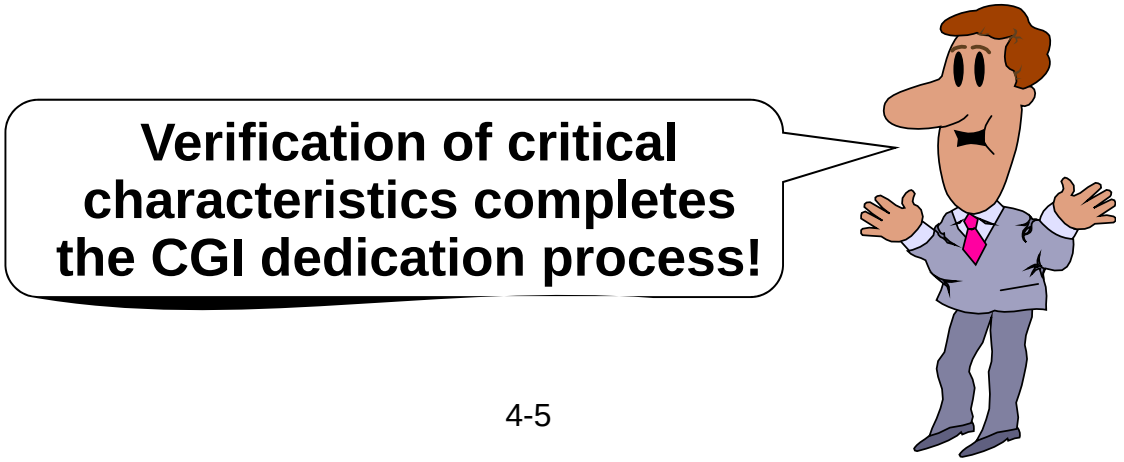
Standard Receipt Inspection vs. Special Tests & Inspections

- ANSI/ASME NQA-1 describes the standard receiving inspection as checking the following:
  - Quantity received
  - Damage
  - General condition of items
  - Part number
- Often referred to as a “kick-and-count” inspection



Standard Receipt Inspection vs. Special Tests & Inspections

- Special Tests and Inspections are one method for verifying selected critical characteristics
- These go beyond the standard receiving inspection activities
- The tests/inspections verify the critical characteristics are conforming to the manufacturer's design



Critical Characteristics and Acceptance Criteria

Critical characteristic	Acceptance criteria
Material	ASTM A276 % Chem Composition
Hardness	Rockwell 70, C scale
Length	1.25” ,+ or - .01”
Durometer	75, + or - 5
Open time	25 sec, + or - 1 sec

- Acceptance Criteria are generally contained in *Engineering Documents* held by the organization responsible for the design of the item. This may be the prime contractor’s engineering organization, or a supplier engineering organization, dependent on the item

Items Not Meeting Acceptance Criteria

- All values tested or inspected must fall within the tolerance range specified in the acceptance criteria
- If the acceptance criteria is NOT met, the item is documented as nonconforming
- Other like items should be evaluated to determine if they would exhibit the same failure (i.e., extent of condition)

Sample Size Considerations

- When sampling is required as part of the acceptance process, a key consideration is how much sampling is appropriate
- Sampling size is dependent on lot homogeneity.
  - High confidence the lot is homogeneous should result in small sample size to provide additional assurance
  - Low confidence the lot is homogeneous should result in a larger sample size to provide the additional assurance.
- Sample selection should be in accordance with a dedicating activity's implementing procedure or recognized standard.
- The logic on how the sampling size was determined needs to be documented since sampling decisions can very from procurement to procurement.

Purpose and Implementation of Supplier Survey (Method 2)

- Purpose
  - To dedicate a CGI or CGS or approval of a suppliers quality program
- Use:
  - MUST be validated through prior implementation of a commercial grade survey/audit
  - MUST verify that the supplier adequately controlled the CC necessary for the dedication
  - Certificates of Conformance
    - Documents surveyed controls applied

Practical Methodology

- Determine if a commercial grade survey has been conducted for the sub-supplier/manufacturer
- If YES, consider the following:
  - Is the survey information current?
  - Was it conducted at the location where the CGI being procured was manufactured?
  - Does it confirm adequate supplier controls over the critical characteristics for acceptance?
  - Are the sub-supplier controls documented so they can be specified in the purchase order?

Practical Methodology

- Determine if a commercial grade survey has been conducted for the sub-supplier/manufacturer
- If NO, consider the following:
  - Is it cost effective to conduct a survey at this time?
  - Would other acceptance methods be more cost effective?
    - Source verification
    - Special tests/inspections

Conducting the Commercial Grade Survey

- Should be “performance-based” (not compliance-based)
- Organizations performing surveys should develop criteria for the personnel and processes used to perform surveys
- The survey should be specific to the scope of the particular commercial grade item or service being procured
- The survey criteria and the Supplier’s documented processes and controls, which should be determined by the dedicating entity, may vary from the item or service and depend on the number and type of critical characteristics to be verified.

Performance-based vs.. Compliance-based

Performance-based approach	Compliance-based approach
What equipment is furnished?	-
What are equipment safety functions?	-
What are the CC?	-
-	What QA program is the supplier committed to?
How are CC controlled?	How is it implemented?
Are controls adequate and documented?	Do they comply?
Are they doing what they committed to do ***and*** are they doing the right things?	Are they doing what they committed to do?
Vendor qualification is “based on performance” and can be graded.	Go or no-go

Preparing for the Commercial Grade Survey

- Determine the scope of commercial grade items to be surveyed
- Provide critical characteristics and/or critical processes (e.g., test control) for each item within the scope of the survey
- Select the survey team (preferably including an engineer technically responsible for procurement)
- Coordinate with the supplier and review quality assurance program documents and procedures including supplier controls for preparation, approval and issuance of Certificate of Conformance

Examining Appropriate Quality Controls

Design Control
Do the supplier's controls assure an identical or equivalent item will be provided?

Material Controls
Is the item controlled from receipt through shipment to assure the correct item is being shipped?

Procurement Control
How are items specified to sub-suppliers?
How are procured items verified as being conforming to design?

Inspection/Test Control Are the inspections and tests controlled and conducted by capable people?

Nonconformance
Are non-conforming materials controlled and properly dispositioned?

Calibration
Is measuring and test equipment controlled in accordance with some program?

Special Processes
How effectively are critical characteristics controlled/imparted during manufacturing?

Certificate of Conformance
Is preparation, approval, and issuance of C of C's properly controlled by procedure?

Addressing Inadequate Supplier Controls

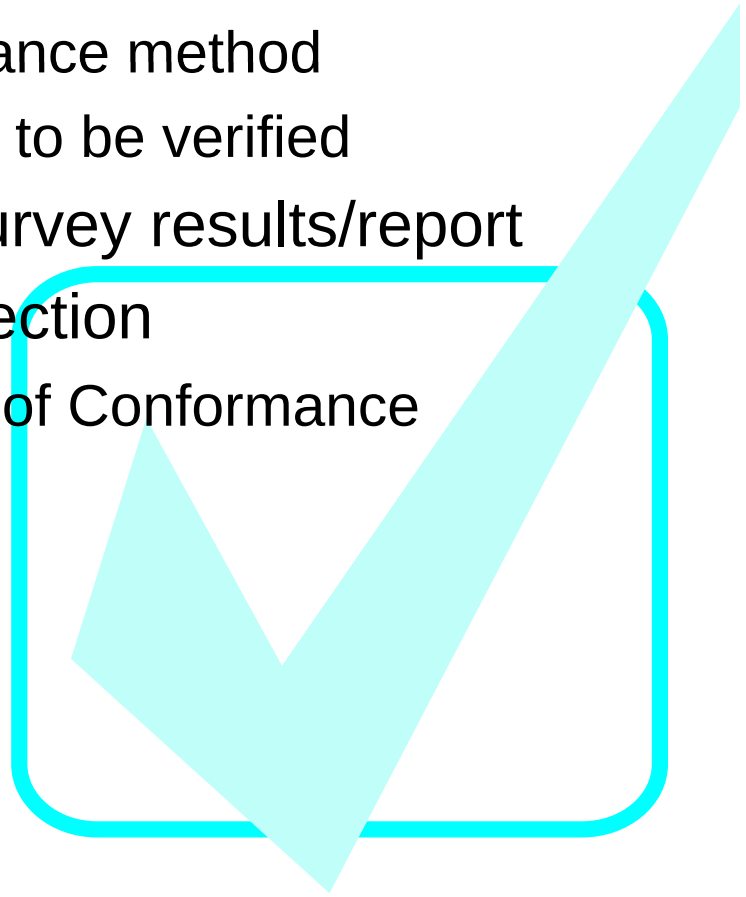
- Determine nature of the inadequacy
  - The supplier is not conforming to current procedures
  - The sub-supplier does not feel the critical characteristic needs to be verified
  - The sub-supplier verifies the critical characteristic, but does not document the verification adequately
- Determine if the sub-supplier is willing/able to enhance the controls to meet customer expectations

Commercial Grade Survey Procurement Clause Examples

- "This order shall be processed in accordance with Superior Pumps Inc. Quality Assurance Manual dated 10/17/05. Any revisions to this manual shall be forwarded to the purchaser for review."
- "This order shall be processed in accordance with the following company procedures:
  - Heat treat procedure 101-63B, Rev. 2
  - Product testing procedure101-77C, Rev 0."
- "Dimensions of valve stem, Part No. XYZ123, shall be controlled in accordance with Erie Valve Inc. Machining & In-process Testing Procedure A754, Rev. 1."

Documentation Associated with Survey

- CGI technical evaluation and dedication plan
  - Identifies the acceptance method
  - Identifies the CCFAs to be verified
- Commercial Grade Survey results/report
- Standard receipt inspection
  - Supplier Certificates of Conformance

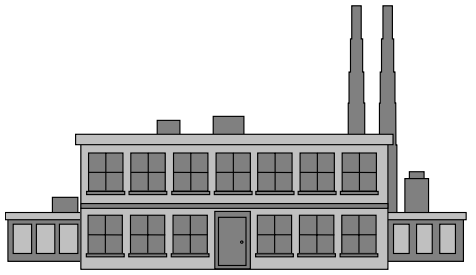


Summary of Acceptance Method 2

- Reliance is placed on the sub-supplier/manufacturer to verify critical characteristics
- The commercial grade survey validates that the supplier has the appropriate quality controls and they are being implemented satisfactorily
- The commercial grade survey results must be documented for use by engineering
- Engineering must specify the appropriate quality controls on each subsequent order
- Evidence that the controls were implemented each time is via supplier documentation (i.e., certificates of conformance)
- Subject to recertification

Purpose and Implementation of Source Verification (Method 3)

- Purpose
  - To accept a CGI by witnessing at the manufacturer's facility that the supplier controls the critical characteristics Source verification is applicable only to the items being purchased
- The purchaser may witness tests or inspections, or may evaluate quality processes as they apply to the critical characteristics of the items being procured



Preparing for the Source Verification

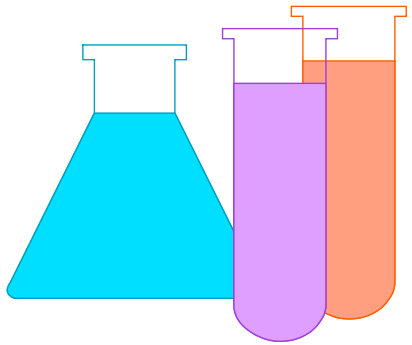
- The scope of commercial grade items is defined in the purchase order which includes supporting technical documents
- Provide critical characteristics for each item being procured
- Select the source verifier
- Coordinate with the manufacturer and review quality assurance program documents and procedures, if applicable
- Ensure right(s) of access are specified in the purchase document prior to issue
- Conduct an entrance meeting

Conducting the Source Verification

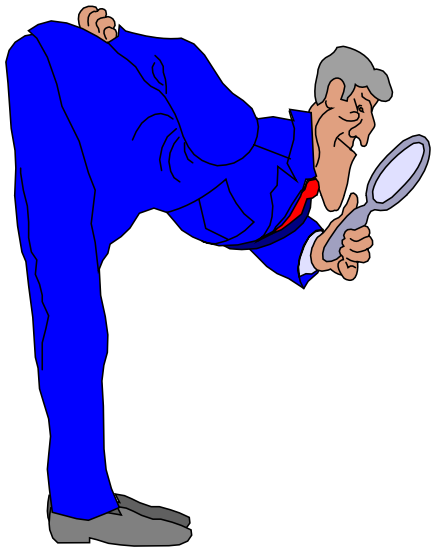
- Source verification personnel are provided the critical characteristics. The source verifier may be an auditor, inspector, or engineer
- The purchaser may witness tests or inspections or may evaluate processes as they apply to the critical characteristics of the items being procured
- The items are released for shipment if the item's critical characteristics are conforming.

Source Verification Activities – Witnessing a Test

- Material hardness
- Nondestructive examinations
- Tensile tests
- Hydrostatic tests
- Leak rate test
- Durometer hardness
- Material type (alloy analysis)
- Calibration
- Operability
- Electrical continuity
- Insulation resistance
- Pressurization



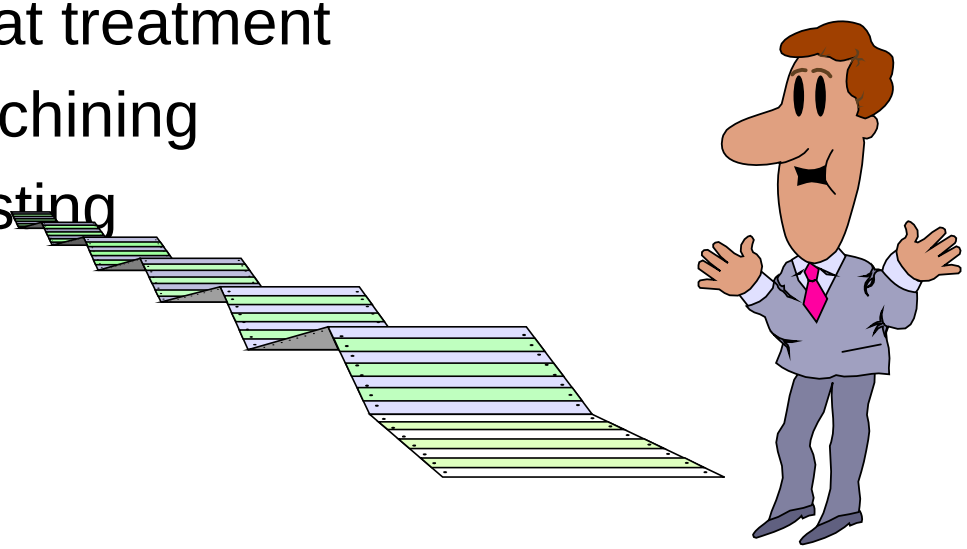
Source Verification Activities – Witnessing an Inspection



- Dimensional
- Configuration
- Coating thickness
- Weld
- Non-destructive examination

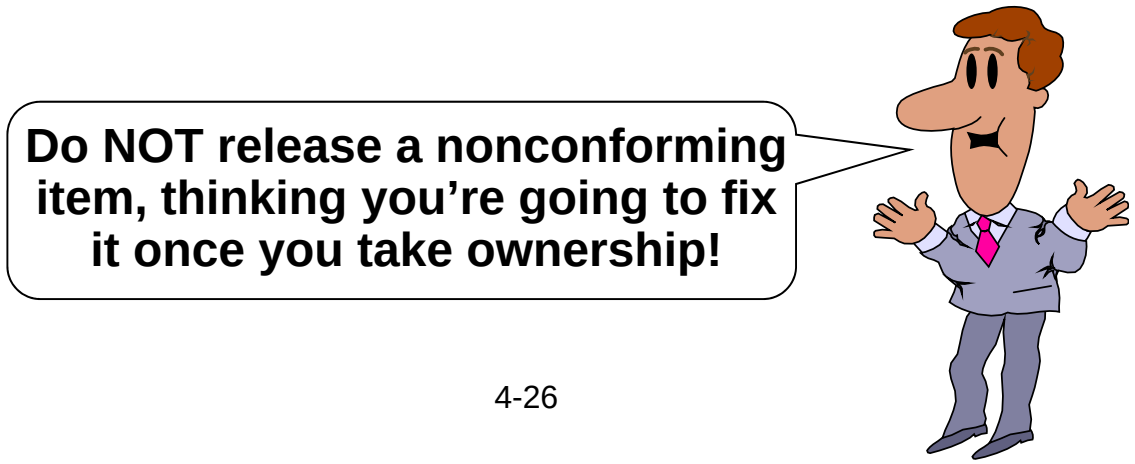
Source Verification Activities – Observing a Process

- Welding
- Assembly
- Insulating
- Coating
- Heat treatment
- Machining
- Testing



Addressing Inadequate Supplier Controls

- Determine nature of the inadequacy
  - The manufacturer is not conforming to current procedures
  - The manufacturer does not feel the critical characteristic needs to be verified
  - The manufacturer verifies the critical characteristic, but does not document the verification adequately
- Determine means by which the manufacturer can correct the non-conformance

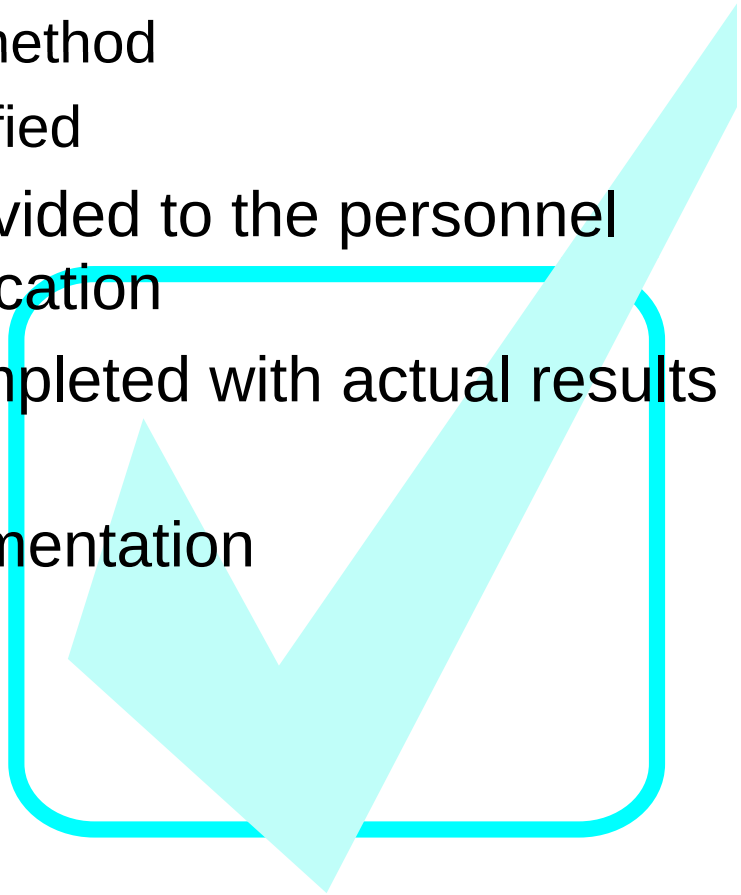


Activities Following the Source Verification

- Conduct an exit meeting
- Prepare and issue the quantified results of the source verification
- Review technical adequacy of the source verification results to ensure all critical characteristics have been properly verified

Documentation Associated with Source Inspection (Method 3)

- CGI technical evaluation and dedication plan
  - Identifies the acceptance method
  - Identifies the CC to be verified
- Source verification plan provided to the personnel conducting the source verification
- Source verification plan completed with actual results documented
- Release for shipment documentation
- Standard receipt inspection



Summary of Acceptance Method 3

- Reliance is placed on the supplier/manufacturer to verify critical characteristics
- The source verification validates that the manufacturer implements appropriate quality controls as the items being procured are manufactured
- Source verification is applicable only to the actual items being procured

Purpose and Implementation of Acceptable Supplier/Item Performance Record (Method 4)

- Allows the purchaser to accept commercial grade items based upon a confidence in the supplied item achieved through proven performance of the item.
- Allows purchaser to take credit for item performance based upon historical verification gained from the successful utilization of Methods 1, 2, and 3.
- Based on:
  - User Historical Performance
    - Results of Monitored Performance
    - Conducting Periodic Maintenance and Surveillance Tests
  - User Historical verification (Methods 1, 2, and 3)
  - Industry-Wide Performance – Must be specific and applicable to the item being accepted if it is to be used to establish and acceptable supplier/item performance record.

Purpose and Implementation of Acceptable Supplier/Item Performance Record, cont.

- Product/Performance Test Results
- INPO Nuclear Parts Reliability Data System
- Seismic Experience/Test Data Bases and Equipment Qualification Data Bank
- Commercial Program Audits/Surveys Conducted by Industry Groups
- Supplier Response(s) to Commercial Grade Program Controls questionnaire
- Utilization of National Codes and Standards

- To utilize Method 4, the purchaser should perform an evaluation of the supplier/item performance record which includes the following:
  - Supplier/item being evaluated.
  - Previously established critical characteristics specific to the item or supplier.

Purpose and Implementation of Acceptable Supplier/Item Performance Record, cont.

- Identification of utility/industry data examined to evaluate the supplier/item
- Basis for determining that industry data substantiates acceptability of the supplier/item
- Statement of the purchaser attesting to the acceptability of the supplier/item.

- If the performance record provides reasonable assurance that the critical characteristics have been met, Method 4 can be used.
- The supporting information should be periodically updated and reviewed to assure the supplier/item maintains an acceptable performance record.

Commercial Grade Item/Services Dedication Documentation

- Documentation of the commercial grade item or service dedication process should be traceable to the item, group of items, or services
- Documentation should include the following information depending on the applicable dedication method
  - Dedication plans or procedures including the essential elements of the dedication process
  - Commercial grade item or service procurement documents
  - Facility commercial grade dedication criteria
  - Technical evaluation of the safety function
  - Critical characteristic identification and acceptance criteria, including or referencing design documents and failure mode analysis

Commercial Grade Item/Services Dedication Documentation, cont.

- Test reports or results, inspection reports, analysis reports
- Commercial grade survey reports
- Source verification reports
- Historical performance information
- Dedication report containing sufficient data to accept the item or service

DOE TRAINING

Commercial Grade Dedication Training

MODULE 5

Supplier Dedication Oversight

U.S. DEPARTMENT OF ENERGY

Office of River Protection

Enabling Objectives

- Describe basic elements under which an NQA-1 supplier performs CGD for a Commercial Sub-Supplier
- Describe how an NQA-1 supplier should implement a CGI/CGS dedication program
- Describe appropriate activities to perform to review suppliers' dedication activities

Commercial Grade Dedication – Supplier Submittals

- Suppliers may be requested to submit procedures or dedication plans when the dedication program requires supplemental assistance or when the significance or complexity of the item warrants oversight
- Supplier submittals related to CGD to consider:
  - Commercial Grade Dedication (CGD) procedure
  - CGD test/inspection plan for items requiring dedication
  - Review supplier's dedication procedure to determine whether it addresses the technical evaluation and acceptance planning processes effectively
  - Verify that technical evaluation process includes either determining safety function or safety function information from the purchase order

Commercial Grade Dedication – Supplier Submittals (cont.)

- Verify that the technical evaluation associated with the safety function results in a logical selection of critical characteristics and acceptance activities commensurate with the significance of the item
- Verify that the supplier inspection, test, sub-supplier audit and source verification activities are prescribed in a concise manner and conducted and documented in a manner that captures the intended results
- Tests results for CGD related tests and inspections including material upgrades as identified by the CGD plan or applicable material specification

Review and Acceptance of Supplier Submitted CGD Procedures

- Submittal review must include an understanding of the scope of the CGID activity
- Scope of Supply Cases:
  - Case 1. Supplier performing CGD as Fabricator
  - Case 2. Supplier performing CGD as both Design and Fabrication and procuring and dedicating items from commercial suppliers

Case 1. NQA-1 Supplier Performing CGD as Fabricator – Scope and Submittals

- Responsible for fabrication and delivery of an item designed by a higher tier supplier
- Responsible for ensuring design requirements are met by the delivered item
- CC defined in drawings, specifications, and other design documents provided by designer
- Scope items: obtaining base metals, simple items (flanges, fittings, piping, weld materials, gaskets, seals)
- Focus on material properties, dimensions

Case 2. Supplier Performing CGD as Both Design and Fabrication Scope

- Procuring and dedicating items of greater complexity from commercial suppliers such as pumps, valves, or electrical and instrumentation equipment
- CGD process must include the development and documentation of design documentation from the analysis of safety functions, and then selects appropriate CC as the basis for item acceptance

Case 2. Supplier Performing CGD as both Design and Fabrication (cont.)

- Submittal reviewer reviews scope of supply to be met by supplier and evaluates supplier CGD procedures, work instructions, and forms considering the following:
  - Has supplier been approved to perform CGD Evaluations by Supplier Quality through supplier survey activities?
  - Does the supplier's scope of supply include provision for design services or for fabrication only?
  - Does the supplier's CGD process contain the correct level of detail for their sub-supplier's scope of supply?

Supplier CGD Plans and Test Results – Review Considerations

- Supplier CGD Plans
  - Basis for selection of CC, acceptance methods, acceptance criteria
  - Reasonable assurance that plan implementation will result in items ordered are received and they perform required functions
- Supplier Test Results
  - Tests properly document completion of acceptance activities and dedicated items meet acceptance criteria
  - Do tests results include post-receipt or post-installation test, inspection or analysis requirements that must be tracked to completion?

Expectations Regarding CGI Dedications by Suppliers

- Supplier must have an appreciation for:
  - The most severe end use application
  - Accident conditions under which the item must function
    - Seismic events
    - Other design basis events
  - The safety functions of the host equipment and the item
- Supplier must select and verify a set of critical characteristics that provides reasonable assurance that the item will perform its intended safety function

Expectations Regarding CGI Dedications by Suppliers

- Supplier has the same flexibility the purchaser has in selecting the optimum means of critical characteristic verification
  - Source inspections of sub-suppliers/manufacturers
  - Audits/surveys of sub-suppliers/manufacturers
  - Tests/inspections of the CGI
    - During receipt of raw material or a manufactured item
    - During and after fabrication of individual piece-parts
    - During and after assembly of the final product

DOE TRAINING

Commercial Grade Dedication Training

MODULE 6

Implementation and Lessons Learned

U.S. DEPARTMENT OF ENERGY

Office of River Protection

Enabling Objectives

- Describe basic elements under which a supplier performs CGD for a Commercial Sub-Supplier
- Describe how a supplier should implement a CGI/CGS dedication program including supplier submittals and their review
- Understand prime contractor expectations regarding:
  - Determination of plant applications
  - Critical characteristics selection
  - Optimization of acceptance methods

CGD Example: FASTENERS

Item – .5” X 1.0” UNC-2A heavy hex screw per ASTM A193 Grade B8M, Class 1

Application – items are stocked for use in plant wide applications

Safety function, service conditions and design margin - service loading that would rely upon the screw having the full mechanical properties for high temperature or high pressure service or other special purpose applications with corrosion resistance as stated in ASTM A193.

Safety significance – the bounding condition for the screw is being relied upon for severe service conditions including maintenance of pressure boundary and seismic qualification, therefore a high level of confidence in the item’s quality is necessary

Example: FASTENERS (cont)

Critical characteristics:

Dimensions:	diameter
	length
	threads
Chemical content:	Carbon
	Manganese
	Phosphorus
	Sulfur
	Silicon
	Chromium
	Nickel
	Molybdenum
Mechanical Properties:	Tensile strength
	Yield strength
	Elongation
	Reduction of Area
	Hardness

Example: FASTENERS (cont)

Acceptance Methods:

Dimensional testing in accordance with ASME B18.18.2M is performed

Chemical analysis and mechanical properties are verified per ASTM F593.

Basis:

This material is manufactured to ASTM A193. This standard has acceptance criteria established for the physical, chemical, configuration and dimensional characteristics required for the fasteners. The application scope such that confidence is needed that the acceptance criteria in the standards are met. The supplier program will maintain material heat traceability and manufacturing lot traceability. Every lot of material will be independently tested, giving a high level of confidence in the material properties. A commercial grade survey will be performed on the fastener manufacturer to evaluate the quality program for controlling forming and machining activities. An inspection will be performed at the supplier's facility on the first lot of items ready for shipment. Taken together, these activities provide a high level of confidence in the items supplied.

CGD Example: MANUAL GATE VALVE

Item – 1” gate valve per ASTM B16.34, handwheel, Class 600, socket weld ends, ASTM A105 material, Valvco model 0829.

Application – Service water system intertie line drain valve

Safety function, service conditions and design margin - The valve serves as service water system pressure boundary with disc closed during operation. The service water system provides cooling for plant Q components that perform critical functions. The service water system has 150% capacity with one of six pumps in reserve.

The valve will be closed when the system is in service and only opened during maintenance.

Service conditions are 85 psi at 88F for fresh lake water. The valve is rated at 1350 psi at 100F.

Safety significance – Maintenance of service water system boundary is important to plant equipment function. The significance of this valve is low considering:

available design margin of over 1000 psi

large system flow capacity margin

a failure mechanism considering the design margin of seat or stem leakage that would result in a small amount of service water loss

Example: MANUAL GATE VALVE (cont)

Critical characteristics:

Dimensions: socket weld end diameter and depth
body and bonnet wall thickness
body - bonnet fastener diameter, threads, length
disc thickness, diameter
seat diameter, width

Material: Body, disc and bonnet compliance with SA105
Fastener compliance with SA193/SA194

Assembly and Test Related Process Controls

- Work control
- Nondestructive examination control
- Test control
- Nondestructive examination control
- Document Control

Example: MANUAL GATE VALVE (cont)

Acceptance Methods:

A survey was performed to evaluate the suppliers quality program for the following:

Procurement control for acceptance of purchased forgings and fasteners

Work control for fabrication of valve parts from purchased material and assembly

Inspection and test control for dimensional control activities and hydrostatic and seat leakage tests per ASTM B16.34

Nondestructive examination control for qualification of personnel and compliance with ASTM standards for performance

Nonconformance control for segregation of defective items

Document control to assure use of the appropriate drawings and procedures

The supplier is required to provide certification with shipment of the valve that the valve was processed under their approved QA program.

Basis: This is a standard commodity valve manufactured to meet ASTM B16.34. It was selected by the system design engineer for this application considering the ratings in ASTM B16.34 in relation to the service conditions.

The commercial grade survey determined that the valve manufacturer placed appropriate controls on their supplier to assure that appropriate assurance of material quality was achieved for the pressure retaining items. ASTM B16.34 requires hydrostatic testing and seat leakage that are incorporated in the supplier's procedures that were evaluated during the program survey.

CGD Example: SERVICE

Service – Qualification testing for building exterior wall siding system

Application – Emergency diesel generator building

Safety function, service conditions and design margin – The Q function of the wall is to protect the diesel generator from the effects of wind and associated high speed debris impingement. The building must remain intact and protect the diesel generator from an 111 mph wind and a 15 pound piece of 2 x 4 lumber traveling at 50 MPH.

Safety significance – The building function is to protect the integrity of the diesel generator who's function is to provide backup power to plant cooling and off gas filtration systems, thus the building wall importance is high. The qualification test is critical to establishing the suitability of the design and will serve the basis upon which the following material and installation acceptance activities will be performed.

Example: SERVICE (cont)

Critical characteristics:

The supplier will be required to perform the qualification test in accordance with the methodology stated in industry standard FM 7882.

Acceptance Methods:

A source surveillance will be performed by the Design Engineer at the supplier's facility to:

- review the supplier's test procedure for compliance with FM 7882
- witness each step of the test to verify performance in accordance with the approved procedure
- verify that the equipment used for the test is calibrated
- verify that results are accurately captured

Basis:

Considering the criticality of the test, a high level of oversight of the supplier's activities was warranted. Each step was observed by the Design Engineer for compliance with his expectations in the contract.

CGD Example: SUPPLIER OVERSIGHT

Item – 5000cfm centrifugal fan assembly (without motor)

Application – Main fabrication facility exhaust system

Safety function, service conditions and design margin – The fan is required to maintain the main fabrication facility at .25 psi negative pressure after a design basis seismic event for 1000 hours at a maximum temperature of 97F and a minimum temperature of 69F. The fan housing is constructed from stainless steel for ease of decontamination. The seismic analysis of the fan determined that the fan has a design margin of over 50%. The supplier was provided with the system performance expectations and selected a fan model with a 30% capacity margin.

Safety significance – The function of the fan provides the motive energy for maintaining a negative pressure for prevention of radioactive gas release from the confined area. Failure of the fan may result in small leakage around seals but not widespread large contamination. Backup provisions exist to prevent significant personnel exposure in this event.

Critical characteristics:

Material: housing, blade, shaft, bearing and sleeve material

Example: SUPPLIER OVERSIGHT (cont)

- ***Acceptance Methods:***
  Each piece of stock material for the housing, blade, shaft, bearing and sleeve was tested to verify chemical and physical properties
- ***Basis:***
  The manufacturer purchases raw material for the fan commercial grade and dedicates it prior to machining, forming and assembling. Each piece is tested to verify specification compliance, thus providing a high level of confidence in the product quality.

Example: SUPPLIER OVERSIGHT (cont)

Dedication Program Oversight:

The customer performed a pre-award audit of the suppliers QA program including dedication activities. The technical specialist on the audit team reviewed the manufacturer's dedication procedure for technical evaluation and acceptance planning activities. It was verified that on other similar nuclear orders the supplier had performed suitability activities effectively, understand safety function development and critical characteristic selection, and had accurately performed the prescribed tests. Sample plans were based on technical understanding of the items performance as related to the characteristics selected. Nonconformance evaluation included consideration of other potentially affected items.

The supplier submitted the dedication plan for the stock material for review prior to purchase. It was verified that:

- the manufacturer stated the fan safety function and significance
- had completed the suitability activities and stated the seismic and capacity design margin
- selected the raw material chemical and mechanical properties for test
- heat traceability to the mill for the raw material was established by audit of the intermediate supplier's material control program

The manufacturer provided a purchase order certification stating that all requirements of the order had been met, including the dedication activities.

Lessons Learned

- "Safety" classification MUST precede the determination of procurement category
- "Safety" classification is NOT determined by the supplier
- "Safety" classification is NOT based on whether the item is supplied as ASME NQA-1 or CGI
- Even though original component specifications may not identify a particular item or its critical design characteristics, it doesn't mean there are no attributes of the item that are important and should be verified.
- Once selected, each CC should be properly verified
- Not every technical requirement specified in a procurement document may need to be verified as a CC

Lessons Learned (cont)

- Failures of commercial grade items should be documented and trended
- Information can be used to adjust the sample size (from one item up to 100%)
- Methods for controlling, tracking and evaluating failed items should be procedurally defined and controlled
- DEDICATION PLANNING INCLUDES SPECIFIC INSPECTION INSPECTION/TEST/SURVEY CRITERIA.

  The output of the dedication planning should include specific information that is able to be directly used by the organization performing the acceptance activity.

  DON'T – State "Test valve to ASTM B16.34"

  DO – State "Perform a hydrostatic test of the valve body at 300 psi. Hold the pressure for 10 minutes then inspect for leakage. No leakage is allowed."

Lessons Learned (cont)

- UNDERSTAND THE DIFFERENCE BETWEEN SUITABILITY AND DEDICATION

  Part of the design process is to establish the suitability of an item for it's intended service. When the Design Engineer selects a candidate item for an application, suitability includes establishing the technical basis for the item being able to perform it's functions in the system. This can be done by testing or analysis, and for safety related applications may include environmental and seismic qualification, etc. When suitability is complete, the technical evaluation for dedication and acceptance planning can be performed based on the approved design documents.

  Lesson learned – Do not incorporate suitability/qualification testing in dedication activities. For example, the dedication activities should not include "Perform environmental qualification to IEEE - 323-1974."

Lessons Learned (cont)

- DEDICATION PLANNING PACKAGES DO NOT NEED TO INCLUDE A COMPILATION OF ALL THE PRESCRIBED INSPECTION AND TEST ACTIVITY RESULTS

  The activities prescribed in the dedication planning package are performed by the groups stated in accordance with their normal work performance procedures and the associated records are captured as specified by those procedures. It is not necessary to also have those records included with the dedication planning package for the items.

  Lesson learned - An effective dedication process integrates planning activities into existing procedures without causing unnecessary duplication.

  DON'T – Have additional copies of inspection test reports also sent to Procurement Engineering to be placed in the dedication planning package.

  DO – Have inspection test reports captured as directed by the governing procedure.

Lessons Learned (cont)

- INDUSTRY GUIDANCE DOCUMENTS ARE JUST THAT - GUIDANCE

  There are several industry guidance documents and standards that are tools to be used to develop a program and to be used by a Procurement Engineer to do individual evaluations. However, each dedication activity is based on plant application, and the technical evaluation of the critical characteristics and the rigor of the acceptance activities are commensurate with the safety significance.

  DON'T – Adapt EPRI JUTG Commercial Grade Item Evaluations as prescriptive consensus methods for dedicating the items addressed.

  DO – Use the evaluations as a compilation of information related to an item to assist in the performance of the technical evaluation, and therefore select characteristics relevant to the plant application.

Examples of CGID Issues

- Failure to recognize the need for a CGID activity to support the procurement process
- Implementing procedures were expert based instead of being developed at the level of detail to support the knowledge and experience level of the organization performing the activity.
- Lack of understanding of the relationship between the safety function, design criteria, critical characteristics, acceptance criteria, and methods for acceptance.

CGID Benchmarking Lessons Learned

- Several positive lessons learned were identified during the review of three commercial power organizations.
  - Utilities have adopted the Electric Power Research Institute (EPRI) NP-5652, Guideline for Utilization of Commercial Grade Items in Nuclear Safety Related Applications (NCIG-07), as the basis for conducting CGD activities.
  - Utility engineering organizations develop the CGD critical characteristics and acceptance requirements based on a detailed technical evaluation.
  - Utility quality organizations are responsible for implementing the CGD requirements.
  - Utilities use the EPRI Sponsored JUTG database to identify critical characteristics of items/ components.

CGID Benchmarking Lessons Learned, cont.

- Utilities stressed early communication and integration of CGD team (Engineering and QA).
- Utilities have implemented Engineering Organization CGD training programs
- Utility QA organizations rely on nuclear power industry QA/quality control training programs
- Utility use of CGD surveys to identify/correct supplier commercial quality program concerns prior to procurement

Questions & Answers

- Questions or Comments

References:

- DOE Order 414.1C**,** *Quality Assurance*
- DOE Guide 414.1-2A, *Quality Assurance Management System Guide*.
  - Discusses using a recognized international consensus standard for conducting Commercial Grade Dedication
- ASME-NQA-1-2004
  - Part I, Introduction (defines commercial grade item (two definitions), commercial grade service, critical characteristics, dedication, and dedicating entity
  - Part I, Requirement 7, *Control of Purchased Items and Services*
  - Part III, NonMandatory Appendix 7A-2, *Guidance on Commercial Grade Items and Services*

References, Cont.

- **EPRI Documents requiring purchase**:
  - JUTG Commercial Grade Item Technical Evaluations
  - Information for Use in Conducting Audits of Supplier Commercial Grade Item Dedication Programs
  - Generic Qualification and Dedication of Digital Components: Project Status and Lessons Learned
  - Generic Qualification/Dedication of Digital Components: Summary of 2004 Generic Qualification Activities
- **Documents free of charge**:
  - Generic Topic of Commercial Grade Dedication:
    - Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications (NCIG-07)
    - Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial Grade Items

References, cont.

- Critical Characteristics
  - Guideline for the Technical Evaluation of Replacement Items in Nuclear Power Plants (NCIG-11), NP-6404
  - Critical Characteristics for Acceptance of Seismically Sensitive Items (CCASSI)
- Digital Equipment
  - EPRI TR-106439, *Guideline on Evaluation and Acceptance of commercial Grade Digital Equipment for Nuclear Safety Applications.*
- Sampling Plan Development
  - EPRI TR-017218-R1, *Guideline for Utilization of Sampling Plans of Commercial Grade Item Acceptance*

References, cont.

- NRC Generic Letter 89-02: Conditionally endorses EPRI NP-5652, *Guideline for the Utilization of Commercial-Grade Items in Nuclear Safety-Related Applications (NCIG-07)*. Promotes the use of method one, test and inspection, and if method two or four are used they must be used in conjunction with additional methods.
- NRC Generic Letter 91-05: Defined critical characteristics. The Enclosure provided characteristics of effective commercial-grade procurement and dedication programs.

References, cont.

- NRC Inspection procedure 38703, *Commercial Grade Dedication*
- NRC Inspection Procedure 43004, *Inspection of Commercial-Grade Dedication Programs*
- NRC Inspection Procedure 38703 and 43004, *Assessing Sampling Techniques*

EM Environmental Management
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Energy Facility Contractors Group

Office of Environmental Management
and
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Quality Assurance
Improvement Project Plan

Project Focus Area	Task # and Description	Deliverable
Project Area 2: Adequate NQA-1 Suppliers	Task #2.22 Submit Project Plan for Implementing EM and EFCOG Joint Supplier Evaluation Program	Implementation Plan

Approvals Needed:	**Yes/No/NA**
Project Managers: S. Waisley, D. Tuttel (7/09)	Y
Executive Committee: D. Chung, J. Yanek, N. Barker, D. Amerine (7/09)	Y
EM QA Corporate Board:	Y

1 BACKGROUND

The Department of Energy (DOE) Office of Environmental Management (EM) has experienced increasing difficulty finding suppliers that are adequately qualified to provide items and services in accordance with the standards of the Quality Assurance Requirements for Nuclear Facility Applications (NQA-1) from the American Society of Mechanical Engineers (ASME). Given that the numbers of those suppliers have been decreasing, EM and its contractors have been duplicating qualification audits of those common few NQA-1 suppliers.

Complicating the issue further is the mandated selection process that must be followed by EM to select suppliers. To illustrate the complications of working with EM, the following needs to be considered:

- EM corporate quality policy and its nuclear safety regulations require procured items and services to meet more rigorous quality requirements than prospective suppliers have experienced with other customers.
- EM also requires prospective suppliers to be evaluated and selected on the basis of specified criteria.
- Lastly, EM requires verification that approved suppliers have established and implemented their processes to provide the specified items and services.

Consequently, the perception from many prospective suppliers is that it is not worth their time and expense to pursue EM contracts. Procurements outside the realm of EM have been such that EM business was not a necessity for success.

2 CURRENT CONDITIONS

Redundant audits of the same supplier have lead to the following undesirable conditions:

- Inconsistent reviews of shared suppliers lead to potential differing interpretations on implementing the standard EM quality requirements

- Organizations within EM are not utilizing all available expertise to evaluate its suppliers, resulting in a less than rigorous review of the shared supplier
- Project schedule slippage due to delays in evaluating a supplier that can only accommodate one audit team from one organization at a time

Whereas, a joint supplier evaluation program of common suppliers would enable the following benefits[1]:

- Decrease Project/Cost Risks
- Achieve Cost Avoidance & Cost Savings
- Improve Supplier Performance
- Decrease Risk of Suspect/Counterfeit Items
- Improve Credibility with Common Suppliers

EM can benefit from those lessons learned that EFCOG already has put in place by adopting EFCOG's Supplier Evaluation Program.

3 GOALS

This Quality Assurance Improvement Project Plan will achieve the following goals:

- Eliminate redundant supplier evaluations
- Establish a consistent approach to evaluating suppliers by a standardized set of quality requirements (i.e., the EM Corporate Quality Policy and the EM Quality Assurance Program, EM-QAP-001)
- Improve the overall quality of supplier evaluations

These goals are interrelated as it is perceived that eliminating redundant audits will lead to a focused coordinated review of common EM suppliers. This along with the consistent approach evaluating suppliers with a standardized set of requirements will ultimately lead to improving the overall quality of supplier evaluations.

[1] Source: EFCOG, "Supplier Evaluation/Qualification Initiative", November 30, 2004

4 ANALYSIS

There is an important distinction between a consolidated list of common suppliers audited under a Joint Supplier Evaluation Program and an EM complex-wide Approved Suppliers List that must be discussed further. An Approved Suppliers List for the EM complex would represent the broad approval of suppliers without requiring additional actions by EM sites to use those suppliers. This broad approval (whether implicit or not) would create unacceptable legal risk with its effect on liability issues arising from an Approved Suppliers List. A consolidated list of common suppliers audited under a Joint Supplier Evaluation Program would not contain such endorsements (implied or otherwise). Rather, it would merely serve as an exchange of information that EM sites could use to make their own determination on the acceptability of a supplier.

5 PROPOSED ACTIONS

The EFCOG Supply Chain Quality Task Team (SCQTT) has established a Supplier Evaluation Program (SEP) that addresses joint evaluations of suppliers that avoids the pitfalls previously mentioned. This implementation plan outlines how EM will integrate its supplier audits and evaluations into the SCQTT SEP by the following actions:

- EM and the SCQTT will adapt the SEP to accommodate the suppliers from EM
- EM will consolidate its list of suppliers and merge it with the SCQTT list of suppliers
- EM and the SCQTT will consolidate their supplier audit schedules into one master audit schedule
- The SCQTT working with EM will establish an additional protocol for those EM suppliers to follow the EM Quality Assurance Program, which adopts the national consensus standard of ASME NQA-1. This protocol will still allow for compatible evaluations done on EM suppliers such that they can still be used by the EFCOG SEP participants

6 RESPONSIBILITIES

The following groups or individuals have responsibilities in this plan:

- Idaho National Laboratory Supplier Management Program Lead:
  This individual is the current team leader for the Supply Chain Quality Task Team. This individual will be point of contact from EFCOG in this effort to integrate EM into their Supplier Evaluation Program.
- EM:
  Individuals from the EM Office of Standards and Quality Assurance will serve as the points of contacts between the INL Supplier Management Program Lead and the EM sites as needed during the process of integration and consolidation as described in this plan.

7 IMPLEMENTATION PLAN

The INL Supplier Management Program Lead, who currently leads the SCQTT, will incorporate an additional 22 identified EM suppliers into the current EFCOG Common Commodity List and Joint Audit Schedule. The anticipated completion date for this task is four (4) weeks after authorization from EM Corporate Quality Assurance Board.

The INL Supplier Management Program Lead in coordination with EM will develop and implement a complex-wide Electronic Management System (using established Oracle Aqualogic Portal controls) in direct support of the consolidated supplier evaluation program. The anticipated completion date for this task and associated subtasks is approximately six (6) weeks after initial authorization; pending funding authorizations and Information Technology work loads. The subtasks include the following system components:

- Program administrative controls (procedures, instructions, memorandums, forms, and attachments, etc.)
- System security and access controls
- A new EM/EFCOG joint audit schedule providing real-time updates

- A new EM/EFCOG common commodity list. The current number of EFCOG common suppliers is approximately 30. Integrating the additional EM suppliers would increase the supplier base by an additional 22 suppliers
- Mutually agreeable and exchangeable audit evaluation information
- Standardized audit notifications (e.g., meetings, alerts, memorandums)
- Records repository for controlled supplier evaluation reports, corrective action documents, checklists, plans, auditor qualifications, and other general supplier information

The INL Supplier Management Program Lead in coordination with EM will upload program documentation, schedules, qualifications, reports, and all other relevant information into the Electronic Management System. The anticipated completion date for this task will be three (3) weeks after development of the Electronic Management System.

The INL Supplier Management Program Lead along with EM will perform a gap analysis review between NQA-1-2000 and NQA-1-2004 requirements and establish new matrix documents (as needed) for commodities (materials or services) in support of the listed EM suppliers. The anticipated completion date for this task, which will require EM Site participation, will be four (4) weeks.

Working cooperatively, EM and the INL Supplier Management Program Lead will develop mutual administrative controls to accomplish the following:

- Further define roles and responsibilities
- Establish primary POCs at each site
- Further define audit reporting minimum requirements
- Define review and approval process
- Develop formal Lead Auditor review and approval validation
- Obtain auditor disclosure statements

To further ensure success of this effort, EM will support and to commit participating on scheduled conference calls, providing representatives to attend meetings with the SCQTT,

dedicating resources to participate on audits, and providing assistance to SCQTT, as needed, in support of the Supply Chain needs (e.g., evaluation basis development specific to commodities).

8 FOLLOW-UP ACTIONS

After development of the new joint SEP between EFCOG and EM, EM will coordinate feedback from its SEP participants after each audit for the first year to gather lessons learned for continuous improvement purposes. EFCOG SCQTT will be encouraged by EM to do the same with its SEP participants. In addition, EM HQ will conduct a survey after the first year of all the EM site SEP participants to gauge the acceptability of the program and look for ways to improve on it. The results of the surveys and the feedback from the individual EM SEP participants will be collated and reported on at a future EM QA Corporate Board Meeting.

9 FUNDING REQUIREMENTS

As outlined in Attachments 2 and 3, the EMS will cost approximately between $25k and $30k, with about $100.00 monthly service fees after the initial start-up. In addition, one Full Time Equivalent (FTE) from INL Supplier Management Program Lead will be needed for the estimated four (4) months to set-up, integrate, and consolidate EM into the Supplier Evaluation Program. EM and its sites will have to contribute some fractional support equivalent to 1 or 1.5 FTEs for roughly the same four-month period.

Attachment 1

The Supplier Evaluation Program Document from the Energy Facility Contractors Group Supply Chain Quality Task Team

http://www.efcog/wg/ism_qa

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

August 2008

Attachment 2

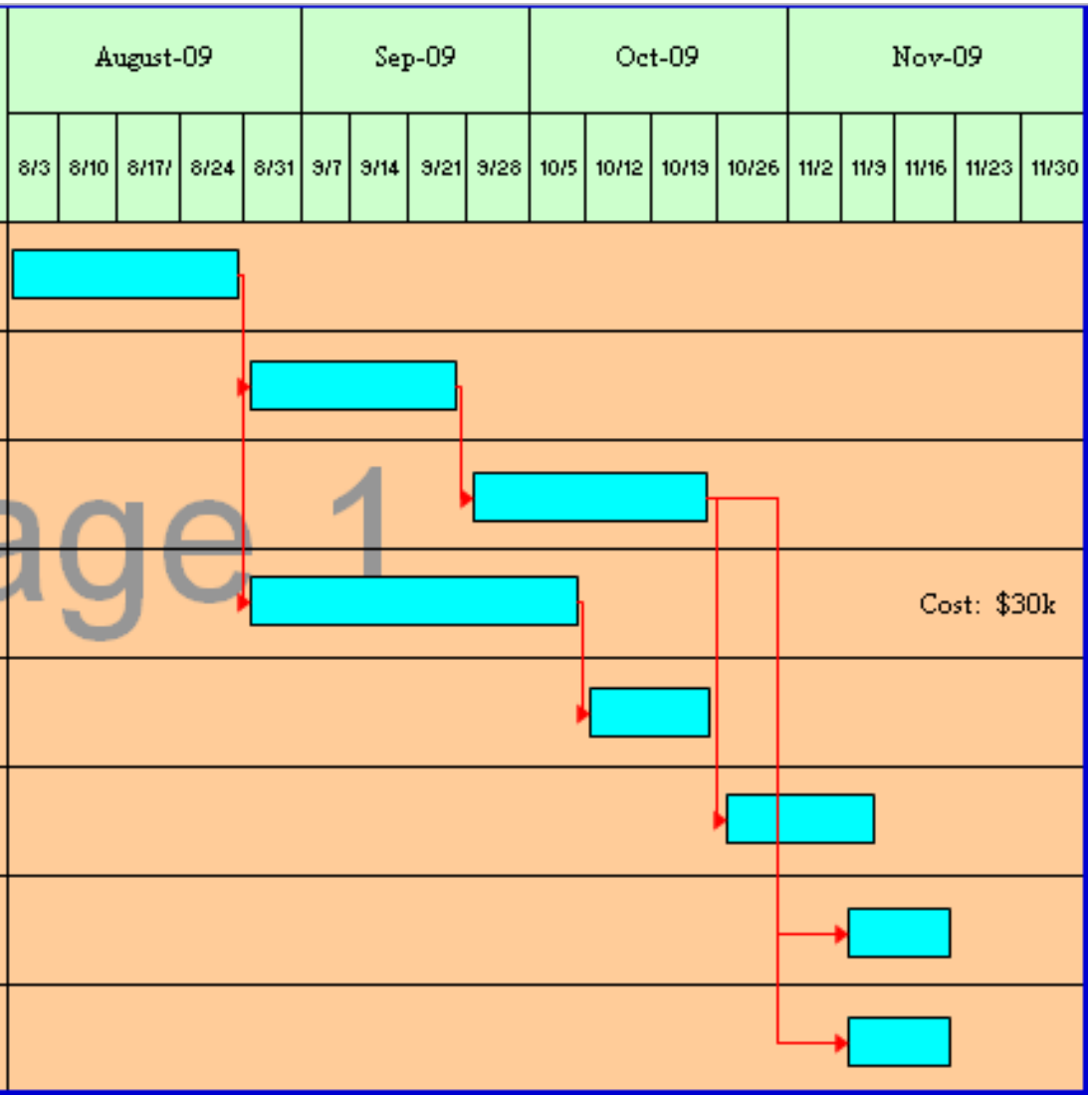
Implementation Path by Tasks for the EM/EFCOG Joint Supplier Evaluation Program

Task #	Task Description	Schedule	Cost	FTE	Responsibility
1	Consolidate and integrate the 22 identified EM suppliers into the current EFCOG Common Commodity and Joint Audit Schedule	4 weeks		1	INL Supplier Management Program Lead, who currently leads the SCQTT
2	Develop a complex-wide Electronic Management System (EMS) using established Oracle Aqualogic Portal controls in direct support of the consolidated supplier evaluation program.	6 weeks	EMS set fee estimated at $25 – 30 K for initial set up fees and a $100.00 monthly service fee thereafter	1	INL Supplier Management Program Lead
3	Upload the information into the Electronic Management System.	3 weeks*		1	INL Supplier Management Program Lead
4	Develop Evaluation Basis Matrix Documents and Conduct Gap Analysis (i.e., NQA-1 2000 vs. 2004): Conduct gap analysis on existing NQA-1 matrix documents specific to each commodity. Develop new NQA-1 matrix documents for EM commodities (materials and services).	4 weeks	Site Participation	1	INL Supplier Management Program Lead with EM Site participation
5	Establish or revise administrative controls to: further define roles and responsibilities; establish primary POCs at each site; further define audit reporting minimum requirements; define review and approval process; develop formal Lead Auditor review and approval validation; obtain auditor disclosure statements.			1	INL Supplier Management Program Lead
6	EM shall coordinate representatives to participate: on scheduled conference calls; in meetings; audits (to include funding for associated travel); with special assignments for support as needed (e.g., evaluation basis development specific to commodities).			1	EM HQ

Attachment 3

Implementation Schedule for the EM/EFCOG Joint Supplier Evaluation Program

ID	Task Name	Start	Finish	Duration
1	Authorization	8/3	8/28	4 w
2	Consolidation	8/31	9/25	4 w
3	Develop Evaluation Basis Matrix Documents and Conduct Gap Analysis	9/28	10/23	4 w
4	Electronic Management System	8/31	10/9	6 w
5	Database/ User Interface Validation	10/12	10/23	2 w
6	Electronic System Information Data Entry	10/26	11/6	3 w
7	Database User Test Period	11/6	11/20	2 w
8	Assign Resources and Initiate Audit	11/6	11/20	2 w



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Quality Assurance
Improvement Project Plan

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

Approvals Needed:	Yes/No/NA
Project Managers: S. Waisley, D. Tuttel (7/09, 8/09)	Y
Executive Committee: D. Chung, J. Yanek, N. Barker, D. Amerine (7/09); Steve Krahn (8/09)	Y
EM QA Corporate Board:	Y

Forward

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

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

This document responds to issues 1 and 4, Requirements Flow Down and Graded Approach to Quality Assurance.

Project Focus Area Team #1 was tasked by the EM QA Corporate Board to develop a model that would provide consistency to the approach for flow down of requirements to subtier suppliers/subcontractors performing work under prime contractors to EM. Project Focus Area Team #4 was tasked to develop a process for application of the Graded Approach for QA in Procurement to be used by both contractor and Federal QA programs.

Both 10 CFR 830 and DOE Order 414.1C state their requirements are to be implemented using a graded approach. The American Society of Mechanical Engineers' (ASME) Quality Assurance Requirements for Nuclear Facility Applications (NQA-1) states an organization shall be responsible for specifying which requirements apply and appropriately relating them to specific items and services. DOE G 414.1-2A, Quality Assurance Management System Guide provides a specific approach to grading. This document does not supplant or conflict with the Rule or Order and is consistent with NQA-1 requirements and DOE guidance.

Rather, this document provides EM with a defined process and standardized best practice for application of a graded approach for QA in both contractor and federal procurement programs and a model for consistent flowdown of QA program requirements to subtier contractors and suppliers. By applying this model and process across EM, consistency in the application of the graded approach is established. In using this document EM Headquarters, EM Field/Project Offices, and EM contractors are not relieved of their responsibility to seek to continuously improve their processes. This document will be modified as user experience identifies better ways of grading procurement.

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Graded Approach for Procurement

1.0 Purpose

This document provides the method for applying a graded approach to procurement activities across Department of Energy (DOE) Environmental Management (EM). The document is to be used by EM Headquarters (HQ), EM Field/Project Offices and EM Contractors to implement procurement processes associated with all work performed for the EM Program.

2.0 Scope and Application

It is intended that each prime contractor to an EM Field/Project Office will use their own procurement system with managerial controls implemented consistent with the expectations established in this document. The managerial controls, commensurate with risk, will be approved by the EM Field/Project Office.

Both 10 CFR 830 and DOE Order 414.1C state their requirements are to be implemented using a graded approach. The American Society of Mechanical Engineers' (ASME) Quality Assurance Requirements for Nuclear Facility Applications (NQA-1) states an organization shall be responsible for specifying which requirements apply and appropriately relating them to specific items and services. DOE G 414.1-2A, Quality Assurance Management System Guide provides a specific approach to grading. This document does not supplant or conflict with the Rule or Order and is consistent with NQA-1 requirements and DOE guidance.

3.0 Background

EM prepared a QA Project Plan to improve QA performance across EM operations. The Project Plan is supported by EM EFCOG representatives. The Project Plan addresses several areas, two of which (Requirements Flow-down, and Graded Approach) resulted in the development of this document.

For Requirements Flow Down, the Project Plan in part states “It is the responsibility of line management to ensure that:

- Appropriate technical and quality-related requirements are specified for products (i.e. System Structures and Components {SSC’s}). Additionally, the appropriate technical resources (e.g., Engineering, QA, and Operations) are involved in the procurement process to define and appropriately tailor QA requirements into procurement documents.
- The QA organization is included in the decision-making process when establishing the QA requirements or when assessing the supplier’s QA program and procedures.
- Requirements are clear with Acceptance/Inspection criteria identified.

- Requirements are flowed down through to suppliers, and, suppliers understand the requirements.
- Procurement processes are flexible enough to specify the applicable QA requirements, and that contractor supplier evaluation processes are adequate, allowing the vendor to satisfy its NQA-1/10 CFR 830-based QA program requirements.
- Requirements are evidenced in the products delivered for use.
- There are adequate oversight functions to ensure completion of all of the above"

For the Graded Approach section, the Project Plan partially states, "The graded approach to quality assurance can be applied consistently in EM complex facilities by establishing a common understanding of why DOE policy allows grading and how grading may be accomplished. In general, grading of quality assurance is based on the relative importance of an item or activity to the success of the mission."

How EM HQ, EM Field/Project Offices, and EM contractors implement the graded approach has been inconsistent. Surveys of various contractor organizations throughout the EM complex completed during the summer of 2008 provided insight into the degree of inconsistency across the complex. The inconsistencies begin as the Department prepares its Requests for Proposal (RFPs) and carry through the various contractor organizations as they prepare service and commodity oriented procurements to meet the needs of operating facilities and construction projects. In addition, with no common expectation, assessments on how the graded approach is implemented may be influenced by the individual assessor's perspective, leading to further inconsistency.

This document provides EM with a defined process for flowdown of requirements and application of a graded approach for QA in both contractor and federal procurement programs. By applying this document across EM, consistency in the flowdown of requirements and application of the graded approach can be established. Application of this document is consistent with the requirements of DOE Order 414.1C, 10 CFR 830, and NQA-1-2004 with addenda through 2007.

4.0 Requirements Flowdown and Graded Approach

The two tasks described above were subsequently recognized to be interdependent in that it is difficult to adequately discuss one without the other. The following discussion considers them separately such that requirements flowdown is addressing "what is required" and the graded approach addresses "how is it implemented." The "what" deals with the specific technical or program elements that are applied to a specific procurement activity, and the "how" deals with the managerial controls applied by the procuring organization that are established commensurate with the risk/consequence associated with the procurement activity.

4.1 Requirements Flowdown

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

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

EM Serving in the Capacity of Owner and Regulator

EM performs its owner/regulator duties while developing (modifying) its contracts. The EM Corporate Quality Assurance Program promulgated by the Principal Assistant Secretary for EM during October 2008 invoked the national consensus quality standard NQA-1-2004 and addenda through 2007.

As EM forms Integrated Project Teams (IPTs) to develop acquisition strategies for new procurements, the IPTs are expected to fully and completely address the quality assurance requirements associated with that acquisition, considering:

- Contract language that meets the needs of the specific project/program.
- Review of the various NQA-1 parts and subparts to ascertain their applicability to procurement's specific scope.[1]

Prime Contractors

As communicated in the model, EM has specific expectations of its prime contractors. Prime contractors are expected to ensure safe design, construction, and operation of EM facilities/projects:

- The "safe operations" expectation requires intimate understanding of a wide variety of topical areas engaging multiple technical and engineering disciplines. Their critical importance makes these responsibilities difficult to delegate through subcontracts to subordinate entities. The body of expertise necessary to ensure safe facility operations is expected to reside with the contractor.
- Analyzing the risk significance of the various SSCs is not generally subcontracted to outside entities. Therefore, the expectation is that the Technical or Design authority will perform this function for the operating facility or project under design or being constructed.
- Identifying critical safety attributes of components or items is expected. Often these attributes are determined acceptable when measured against various national consensus codes and standards that address the particular commodity.[2]

[1] As expressed in the Introductions to Parts I and II, Requirement 300 of NQA-1 requires "the organization invoking this Part shall be responsible for specifying which requirements, or portions thereof, apply, and appropriately relating them to specific items and services." Applying Parts III and IV of NQA-1 should also be a consideration.

[2] For example, in terms of concrete, critical attributes will likely be measured against the various consensus standards promulgated by the American Society of Testing Materials (ASTM) and in engineering specifications developed in accordance with design approaches described by the American Concrete Institute (ACI).

- Procurement documents are expected to:
  - Communicate to subcontractors the key engineering/performance attributes and how they will be measured at delivery
  - Provide contractual expectations regarding quality requirements to subordinate subcontractors or material suppliers. Taking care to precisely describe those technical and quality requirements applicable to the item or service to be delivered under the procurement is expected.

Subcontractors Performing Work Directly For EM or EM Prime Contractors

Suppliers/Subcontractors to EM or Prime Contractors have the responsibility to develop and implement quality programs that assure the EM or Prime Contractor identified technical and quality requirements are adequately addressed by their work processes, or if procured, through their procurement process. Expectations include, but are not limited to:

- Flowdown of the appropriate requirements to their suppliers
- Ensuring the adequacy of subtier subcontractor performance through surveillance, assessments, audits (capability and compliance) and receipt inspection
- Material receipt, inspection and testing
- Storage and segregation of materials
- Ensuring adequate measurement and test equipment (M&TE)

Subtier Suppliers/Subcontractors Performing Work

Subtier Suppliers/Subcontractors to Subcontractors have the responsibility to develop and implement quality programs that assure the identified technical and quality requirements that were flowed down are adequately addressed by their work processes, or if procured, through their procurement process. Expectations include:

- Flowdown of the appropriate requirements to their suppliers
- Ensuring the adequacy of subtier subcontractor performance through surveillance, assessments, audits (capability and compliance) and receipt inspection
- Material receipt, inspection and testing
- Storage and segregation of materials
- Ensuring adequate measurement and test equipment (M&TE)

4.2 Graded Approach

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

- Procure items and services that meet established requirements and perform as specified;
- Evaluate and select prospective suppliers on the basis of specified criteria; and
- Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.

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

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

Along with the Order and Rule, NQA-1 allows implementing these requirements through a graded approach. While there are many different interpretations or definitions of graded approach, one that has been selected as representative of these is quoted below from Subpart 4.2 of NQA-1, paragraph 300 which states:

> *The graded approach is the application process for administrative controls. It is a process by which the level of analysis, extent of documentation, and degree of rigor of process control are applied commensurate with their significance, importance to safety, life cycle state of a facility or work, or programmatic mission.*

The graded approach does not allow for a requirement to be waived, but rather allows for varying levels of managerial controls to be applied to provide adequate assurance, commensurate with risk, that the requirement is being met. As such, for all procurement activities the expectation is that all areas are addressed. However, the methods used to implement the requirements can vary commensurate with the risk of the activity. The graded approach, when implemented, is applied to the following key process activities associated with procurement:

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

This document describes the framework to be used by EM Field/Project Offices and EM Contractors. The framework minimizes the subjective nature of the graded approach by specifying "how" requirements are implemented, primarily at the Federal Project and

Prime Contractor level, however similar application by subcontractors and suppliers is appropriate. This document does not address attributes associated with the procurement process in such areas as:

- Sole Source Justifications
- Funding approval requirements
- Classification/Declassification
- Offer Solicitations
- Contract Award
- Payment for items/services
- Contract closeout
- Claims

5.0 Implementation

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

- Identification and flowdown of requirements into procurement documents
- Use of the standard EM procurement risk assessment process (see section 5.2) to quantify the risk
  Note: EM Office of Standards and Quality Assurance will provide the standard risk assessment process to be used by EM HQ, EM Field/Project Offices, and EM Contractors
- Establishing Quality Levels (QLs) or equivalent identifier based on the quantified risk (to establish the rigor to be applied)
- How each QA program requirement associated with procurement is implemented consistent with the QL of the procurement and compliant with this document.

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

Note: Due to the wide variance in types of work activities performed, each prime contractor shall establish the appropriate number of Quality Levels for their work scope and clearly demonstrate (map) their levels to the expectations of this document.

6.0 Procurement Process Attributes

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

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

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

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

- Establish the QL
- Implement procurement controls as prescribed by the QL

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

6.1 Identify Requirements Applicable to Item/Service

Identification of requirements is a design input, and establishes the technical and quality program requirements to be applied to the item or service consistent with the intended use or application. The graded approach of "how" the requirements are to be applied is generally not used in flow down of requirements. Generally requirements either are or are not applicable to the item or service. The requirements associated with the item or service to be procured are defined by the customer organization and usually involve the technical authority or subject matter expert to ensure that appropriate national standards, codes, quality requirements, state requirements, laws, regulations, etc. are applied to the procured item.

Identification of requirements applicable to the item or service not only involves technically oriented codes and standards, but also includes a well described expectation for implementation of QA standards with particular emphasis regarding the flow down of QA requirements to subcontractors and suppliers. Prime contractors are expected to describe which requirements of Part I and Part II of NQA-1 will be applied to the subordinate contractor's QA program. These are usually called out as QA specifications, or QA requirements. In addition to any applicable NQA-1 requirements, other QA requirements that may be applicable such as Suspect/Counterfeit Items (SCI) controls, laboratory standards, or other stakeholder QA expectations that are not covered by NQA-1 are also addressed. Whether to submit QA program documents with bids and whether acceptance of the Supplier's QA Program is a condition of procurement shall be identified.

> **Note: It is not the intent to flowdown "NQA-1" to a supplier, but rather that the applicable requirements of NQA-1 are flowed down and the supplier's QA program is to be evaluated against those specific requirements.**

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

In addition to identifying the requirements for the supplier's QA program, the QA specification shall be used to communicate the purchaser's expectations for implementation of the supplier's QA program, and to establish communication protocols for oversight functions. The QA specification shall be clear regarding the right of access by project and customer representatives to perform oversight functions such as audits and surveillances. Other considerations such as those listed below

should be addressed as part of the graded approach dependent on risk/consequence of the activity and include:

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

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

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

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

- Define a process for submittal and approval of requests for variances to design, fabrication, schedule requirements, etc. (e.g., supplier deviation requests) as appropriate.

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

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

- The purchaser's right to stop work at a supplier due to non-compliances with the QA program

6.2 Determine Risk of Failure

This is the critical step in applying a graded approach to procurement. The rigor must be commensurate with the risk of failure. DOE O 414.1C provides a list of attributes to be evaluated when determining the risk of failure. Through this document EM provides a common questionnaire as a process for evaluating risk. The risk evaluation looks at risk of failure from two perspectives: 1) Safety and 2) Mission Criticality.

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

The EM provided common computer-based procurement risk assessment process is simply a computer based questionnaire designed around the critical attributes addressed in DOE O 414.1C for evaluation when determining risk of failure. The questionnaire addresses the following attributes:

- Adverse Safety Impacts
- Mission Interruption
- Environmental Damage
- Negative government or public perception
- Adverse Cost
- Expected Lifecycle
- Design Complexity
- Degree of Standardization
- Ease of failure detection
- Level of Personnel Qualifications/Special Skills
- Problem History
- Mission Critical

Depending on how the questions above are answered, a level of overall risk is obtained and used in establishing increased or decreased rigor associated with the procured item or service.

6.3 Establish the Quality Level

Based on the applicable requirements and the subsequent risk determination, a QL is assigned for the procurement activity. The QL establishes how key attributes of the procurement process (managerial controls) are applied for:

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

This document suggests four QLs as described in the following section. For most EM Field/Project Offices and EM Contractors, four quality levels provide sufficient latitude to establish varying levels of procurement rigor. Some EM Field/Project Offices and EM Contractors may find having fewer (or more) levels is appropriate for

the scope of work being performed. Each EM Field/Project Office and EM Contractor needs to develop a process that prescribes what quality levels are used to bin the above activities meeting the expectations identified in Table 1.
It is not intended each organization change their process to use the QL convention. Each implementing organization needs to identify the convention used within their process that represents the same intent of quality levels, such as:

- Procurement levels (PL-1, PL-2, PL-3, PL-0)
- Quality Control levels (QC-1, QC-2, QC-3)
- Alpha/numeric levels (A, B, C, D or 1, 2, 3, 4)
- Full Quality, Enhanced Quality, Commercial Quality
- Construction, Technical Services, Engineered Item, Commercial
- Other conventions that conveys the intent of this expectation

Regardless of the convention used, the implementing organization must demonstrate how their convention implements the intent of the expectations of section 6.0 and Table 1.

7.0 Quality Levels

QLs are established based on risk such that higher risk activities result in higher rigor associated with the review and approval of the procurement, supplier evaluation, supplier monitoring, and acceptance activities. Risk is defined by a cumulative evaluation using the standard EM process against variables such as Nuclear Safety, Personnel Safety, Environmental Impacts, Mission Impacts, Cost, Regulatory Requirements, and Stakeholder perception. For a four level system, based on cumulative risk, the QLs are:

- QL-1 – High risk
- QL-2 – Medium risk
- QL-3 – Low risk
- QL-4 – Commercial quality or very low risk

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

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

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

QL-4: Minimal, if any, safety or mission impact - level of controls for those items, services, or processes where no additional quality controls beyond the providers published or stated attributes of the item, service, activity, or process are required. General acceptance processes to ensure item, quantity, and other characteristics are met.

7.1 Review and Approval

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

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

Table 1 provides EM's minimum expectations for review and approval based on risk.

7.2 Supplier Evaluation

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

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

The rigor behind the selected approach takes into account the risk determined QL. Which approach to take is generally determined based on current supplier knowledge, the item or service being procured, and the QL.

For low risk activities, such as office supplies, purchasing from a reputable vendor based solely on commercial industry presence can be sufficient to meet this requirement, as long as the decision to use the vendor for this service is documented (i.e., a material request form identifying the supplier). As the risk escalates additional evaluations may be warranted, but can be met by reviewing requested documents (to

include the suppliers QA program and appropriate implementing procedures) that support the objective evaluation of the supplier's capabilities during the bid proposal.

For higher risk activities, an onsite evaluation of the implementation of the suppliers program using a detailed crosswalk to document implementation against the applicable NQA-1 sections that are flowed down becomes the most prominent method to ensure the supplier is capable of meeting the needs. Table 1 provides EM's minimum expectations for supplier evaluation based on risk.

7.3 Supplier Monitoring

Periodic monitoring of a suppliers performance is an area where implementation may vary. Although risk plays a role in determining the monitoring methods and frequency, scope of the activity also influences supplier evaluation. (For example, where the scope includes welding then enhanced supplier oversight and examination requirements for welder qualifications and performance should be considered early in the fabrication process especially for medium and high risk components.)

For low risk activities, monitoring can be performed simply through receipt inspection of deliverables. As risk escalates, the monitoring strategy should address:

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

For higher risk activities, development of a subcontractor oversight plan is warranted to ensure intentional monitoring of the subcontractors performance. The oversight plan would address the specific time frames and scope of any on-site surveillances/assessments to provide assurance of quality of the deliverable. Depending on the nature of the subcontracted activity, the plan could also address the use of an integrated team of subject matter experts (engineers, inspectors, project managers, etc) to provide a broader perspective of the suppliers performance..

See Table 1 for EM's minimum expectations for supplier monitoring based on risk.

7.4 Acceptance of Items

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

- Supplier Certificate of Conformance (COC)[3]
- Source Verification
- Receiving Inspection
- Post installation test
- Combination of the above
- For services only, any or all of the following may be used:

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

- Technical verification of data produced
- Surveillance and/or audit of the activity
- Review of objective evidence for conformance to the procurement document requirements

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

Figure 1
FLOW DOWN OF QUALITY ASSURANCE SPECIFICATIONS AND PROCUREMENT OF ITEMS AND SERVICES - GRADED APPROACH APPLICATION

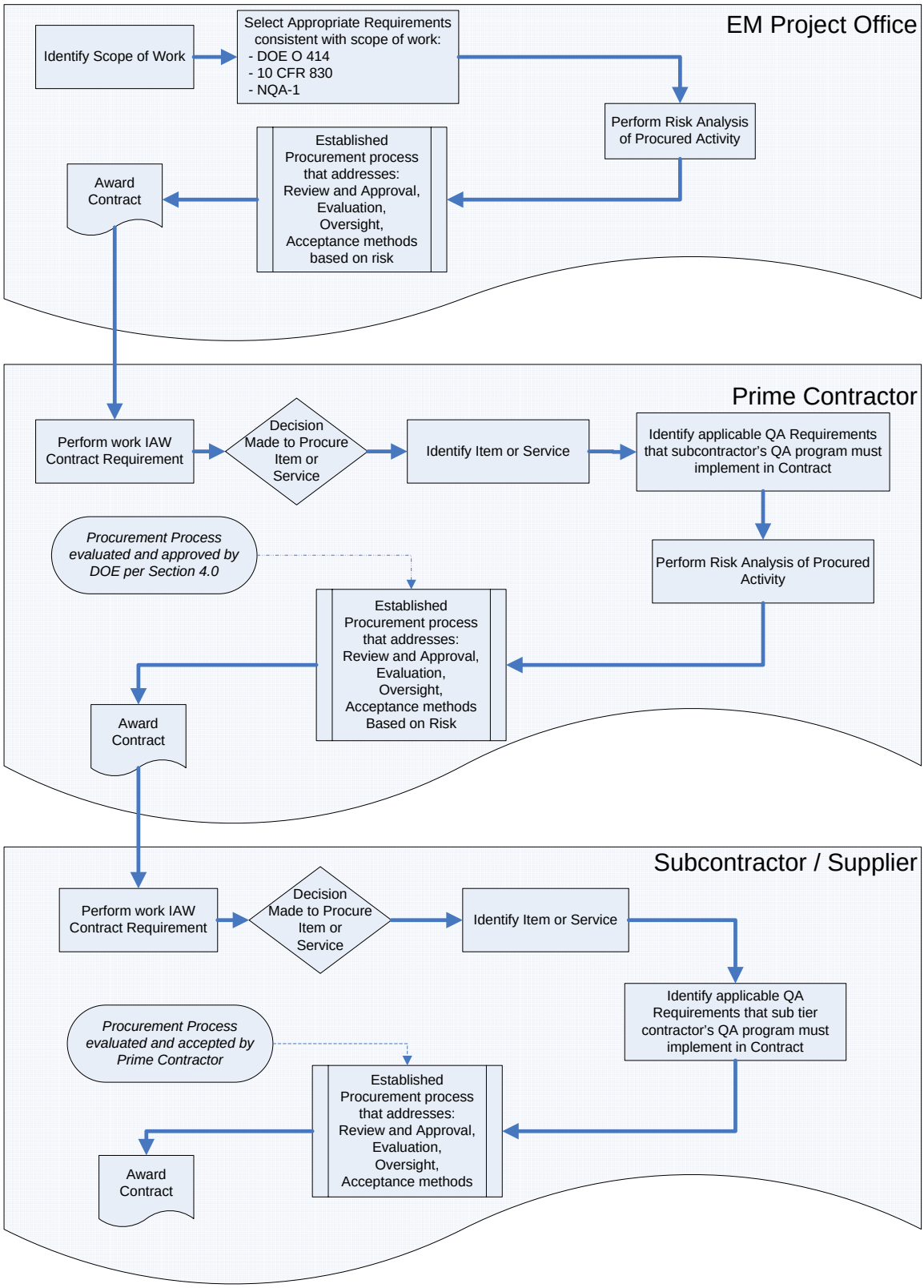

Table 1 – EM Graded Approach QL Level and Activity Matrix Minimum Expectations

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

(1) Scope Dependent
(2) Due to higher risk, intentional oversight activities are planned out – could range from periodic surveillance to in-process inspections/witness or hold points.
(3) Acceptance and Monitoring methods listed need to be evaluated for implementation commensurate with the scope and nature of the activity.

SUMMARY OF EM FEDERAL AND CONTRACTOR SITE QA RESOURCES

SITE LOCATION	TOTAL FEDERAL FTEs	QA RESOURCES (Incl. Support Contractors & Projected Hires)	PERCENT OF HQ/SITE FEDERAL FTEs	TOTAL CONTRACTOR FTEs	QA RESOURCES (Prime and Subcontractors)	PERCENT OF SITE CONTRACTOR FTEs
Headquarters	331	19	5.7%	NA	NA	NA
EMCBC	171	2	1.2%	NA	NA	NA
EM Small Sites: (GJ/MOAB, SPRU, BNL, ETEC, Mound, WV)	33	6	18.2%	512	18	3.5%
River Protection	138	8	5.8%	4,545	138	3.0%
Richland	269	6	2.2%	4,583	127	2.8%
Savannah River	331	5.5	1.7%	8,611	153**	1.8%
Idaho	67	6.5	9.7%	1,662	46.25***	2.8%
Oak Ridge	81	4.1	5.1%	2,539	51.5	2.0%
Paducah /Portsmouth	46	6.75	14.7%	1,258	49.5	3.9%
Carlsbad (WIPP)	44	28	63.6%	820	56	6.8%
Total EM Resources	1511*	91.85	6.1%	24,530	639.25	2.6%

*Excludes NNSA sites FTEs funded by EM Program and EM Prof Development Corp which brings the total to 1610 FTEs 8/01/09

** 20 additional FTEs projected to be hired by Parsons, bringing the QA Resources total to 175 FTEs

*** 8 additional FTEs to be hired by Bechtel-BWXT and CWI, bringing the total to 54.25 FTEs

Note 1: EM work scope varies in terms of type of work (construction, operational, or D&D), technical complexity, and funding amounts

Note 2: Industry averages 4% - 7% of total workforce for operational work; 5-10% range for construction projects

Summary of EM Contractors Site QA Resources
(Revised August 1, 2009)

SITE AND CONTRACTORS	TOTAL CONTRACTOR FTEs	QA RESOURCES (PRIME AND SUBCONTRACTORS)	PERCENT OF SITE CONTRACTOR FTEs
Hanford (ORP)	**4,545**	**138**	**3.0%**
Bechtel National, Inc. (BNI)	**3,400**	**106**	**3.1%**
Washington River Protection Solution (WRPS)	**1,075**	**29**	**2.7%**
Advanced Technologies and Laboratories Internationals, Inc. (ATL)	**70**	**3**	**4.3%**
Hanford (DOE-RL)	**4,583**	**127**	**2.8%**
CH2M Hill	**1,800**	**61**	**3.4%**
Washington Closure Hanford, LLC	**1,000**	**27**	**2.7%**
Fluor Hanford, Inc – Project Hanford Management Contract (PHMC)	**1,700**	**38**	**2.2%**
AdvaceMed Hanford, a CSC Company	**83**	**1**	**1.2%**
Savannah River	**8,611**	**153**	**1.8%**
Washington Savannah River Company (WSRO)	**1,995**	**33**	**1.7%**
Parsons	**455** (FTEs will vary between 455-800)	**33** (additional 20 FTEs projected, bringing total to 53)	**7.3%**
Savannah River Nuclear Solutions, LLC	**6,161**	**87**	**1.4%**
Idaho	**1,662**	**46.25 (increase to 54.25)**	**2.8% (3.2%)**
Bechtel-BWXT, LLC	**Est. 900**	**24** (projected to increase to 26 FTEs)	**2.7%**
CWI (SBWTU)	**378** (increase to 420 by 8/30/09)	**18** (increases to 20 by 8/31/09)	**4.7%**
CWI (RWMC – ARP and D&D)	**384**	**4.25** (increases to 8.25 w/ ARRA funding)	**1.1%**

SITE AND CONTRACTORS		TOTAL CONTRACTOR FTEs	QA RESOURCES (PRIME AND SUBCONTRACTORS)	PERCENT OF SITE CONTRACTOR FTEs
Oak Ridge, ETTP, and Y12		**2,539**	**51.5**	**2.0%**
	Bechtel Jacobs Company, LLC (BJO) - for all three sites	**2100**	**30**	**1.4%**
	Isotek Systems, LLC – only ORNL U233 Material Downblending and Disposition Project	**125**	**9.5** (2 projected hires)	**7.6%**
	Energx, LLC – only ORNL TWPC	**314**	**12**	**3.8%**
Paducah		**716**	**28**	**3.9%**
	Swift & Staley Mechanical Contractors – Gaseous Diffusion Plant	**86**	**4**	**4.7%**
	Paducah Remediation Services, LLC	**479**	**16**	**3.3%**
	Uranium Disposition Services (UDS)	**151**	**8**	**5.3%**
Portsmouth		**542**	**21.5**	**4.0%**
	LATA/Parallax Portsmouth, LLC (LPP)	**228**	**5**	**2.2%**
	Uranium Disposition Services (UDS)	**179**	**9.5**	**5.3%**
	Theta Pro2Serve Management Company, LLC (TPMC) – Portsmouth Gaseous Diffusion Plant	**135**	**7**	**5.2%**
WIPP		**820**	**56**	**6.8%**
	Navarro Research and Engineering	**50**	**28**	**56%**
	Washington TRU Solutions, LLC, URS	**650**	**23**	**3.5%**
	Los Alamos National Laboratory-Carlsbad Operations Office (LANL-CO)	**58**	**1**	**1.7%**
	Sandia National Laboratory-Carsbad Programs Group	**62**	**4**	**6.5%**

SITE AND CONTRACTORS		TOTAL CONTRACTOR FTEs	QA RESOURCES (PRIME AND SUBCONTRACTORS)	PERCENT OF SITE CONTRACTOR FTEs
EM Small Sites		**512**	**18**	**3.5%**
Grand Junction Moab UMTRA Project	S&K Aerospace, Inc. (TAC) Energy*Solutions* Federal Services (RAC)	**115**	**7**	**6.1%**
Brookhaven National Laboratory	Brookhaven Science Associates	59	**2**	**3.4%**
Separations Process Research Unit (SPRU)	Accelerated Remediation Company (aRc)	**12**	**0**	**0%**
Energy Technology Engineering Center (ETEC)	The Boeing Company	**5**	**1**	**20%**
Separations Process Research Unit (SPRU)	URS Washington Group	**46**	**2**	**4.3%**
Mound OU-1 Project	Accelerated Remediation Company	**25**	**1**	**4%**
West Valley Demonstration Project	West Valley Environmental Services	**250**	**5**	**2%**

SITE AND CONTRACTORS	TOTAL CONTRACTOR FTEs	QA RESOURCES (PRIME AND SUBCONTRACTORS)	PERCENT OF SITE CONTRACTOR FTEs
Total EM Contractor Resources	**24,530**	**639.25**	**2.6%**

Note: Industry averages 4% - 7% of total workforce for operations; 5% - 10% for construction

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Quality Assurance
Improvement Project Plan

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

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

OFFICE OF ENVIRONMENTAL MANAGEMENT

Standard Review Plan (SRP)

Quality Assurance (QA)

For Capital Project Critical Decision

Review Module

August 2009

FOREWORD

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

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

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

[1] *The entire EM SRP and individual Review Modules can be accessed on EM website at http://em.doe.gov, or on EM's intranet Portal) at https://edoe.doe.gov/portal/server.pt Please see under /Programmatic Folder/Project Management Subfolder*

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ABBREVIATIONS AND ACRONYMS

ASME	American Society of Mechanical Engineers
CD	Critical Decision
FPD	Federal Project Director
IPT	Integrated Project Team
ISMS	Integrated Safety Management System
LOI	Line of Inquiry
NQA-1	Nuclear Quality Assurance-1
QAP	Quality Assurance Plan
QA	Quality Assurance
QIP	Quality Assurance Implementation Plan

I. INTRODUCTION

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

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

II. PURPOSE

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

III. ROLES AND RESPONSIBILITIES

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

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

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

Position	Responsibility
	Forwards the final review report to the FPD and EM management for consideration in making the decision to authorize start of construction.
	Participates, as necessary in the closure verification of the findings from the review report.
Review Team Member	Refines and finalizes the criteria for assigned area of the review.
	Develops and provides the data call of documents, briefings, interviews, and presentations needed for his/her area of the review.
	Completes training and orientation activities necessary for the review. Conducts any necessary pre visit document review.
	Participates in the on-site review activities, conducts interviews, document reviews, walk downs, and observations as necessary.
	Based on the criteria and review approaches in the Review Plan, assesses whether his/her assigned criteria have been met.
	Documents the results of the review for his/her areas. Prepares input to the review report.
	Makes recommendations to the Review Team Leader for characterization of findings in his/her area of review.
	Resolves applicable Federal and Contractor factual accuracy comments on the draft review report.
	Prepares the final review report for his/her area of review.

IV. REVIEW SCOPE AND CRITERIA

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

The QA review as defined by Appendix A relies on the more detailed set of LOIs as defined for each of the 10 QA Criteria of the EM Corporate QAP. The QA review teams should refer to the LOIs contained in Table 1 and Table 2 of the *Protocol for EM-HQ Review of EM Field/Site-Specific Quality Assurance Program (QAP)/Implementation Plans (QIP),* dated, August 2009. Table 1 contains the LOIs for each of the 10 EM QAP QA Criteria. The italicized text reflects *Assessment Expectations for Federal Project Directors (FPDs) and Integrated Project Teams (IPTs) Review Attributes/Characteristics* developed by the Office of Environmental Management and Energy Contractors Group Quality Assurance Improvement Project Plan, Task #5.8.

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

The combination of this review module, the *Protocol for EM-HQ Review of Site-Specific Quality Assurance Program (QAP) and Quality Assurance Implementation Plan (QIP)*, dated August 2009, and the NQA-1 review protocol, provides a complete technical basis for use by appropriate EM personnel to evaluate all aspects of a project with regard to the QA program.

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

Project Approval of Mission Need

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

Approval of Alternative Selection and Cost Range

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

Approval of Performance Baseline

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

Approval of Start of Construction

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

Approval of Start of Operations and Project Completion

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

V. REVIEW PLANS AND DOCUMENTATION

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

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

- Subsequent to the selection, formation and chartering of the review team and receipt and review of the prerequisite documents; assignment of responsibilities for the development of specific lines of inquiry should be made.
- The review team members should develop specific lines of inquiry utilizing the topics and areas listed in the respective appendices of this guide.
- The individual lines of inquiry should be compiled and submitted to the manager authorizing the review for concurrence prior to starting the review. Once approved by the manger they should be provided to the organization being reviewed along with a schedule for the planned assessment.
- The project-specific review plan should be compiled with a consistent and uniform numbering scheme that provided for a unique identifier for each line of inquiry, arranged by subject area such that the results of each line of inquiry can be documented and tracked to closure.
- The lines of inquiry should be satisfied via document review and personnel interviews and any combination of these methods. For the field assessment these techniques are augmented by the direct observation of work to verify procedure execution as appropriate. The method used the basis for closure/comment/finding and the result of the inquiry should all be documented and tracked.

VI. REFERENCE MATERIAL

- 10 CFR 830.120, *Quality Assurance Requirements*
- DOE Order O 414.1C, *Quality Assurance*
- DOE O 413.3A, Change 1, *Program and Project Management for the Acquisition of Capital Asset*
- ASME NQA-1 2004, *Part I: Requirements for Quality Assurance Programs for Nuclear Facilities*, and addenda through 2007
- *Quality Assurance Program Plan*, Office of Environmental Management Headquarters, May 2008
- *Protocol for EM-HQ Review of EM Field/Site-Specific Quality Assurance Program (QAP)/Implementation Plans (QIP)*, draft, July 2009
- DOE G 413.3-2, *Quality Assurance Guide for Project Management*, June 2008
- ANSI/ASQ Q 9001-2000, *Quality Management System Requirements*;

- ANSI/ASQ Z 1.13, *Quality Guidelines for Research;*
- DOE P 450.4, *Safety Management System Policy*;
- DOE P 450.5, *Line Environment, Safety and Health Oversight*;
- Quality Assurance Improvement Initiative, EM Centralized Training Platform Project Plan, April 2009
- DOE-STD-1150-2002, *Quality Assurance Functional Area Qualification Standard*
- DOE 5480.20A, *Personnel Selection, Qualification and Training Requirements for DOE Nuclear Facilities*
- DOE G 414.1-1B, *Management Assessment and Independent Assessment Guide*
- DOE G 414.1-2A, *Quality Assurance Management System Guide*
- DOE G 414.1-3, *Suspect/Counterfeit Items Guide*
- DOE G 414.1-4, *Safety Software Guide*
- DOE G 414.1-5, *Corrective Action Program Guide*
- Office of Environmental Management and Energy Contractors Group Quality Assurance Improvement Project Plan, Task #5.8, CD Tables w/Requirements and Performance Objectives, Measures & Commitments
- Office of Environmental Management and Energy Contractors Group Quality Assurance Improvement Project Plan, Task #5.8, Assessment Expectations for Federal Project Directors (FPDs) and Integrated Project Teams (IPTs) Review Attributes/Characteristics.
- *Protocol for EM-HQ Review of EM Field/Site-Specific Quality Assurance Program (QAP)/Implementation Plans (QIP),* draft, July 2009.

Appendix A

QA Performance Objectives and Criteria for Review of Critical Decision (CD) Documents and Activities

Legend of Quality Assurance Review Topics

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

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

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

[3] The review team should request that the technical basis and assumptions be provided in support of the answers provided for each Line of Inquiry. If needed, the reviewer(s) should perform independent verification of the technical basis and assumptions.

ID #	Performance Objectives and Criteria[2] [3]	Met?
	For preparing the **Conceptual Design Report (CDR)**, are the following expectations being implemented? (CD-1.1) • Criterion 4 (Document and Records) *to ensure that processes for preparation, review, approval, issuance, use, and revision of the CDR are implemented.* • Criterion 4 *to ensure that processes for specification, preparation, review, approval, and maintenance of records are implemented.* • Criterion 6 (Design) *to ensure that a design process is in place that provides appropriate control of design inputs, outputs, verification, configuration a design changes, and technical and administrative interfaces* • Criterion 6 *to ensure that design activities are verified and documented*	
	For preparing the **Acquisition Strategy**, is Criterion 4 (Document and Records) being implemented to ensure that processes for preparation, review, approval, issuance, use, and revision of the Acquisition Strategy document are implemented? (CD-1.2)	
	Criterion 7 - Determine that a procurement (acquisition) process to ensure items and/or services provided by suppliers meets the requirements and expectations of the end user is developed and implemented and that quality level determination are factored into the acquisition strategy, especially when procuring services to perform work.	
	Criterion 7 - Verify that QA expertise is utilized to assist with procurement (acquisition) planning.	
	For preparing a **Preliminary Project Execution Plan (PEP)**, is Criterion 4 (Documents and Records) *being implemented to ensure that processes for preparation, review, approval, issuance use, and revision of the PEP are implemented*? (CD-1.3)	
	Determine that significant QA participation is emphasized in the development and review of the PEP	
	For the selection and approval of the **Federal Project Director**, is Criterion 2 (Personnel Training and Qualification) being implemented to *ensure that policies and procedures that describe personnel selection, training, and qualification requirements are developed and implemented*? (CD-1.4)	
	For establishing and chartering the **Integrated Project Team (IPT)**, is Criterion 2 (Personnel Training and Qualification) being implemented to ensure that: • *policies and procedures that describe personnel selection, training, and qualification requirements are developed and implemented* • *a QA representative is a member of the IPT* (CD-1.5)	

ID #	Performance Objectives and Criteria[2] [3]	Met?
	For conducting design review of the **Conceptual Design**, are the following expectations being implemented? (CD-1.6) • Criterion 2 (Personnel Training and Qualification) to ensure that personnel achieve initial proficiency; maintain proficiency; and adapt to changes in technology, methods, or job responsibilities. • Criterion 4 (Document and Records) *to ensure that processes for preparation, review, approval, issuance, use, and revision of design review documents are described and implemented.* • Criterion 6 (Design) to ensure that: o the design inputs were correctly selected and incorporated; o assumptions necessary to perform the design were adequately described, reasonable, and where applicable, identified as requiring confirmation as the design proceeds; o appropriate design methods, and computer programs when applicable, were used; o design outputs are reasonable compared to design inputs; and o the necessary design inputs from interfacing organizations were specified in the design documents • Criterion 10 (Independent Assessment) to ensure that persons conducting reviews are technically qualified and knowledgeable in the review areas • Criterion 10 to ensure that persons conducting independent reviews have sufficient authority and freedom from line management.	
	For preparing the **Project Data Sheet (PDS)**, is Criterion 4 (Document and Records) being implemented to ensure that: • Processes for preparation, review, approval, issuance, use, and revision of PDS are implemented? and • Processes for specification, preparation, review, approval, and maintenance of records are implemented? (CD-1.7)	
	For **Long-Lead Procurement** approval, are the following expectations being implemented? (CD-1.8) • Criterion 4 (Document and Records) to ensure that processes for specification, preparation, review, approval, and maintenance of records are implemented. • Criterion 5 (Work Processes) *to ensure that work processes consist of a series of actions planned and carried out by qualified personnel using approved procedures, instructions and equipment under administrative, technical, and environmental controls.* • Criterion 7 (Procurement) to ensure that the selection of procurement requirements is commensurate with the importance of the end use of the purchased item or service and that management controls exist for DOE procurement and subcontracts.	

ID #	Performance Objectives and Criteria[2 3]	Met?
	For implementing an **Integrated Safety Management System (ISMS)**, are the following expectations being implemented? (CD-1.9) • Criterion 1 (Program) to ensure that the QA program complements and is integrated with ISMS. • Criterion 1 to ensure that the QA program provides processes and tools for ensuring that ISMS objectives are achieved. • Criterion 5 (Work Processes) *to ensure that work processes consist of a series of actions planned and carried out by qualified personnel using approved procedures, instructions and equipment under administrative, technical, and environmental controls.* • Criterion 5 to ensure that the control of processes, skills, hazards, and equipment are clearly specified, understood, and fully documented.	
	For preparing **Environmental Documents** including National Environmental Policy Act (NEPA) Strategy and Analyses, and Permit Applications, is Criterion 4 (Document and Records) being implemented to ensure that: • Processes for specification, preparation, review, approval, and maintenance of records are implemented? • Procedures, work instructions, or other appropriate means used to define work processes are documented and controlled? • Processes for preparation, review, approval, issuance, use, and revision of documents are implemented? (CD-1.10)	
	For addressing and documenting **High Performance Sustainable Building** design considerations, is Criterion 6 (Design) being implemented to ensure that applicable design inputs are controlled? (CD-1-11)	
	For preparing the **Preliminary Security Vulnerability Assessment Report**, is Criterion 4 (Documents and Records) being implemented to ensure that: • Processes for *specification, preparation, review, approval, and maintenance of records are implemented*? • Processes for preparation, review, approval, issuance, use, and revision of documents are implemented? (CD-1-12)	
	For preparing the **Initial Cyber Security Plan**, is Criterion 5 (Work Processes) being implemented to ensure that: • *Work processes consist of series of actions planned and carried out by qualified personnel using approved procedures, instructions and equipment under administrative, technical, and environmental controls*? • Procedures, work instructions, or other appropriate means used to define work processes are documented and controlled? (CD-1-13)	

ID #	Performance Objectives and Criteria[2] [3]	Met?
	For preparing the **Conceptual Safety Design Report (CSDR)**, are the following expectations being implemented? (CD-1.14) • Criterion 4 (Document and Records) to ensure that processes for preparation, review, approval, issuance, use, and revision of the CSDR are implemented • Criterion 4 to *ensure that processes for specification, preparation, review, approval, and maintenance of records are implemented* • Criterion 6 (Design) to ensure that design processes that provide appropriate control of design inputs, outputs, verification, configuration and design changes, and technical and administrative interfaces are implemented • Criterion 6 to *ensure that processes for verification of design activities are implemented*	
	For preparing the **Preliminary Hazard Analysis Report**, are the following expectations being implemented? (CD-1.15) • Criterion 4 (Document and Records) *to ensure that processes for specification, preparation, review, approval, and maintenance of records are implemented* • Criterion 1 (Program) to ensure that processes (which adequately addresses hazards) for grading the application of requirements are implemented	
	For preparing the **Conceptual Safety Validation Report**, are the following expectations being implemented? (CD-1.16) • Criterion 4 (Document and Records) *to ensure that processes for specification, preparation, review, approval, and maintenance of records are implemented* and followed DOE-STD-1104 • Criterion 6 (Design) *to ensure processes for verification of design activities are implemented and followed* DOE-STD-1104	
	For determining if the **Quality Assurance Program** is acceptable, are the following expectations being implemented? (CD-1.17) • Criterion 1 (Program) to *ensure that the QA program describes the established organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work* • Criterion 1 to *ensure that adequate resources have been identified for quality program activities, such as planning, auditing, supplier qualification, technical document review, inspection, and calibration* • *Ensure that sufficient quality resources are planned and included in project baseline to support quality systems, processes, and procedures required for design work after CD-1 approval.* • Criterion 9 (Management Assessment) *to ensure that managers at every level periodically assess their organizations and functions to determine how well they meet customer and performance expectations and mission objectives, identify strengths or improvement opportunities, and correct problems*	

ID #	Performance Objectives and Criteria[2] [3]	Met?
	For developing the **Safety Design Strategy (SDS)**, are the following expectations being implemented (CD-1.18) • Criterion 4 (Document and Records) to ensure that processes for preparation, review, approval, issuance, use, and revision of the SDS are implemented. • Criterion 4 *to ensure that processes for specification, preparation, review, approval, and maintenance of records are implemented.* • Criterion 5 (Work Processes) *to ensure that work processes consist of series of actions planned and carried out by qualified personnel using approved procedures, instructions and equipment under administrative, technical, and environmental controls?*	
Approval of Performance Baseline		
CD-2	Are the QA activities integrated into the project activities prior to CD-2 approval?	
	GENERAL: *Verify that processes (which adequately addresses hazards) for grading the application of requirements are implemented.*	
	Criterion 5 - Verify that work processes consist of a series of actions planned and carried out by qualified personnel using approved procedures, instructions, and equipment under administrative, technical, and environmental controls.	
	Verify that software quality assurance process implementation is performed in accordance with the Corporate DOE Office of Environmental Management Quality Assurance Program.	
	For establishing the **Performance Baseline**, is Criterion 4 (Document and Records) being implemented to ensure that the processes for document preparation, review, approval, and change control are implemented? (CD-2.1)	
	For updating the **Project Execution Plan**, is Criterion 4 (Document and Records) being implemented to ensure that processes for preparation, review, approval, issuance, use, and revision of documents are implemented? (CD-2.2)	
	For establishing the **Earned Value Management System (EVMS),** is Criterion 4 (Document and Records) being implemented to ensure that the processes for document preparation, review, approval, and change control are implemented? (CD-2.3)	

ID #	Performance Objectives and Criteria[2] [3]	Met?
	For conducting **Performance Baseline Validation** External Independent Review (EIR) or Performance Baseline Validation Independent Project Review (IPR), are the following expectations being implemented? (CD-2.4) • Criterion 4 (Document and Records) to ensure that the processes for document preparation, review, approval, and change control are implemented • Criterion 10 (Independent Assessment) to ensure that the processes to plan and conduct independent reviews, to measure item and service quality and the adequacy of work performance, and to promote improvement are implemented • Criterion 10 to ensure that the persons conducting reviews are technically qualified and knowledgeable in the areas to be reviewed • Criterion 10 to ensure that the persons conducting independent reviews have sufficient authority and freedom from line management	
	For developing **Independent Cost Estimate or Performing Independent Cost Review**, are the following expectations being implemented? (CD-2.5) • Criterion 4 (Document and Records) to ensure that the processes for document preparation, review, approval, and change control are implemented • Criterion 10 (Independent Assessment) *to ensure that the processes to plan and conduct independent reviews, to measure item and service quality and the adequacy of work performance, and to promote improvement are implemented* • Criterion 10 *to ensure that the persons conducting reviews are technically qualified and knowledgeable in the areas to be reviewed* • Criterion 10 *to ensure that the persons conducting independent reviews have sufficient authority and freedom from line management*	
	For determining if the **Quality Assurance Program** is acceptable and continued to apply, are the following expectations being implemented? (CD-2.6) • Criterion 1 (Program) *to ensure that the QA program describes the established organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work* • Criterion 1 to *ensure that adequate resources have been identified for quality program activities, such as planning, auditing, supplier qualification, technical document review, inspection, calibration, etc.* • Criterion 9 (Management Assessment) to ensure that managers at every level periodically assess their organizations and functions to determine how well they meet customer and performance expectations and mission objectives, identify strengths or improvement opportunities, and correct problems	

ID #	Performance Objectives and Criteria[2] [3]	Met?
	For preparing the **Preliminary Design**, are the following expectations being implemented? (CD-2.7) • Criterion 2 (Personnel Training and Qualification) *to ensure that processes are implemented for personnel to achieve initial proficiency; maintain proficiency; and adapt to changes in technology, methods, or job responsibilities* • Criterion 4 (Document and Records) *to ensure that processes for preparation, review, approval, issuance, use, and revision of documents are implemented* • Criterion 4 to *ensure that processes for specification, preparation, review, approval, and maintenance of records are implemented* • Criterion 4 *to ensure that processes for appropriate control of design inputs, outputs, verification, configuration, and design changes and technical and administrative interfaces are implemented.* • Criterion 4 to *ensure that design processes use sound engineering/scientific principles and appropriate standards; incorporate applicable requirements and design bases in design work and design changes; identify and control design interfaces; verify/validate the adequacy of design products using individuals or groups other than those who performed the work; verify/validate work before approval and implementation of the design* • Criterion 4 *to ensure that processes for verification of design activities are implemented*	
	For updating the **Project Data Sheet**, is Criterion 4 (QA Documents and Records) being implemented to ensure that: • Processes for preparation, review, approval, issuance, use, and revision of documents are implemented? • Processes for specification, preparation, review, approval, and maintenance of records are implemented? (CD-2.8)	

ID #	Performance Objectives and Criteria[2] [3]	Met?
	For conducting design review of **Preliminary Design**, are the following expectations being implemented? (CD-2.9) • Criterion 5 (Design) to ensure that: o the design inputs were correctly selected and incorporated o assumptions necessary to perform the design were adequately described, reasonable, and where applicable, identified as requiring confirmation as the design proceeds o appropriate design methods, and computer programs when applicable, were used o design outputs are reasonable compared to design inputs o the necessary design inputs from interfacing organizations were specified in the design documents • Criterion 4 (Documents and Records) to ensure that processes for preparation, review, approval, issuance, use, and revision of documents are implemented • Criterion 10 (Independent Review) to ensure that persons conducting reviews are technically qualified and knowledgeable in the areas to be reviewed • Criterion 10 to ensure that persons conducting independent reviews have sufficient authority and freedom from line management • Criterion 2 (Personnel Training and Qualification) to ensure that personnel achieve initial proficiency; maintain proficiency; and adapt to changes in technology, methods, or job responsibilities	
	For preparing the **Preliminary Safety Design Report**, are the following expectations being implemented? (CD-2.10) • Criterion 4 (Documents and Records) to ensure that processes for preparation, review, approval, issuance, use, and revision are implemented? • Criterion 4 to ensure that processes for specification, preparation, review, approval, and maintenance of records are implemented • Criterion 6 (Design) to ensure that design processes that provide appropriate control of design inputs, outputs, verification, configuration and design changes, and technical and administrative interfaces are implemented • Criterion 6 to ensure that processes for verification of design activities are implemented	
	For updating the **Preliminary Security Vulnerability Assessment Report**, is Criterion 4 (QA Documents and Records) being implemented to ensure that processes for preparation, review, approval, issuance, use, and revision of documents are implemented? (CD-2.11)	
	For updating the **Initial Cyber Security Plan**, is Criterion 4 (Documents and Records) being implemented to ensure that processes for preparation, review, approval, issuance, use, and revision of the Initial Cyber Security Plan are implemented? (CD-2.12)	

ID #	Performance Objectives and Criteria[2] [3]	Met?
	For preparing the **Preliminary Safety Validation Report (PSVR)**, are the following expectations being implemented? (CD-2.13) • Criterion 1 (Program) to ensure that the PSVR follows DOE-STD-1104 • Criterion 4 (Document and Records) to ensure that the processes for preparation, review, approval, issuance, use, and revision of the PSVR are implemented and followed DOE-STD-1104	
	For incorporating **High Performance Sustainable Building** design provisions into Preliminary Design and Design Review, is Criterion 6 (Design) being implemented to ensure that the applicable design inputs are controlled? (CD-2.14)	
	For finalizing and obtaining approval of **NEPA** documentation, is Criterion 4 (Documents and Records) being implemented to ensure that processes for preparation, review, approval, issuance, use, and revision of the NEPA documents are implemented? (CD-2.15)	
Approval of Start of Construction		
CD-3	Are the QA activities integrated into the project activities being implemented for CD-3 approval for start of construction?	
	GENERAL: Criterion 4 Verify that processes for preparation, review, approval and issuance, use and revision of documents that prescribe processes requirements and designs are implemented.	
	Verify that processes (which adequately addresses hazards) for grading the application of requirements are implemented.	
	Criterion 4 - Ensure that the processes for specification, preparation, review, approval, and maintenance of records are implemented	
	Verify that suspect/counterfeit item process prevention is developed and implemented in accordance with the Corporate DOE Office of Environmental Management Quality Assurance Program.	

ID #	Performance Objectives and Criteria[2] [3]	Met?
	For activities regarding to completing and reviewing the **Final Design** or determining if the design is sufficiently mature to start procurement or construction, are the following expectations being implemented? (CD-3.1) • Criterion 2 (Personnel Training and Qualification) *to ensure that processes are implemented for personnel to achieve initial proficiency; maintain proficiency; and adapt to changes in technology, methods, or job responsibilities* • Criterion 6 (Design) to ensure that applicable design inputs are controlled • Criterion 6 to *Verify that design inputs (such as design bases, conceptual design reports, performance requirements, regulatory requirements, codes and standards) are controlled and documented and changes from approved design inputs and reasons for the changes are identified, approved, documented and controlled.* • Criterion 6 to ensure that processes for conducting design reviews are implemented to ensure that: o the design inputs were correctly selected and incorporated; o assumptions necessary to perform the design were adequately described, reasonable, and where applicable, identified as requiring confirmation as the design proceeds; o appropriate design methods, and computer programs when applicable, were used; design outputs are reasonable compared to design inputs; and o the necessary design inputs from interfacing organizations were specified in the design documents • Criterion 6 to ensure that design processes: o *use sound engineering/scientific principles and appropriate standards;* o *incorporate applicable requirements and design bases in design work and design changes;* o *identify and control design interfaces;* o *verify/validate the adequacy of design products using individuals or groups other than those who performed the work; and* o *verify/validate work before approval and implementation of the design* • Criterion 6 to ensure that processes for verification of design activities are implemented	
	For activities regarding the **updating of CD-2 project management documents** (including PEP, Performance Baseline, Risk Management, etc), is Criterion 4 (Documents and Records) being implemented to ensure that: • processes for preparation, review, approval, issuance, use, and revision of the project management documents are implemented? • processes for document preparation, review, approval, and change control are implemented? (CD-3.2)	

ID #	Performance Objectives and Criteria[2] [3]	Met?
	For performing **independent review** for construction readiness and readiness assessment, is Criterion 10 (Independent Assessment) being implemented to ensure that: • *processes to plan and conduct independent reviews, to measure item and service quality and the adequacy of work performance, and to promote improvement are implemented*? • *persons conducting reviews are technically qualified and knowledgeable in the areas to be reviewed*? • *persons conducting independent reviews have sufficient authority and freedom from line management*? (CD-3.3)	
	For preparing the **Preliminary Documented Safety Analysis (PDSA),** are the following expectations being implemented? (CD-3-4) • Criterion 1 (Program) to ensure that the PDSA follows the guidance of DOE-STD-1189 and DOE-STD-3009? • Criterion 1 *to ensure that the processes for specification, preparation, review, approval, and maintenance of records are implemented*? • Criterion 4 (Document and Records) to ensure that processes for preparation, review, approval, issuance, use, and revision of the PDSA are implemented? • Criterion 6 (Design) to ensure that design processes that provide appropriate control of design inputs, outputs, verification, configuration and design changes, and technical and administrative interfaces are implemented?	
	For updating the **Security Vulnerability Assessment Report**, is Criterion 4 (Documents and Records) being implemented to ensure that processes for preparation, review, approval, issuance, use, and revision of the Security Vulnerability Assessment Report are implemented? (CD-3.5)	
	For updating the **Cyber Security Plan**, is Criterion 4 (Documents and Records) being implemented to ensure that: • processes for preparation, review, approval, issuance, use, and revision of the Cyber Security Plan are implemented? • process for specification, preparation, review, approval, and maintenance of records are implemented? (CD-3.6)	
	For preparing the **Safety Evaluation Report (SER)**, are the following expectations being implemented? (CD-3.7) • Criterion 1 (Program) to ensure DOE-STD-1104 guidance are met? • Criterion 4 (Documents and Records) to ensure that processes for preparation, review, approval, issuance, use, and revision of the SER are implemented? • Criterion 4 to ensure that process for specification, preparation, review, approval, and maintenance of records are implemented?	

ID #	Performance Objectives and Criteria[2] [3]	Met?
	For preparing the **Construction Project Safety and Health Plan**, is Criterion 4 (QA Documents and Records) being implemented to ensure that processes for preparation, review, approval, issuance, use, and revision of the plan are implemented? (CD-3.8)	
	For incorporating the final **High Performance Sustainable Building** design provisions into the Final Design, is Criterion 6 (Design) being implemented to ensure that applicable design inputs are controlled? (CD-3.9)	
	In updating the **QAP** for construction, field design changes and procurement activities, are the following expectations being implemented? (CD-3.10) • Criterion 1(Program) to ensure that the QA program describes the established organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work • Criterion 9 (Management Assessment) t*o ensure that managers at every level are periodically assessing their organizations and functions to determine how well they meet customer and performance expectations and mission objectives, identify strengths or improvement opportunities, and correct problems*	
Approval of Start of Operations and Project Completion		
CD-4	Are the QA activities integrated into the project activities prior to CD-4 approval and into post-CD-4 activities?	
	GENERAL: Verify that processes for preparation, review, approval, issuance, use and revision of documents that prescribe processes, requirements, and design are implemented (including change control for revision).	
	to ensure that actions are planned and carried out by qualified personnel using approved procedures, instructions, and equipment under administrative, technical, and environmental controls	
	Verify that design processes that provide appropriate control of design inputs, outputs, verification, configuration and design changes, and technical and administrative interfaces are implemented.	
	When verifying **Key Performance Parameters or Project Completion Criteria** have been met and mission requirements achieved, are the following expectations being implemented? (CD-4.1) • Criterion 3(Quality Improvement) *to ensure that processes to identify, control, and correct items, services, and processes that do not meet established requirements are implemented* • Criterion 5 (Work Processes) *to ensure that work is performed consistent with technical standards, administrative controls, and hazard controls adopted to meet regulatory or contract requirements using approved instructions, procedures, etc.*	

ID #	Performance Objectives and Criteria[2] [3]	Met?
	When conducting **Readiness Assessment or Operational Readiness Review**, are the following expectations being implemented? (CD-4.2) • Criterion 3(Quality Improvement) *to ensure that processes to identify, control, and correct items, services, and processes that do not meet established requirements are implemented* • Criterion 5 (Work Processes) *to ensure that the planned scope of work demonstrates that work prerequisites have been satisfied, personnel have been suitably trained and qualified, detailed implementing documents and management controls are available and approved* • Criterion 10 (Independent Assessment) to *ensure that persons conducting reviews are technically qualified and knowledgeable in the areas to be reviewed*	
	For preparing the **Checkout, Testing, and Commissioning Plan**, are the following expectations being implemented? (CD-4.3) • Criterion 4 (Documents and Records) to ensure that processes for preparation, review, approval, issuance, use, and revision of the plan are implemented • Criterion 8 (Inspection and Acceptance Testing) *to ensure that performance expectations, acceptance criteria, inspections and tests, and hold points, and calibration of measuring and testing equipment are addressed*	
	For preparing the **Project Transition to Operations Plan,** are the following expectations being implemented? (CD-4.4) • Criterion 1 (Program) to ensure that processes to implement a quality management approach are established and implemented • Criterion 4 (Documents and Records) to ensure that processes for preparation, review, approval, issuance, use, and revision of the plan are implemented	
	For preparing the updated **Quality Assurance Plan (QAP)**, are the following expectations being implemented? (CD-4.5) • Criterion 1 (Program) *to ensure that processes to implement a quality management approach are established and implemented* • Criterion 4 (Documents and Records) to ensure that processes for preparation, review, approval, issuance, use, and revision of the QAP are implemented • *Verify that the QA program describes the established organizational structure, functional responsibilities, levels of authority and interfaces for those managing, performing and assessing the work.* • *Verify the process to implement a quality management approach are established and implemented.* • *Determine that sufficient quality resources are planned and included in the project baseline to support quality systems, processes, and procedures required for design work after CD-1 approval.*	

ID #	Performance Objectives and Criteria[2] [3]	Met?
	For preparing the **Environmental Management System (EMS),** are the following expectations being implemented? (CD-4.6) • Criterion 4 (Documents and Records) to ensure that processes for preparation, review, approval, issuance, use, and revision of the EMS are implemented • Criterion 5 (Work Processes) *to ensure that actions are planned and carried out by qualified personnel using approved procedures, instructions, and equipment under administrative, technical, and environmental controls*	
	For preparing the **Documented Safety Analysis (DSA) and Technical Safety Requirements (TSR),** are the following expectations being implemented? (CD-4.7) • Criterion 4 (Documents and Records) to ensure that processes for preparation, review, approval, issuance, use, and revision of the DSA and TSR documents are implemented • Criterion 6 (Design) to ensure that applicable design inputs are controlled	
	For preparing the updated **Construction Project Safety and Health Plan**, are the following expectations being implemented? (CD-4.8) • Criterion 4 (Documents and Records) to ensure that processes for preparation, review, approval, issuance, use, and revision of the plan are implemented • Criterion 5 (Work Processes) to ensure that actions are planned and carried out by qualified personnel using approved procedures, instructions, and equipment under administrative, technical, and environmental controls	
	For preparing the final **Security Vulnerability Assessment Report,** is Criterion 4 (Documents and Records) being implemented to ensure that processes for preparation, review, approval, issuance, use, and revision of the report are implemented? (CD-4.9)	
	For preparing the final **Cyber Security Plan**, is Criterion 4 (Documents and Records) being implemented to ensure that: • processes for preparation, review, approval, issuance, use, and revision of the plan are implemented? • *processes for specification, preparation, review, approval, and maintenance of records are implemented*? (CD-4.10)	
	For preparing the **Safety Evaluation Report (SER)**, are the following expectations being implemented? (CD-4.11) • Criterion 4 (Documents and Records) to ensure that processes for preparation, review, approval, issuance, use, and revision of the SER are implemented • Criterion 5 (Work Processes) to ensure that actions are planned and carried out by qualified personnel using approved procedures, instructions, and equipment under administrative, technical, and environmental controls	

ID #	Performance Objectives and Criteria[2] [3]	Met?
	For performing **Final Administrative and Financial Closeout** and preparing the **Final Project Closeout Report,** are the following expectations being implemented? (CD-4.12) • Criterion 3 (Quality Improvement) to ensure that organization has established, implemented, and documented processes to detect and prevent quality problems and that problems have been corrected • Criterion 4 (Documents and Records) to ensure that processes for preparation, review, approval, issuance, use, and revision of the documents are implemented	
	For preparing **the Lessons Learned Report,** are the following expectations being implemented? (CD-4.13) • Criterion 3 (Quality Improvement) *to ensure that processes to detect and prevent quality problems are implemented* • Criterion 4 (Documents and Records) to ensure that processes for specification, preparation, review, approval, and maintenance of records are implemented	
	For preparing the **Project Required Operational Documentation**, is Criterion 4 (QA Documents and Records) being implemented to ensure that processes for specification, preparation, review, approval, and maintenance of records are implemented? (CD-4.14)	
	For conducting **Post Implementation Review,** is Criterion 9 (Management Assessment) being implemented to ensure that processes to plan and conduct reviews to measure item and service quality and the adequacy of work performance and to promote improvement are implemented? (CD-4.15)	

Top 20 Quality Assurance Issues and Priorities Identified in 1st Corporate Board Meeting in March, 2008

1. Requirements flowdown
    a. Direction
    b. Execution
    c. Communication
    d. Verification
2. Adequate NQA-1 suppliers (the numbers are going down)
3. Commercial Grade Dedication - implementation
4. Graded approach to quality – implementation
5. Federal understanding of QA and Oversight
6. Resources – benchmark industry
7. Procedural compliance/execution
8. FY09 budget impacts
9. Science is moving to ISO 9000: creates inconsistency between NQA-1 for feds and ISO-9000 for contractors
10. Design QA
11. Effectiveness of corrective actions regarding human performance
12. Vendor issues
13. Supplier Quality Assurance
14. GFSI communications/interface agreements/MOA
15. Production pressures
16. Consistent application of regulations/requirements, and consistent interpretations
17. Inspector training/mentoring and understanding inspector expectations. (Note: There was discussion on contractor assurance and inconsistency in how this is applied at different EM sites)
18. Regulatory and oversight reviews come in waves (stacked reviews) – there is a need for coordination or possibly an integrated project team for these activities.
19. Scope creep – function of new of revised standards, codes, requirements etc
20. Qualified Supplier (combined with item #2 above)

Department of Energy
Washington, DC 20585

FEB 2 5 2009

MEMORANDUM FOR DISTRIBUTION

FROM: INÉS R. TRIAY
ACTING ASSISTANT SECRETARY FOR
ENVIRONMENTAL MANAGEMENT

SUBJECT: Safety of Work Created Under the American Recovery and Reinvestment Act

Under the American Recovery and Reinvestment Act (ARRA), the Environmental Management (EM) program has an unprecedented opportunity to accelerate cleanup activities and to reduce our site footprint, risk and future costs, while generating meaningful jobs for over 12,000 workers. The purpose of this memorandum is to focus attention on keeping these new workers and operations, as well as our current workers, safe as we take advantage of the opportunities afforded under the ARRA.

As important as it is to expedite the start of these ARRA related work activities, it is even more important for us to ensure this work surge is planned and conducted to meet the high safety standards and performance expected within EM. Safety must be integral and robust from the beginning of this effort. Poor safety performance due to inadequate safety infrastructure, immature safety management programs, inadequate safety training or the lack of work planning will not be acceptable or tolerated.

While our current EM safety performance has been very good in relation to comparable private construction and waste remediation industries (Attachment 1), the EM injury/illness rates increased in Calendar Year 2008 after a long period of annual improvement (Attachment 2). Last fall, we encouraged you and your contractors to identify and implement "breakthrough strategies" in your Integrated Safety Management (ISM) efforts in order to again show improvement in individual contractor performance where needed and in the overall EM safety performance.

To help us meet these safety expectations, I expect that you and your contractors establish and implement a self-assessment process that would provide a high level of assurance that any new or significantly increased work load under the ARRA is demonstrably ready from a safety perspective prior to conducting the work. Attributes of contractor readiness would include, but not be limited to:

- ISM systems and safety management programs cover new or enhanced work;
- Safety and quality assurance requirements are included in sub-tier or indefinite delivery/indefinite quantity contracts and that sub-tier contractors have successfully submitted and/or met all safety and quality assurance contract deliverables;
- New workers are fully trained and have met occupational medical screening/surveillances as required by safety rules and standards, and that they fully understand Department of Energy and EM work and safety expectations;
- Contractors provide rigorous day-to-day oversight of sub-tier contractor work and provide mentoring where needed to ensure subcontractors are fully prepared to conduct the work safely;
- Nuclear/radiological material or waste can be safely packaged and transported when included in the work scope; and
- Safety performance metrics for new and enhanced work is tracked and reported separately in the contractor's Quarterly Safety/Recurring Event Analysis reports per DOE Order 210.2, DOE Corporate Operating Experience Program.

Field managers are to reevaluate resources (subject matter experts, project controls staff, and safety and operations oversight personnel) necessary to provide line oversight of the new or increased workload contractor work, including additional shift work, prior to the conduct of the work. Augmentation by government support service contractors or qualified staff from the EM Consolidated Business Center should be considered, if necessary, to ensure timely oversight support to the ARRA related work.

By March 12, 2008, please provide Mr. Dae Chung, Deputy Assistant Secretary for Safety Management and Operations and Ms. Cynthia Anderson, ARRA Program Manager, your contractor ARRA activity readiness self-assessment plans and your Federal resource plan to provide adequate oversight for the new or increased work activities.

The Office of Safety Management and Operations will perform targeted reviews of these self-assessment efforts and independent onsite assessments of the sites' ability to conduct ARRA related work safely.

If you have any further questions regarding this issue, please contact Mr. Chung, at (202) 586-5151.

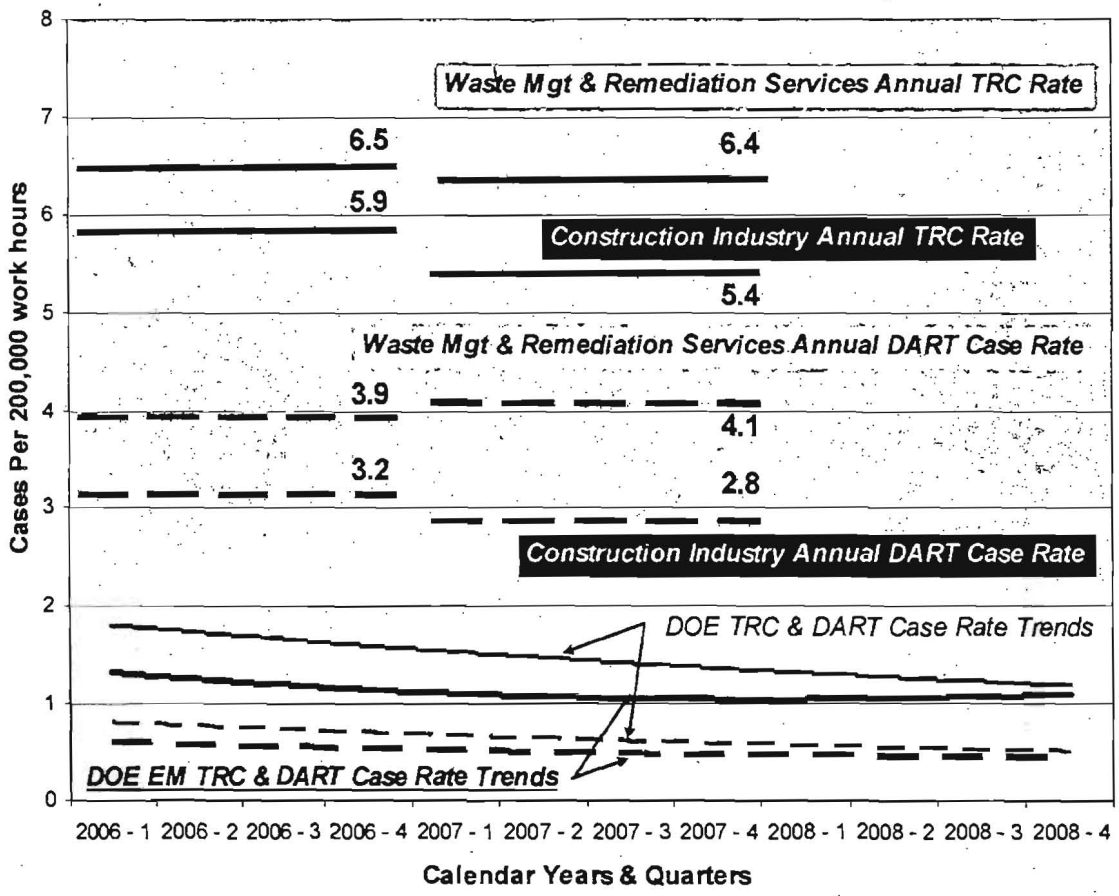
Attachments

DISTRIBUTION

David A. Brockman, Manager, Richland Operations Office (RL)
Shirley Olinger, Manager, Office of River Protection (ORP)
Jeffrey M. Allison, Manager, Savannah River Operations Office (SR)
David C. Moody, Manager, Carlsbad Field Office (CBFO)
William E. Murphie, Manager, Portsmouth/Paducah Project Office (PPPO)
Jack Craig, Director, Consolidated Business Center (CBC)
Dennis Milota, Acting Manager, Idaho Operations Office (ID)
Gerald Boyd, Manager, Oak Ridge Office (OR)

cc:
J. Owendoff, EM-3
C. Anderson, EM-3
F. Marcinowski, EM-10
M. Gilbertson, EM-20
M. Sykes, EM-30
D. Cochran, EM-40
J. Surash, EM-50
D. Chung, EM-60
R. Provencher, ID
S. McCracken, OR
B. Smith, EM-3.2
M. Moore, EM-3.3
F. Lockhart, EM-51
T. Vero, BNL
R. Schassburger, OAK
J. Rampe, SPRU
B. Bower, WVDP
D. Metzler, MOAB

DOE / EM / Construction & Waste Disposal Industry Standards - TRC & DART Case Comparisons



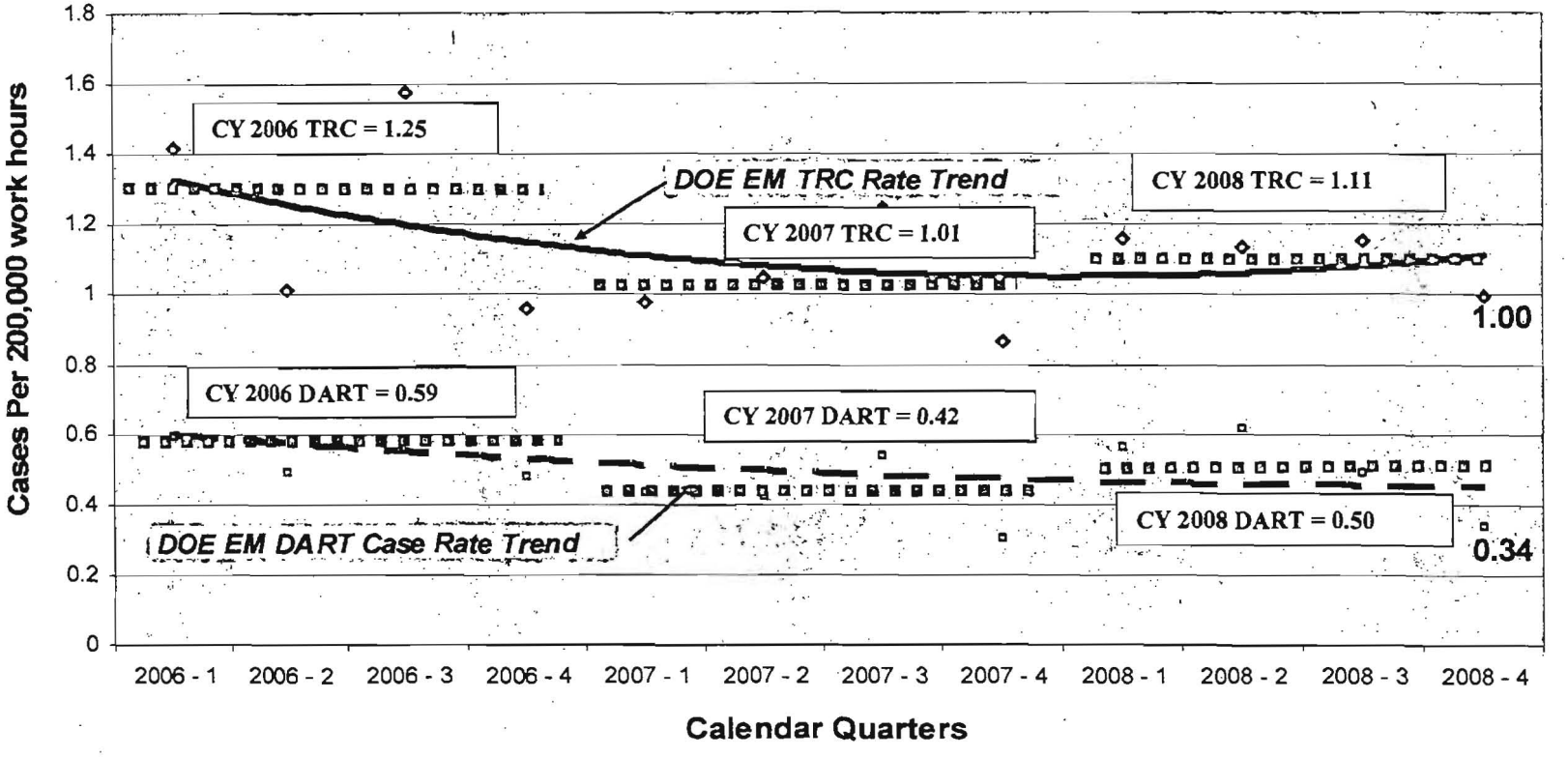
DART Case: Lost Work Days Cases - Days Away from work, Restricted or on job Transfer (DART) case rate per 200,000 work hours.
TRC: Occupational Injury Safety – Total Recordable Case (TRC) rate per 200,000 work hours.

**This DOE data is collected in the Computerized Accident& Injury Reporting System (CAIRS).. Data as of February, 12 2009.*

***Industry rates taken from NAICS code 23 and 562 of the Bureau of Labor Statistics 2007 Industry Injury and Illness Data*

Attachment 1

EM TRC & DART Case Rate Trends



DART Case: Lost Work Days Cases - Days Away from work, Restricted or on job Transfer (DART) case rate per 200,000 work hours.
TRC: Occupational Injury Safety – Total Recordable Case (TRC) rate per 200,000 work hours.

Attachment 2

Department of Energy
Washington, DC 20585

AUG 2 1 2009

MEMORANDUM FOR DISTRIBUTION

THROUGH: JAMES M. OWENDOFF
CHIEF OPERATIONS OFFICER FOR
ENVIRONMENTAL MANAGEMENT

FROM: J. E. SURASH 8/21/2009
DEPUTY ASSISTANT SECRETARY FOR
ACQUISITION AND PROJECT MANAGEMENT

SUBJECT: New Quality Assurance (QA) Clause for Work Affecting Nuclear Safety

The success of the Office of Environmental Management (EM) depends upon the extent of its products and services to satisfy customer requirements and expectations. By a memorandum dated November 5, 2008, Dr. Inés Triay, as Principal Deputy Assistant Secretary, approved the issuance and implementation of the *EM Quality Assurance Program* (EM-QA-001, Revision 0, 10/20/2008) (EM-QAP). EM-QA-001 (EM-QAP) adopts the ASME NQA-1-2004 *Quality Assurance Requirements for Nuclear Facility Applications* and addenda through 2007 as the national consensus standard to facilitate consistent implementation of quality assurance across all of EM's activities and projects. Requirements of the EM QAP are applied in a graded fashion commensurate with the type and importance of work being performed. It is expected that the requirements of DOE O 414.1C "*Quality Assurance*" and 10 CFR 830, Subpart A "*Quality Assurance Requirements*" will be met though implementation of the EM QAP.

The EM QAP focuses on customer requirements and expectations, embraces continuous improvement and ensures work is performed correctly. The EM QAP reflects industry experience and current understanding of the quality assurance requirements for establishing and executing quality assurance programs during siting, design, construction, operation and decommissioning of nuclear facilities affecting nuclear safety. In order to implement the EM QAP as a part of the Contractor's Quality Program, the attached Section H clause entitled "Quality Assurance (QA) Work Affecting Nuclear Safety," is required to be included in all new contracts awarded after October 1, 2009, that deal with work affecting nuclear safety.

If you have questions, please contact Mike Howard, Director, Office of Procurement Planning, at (202) 586-8162 or Sandra Waisley, Director, Office of Standards and Quality Assurance, at (202) 586-3087.

Attachment

cc:
Dae Chung, Deputy Assistant Secretary for Environmental Management, EM-2
Frank Marcinowski, Deputy Assistant Secretary for Regulatory Compliance, EM-10
Mark A. Gilbertson, Deputy Assistant Secretary for Engineering and Technology, EM-20
Merle Sykes, Deputy Assistant Secretary for Program Planning and Budget, EM-30
Diane Cochran, Deputy Assistant Secretary for Human Capital and Business Services, EM-40
Steven L. Krahn, Acting Deputy Assistant Secretary for Safety Management and Operations, EM-60
Thad T. Konopnicki, Associate Administrator for Infrastructure and Environment, NA-50
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Gerald Boyd, Manager, Oak Ridge Office (OR)

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Richard Schassburger, Director, Oakland Projects Office
John Rampe, Director, Separations Process Research Unit (SPRU)
Bryan Bower, Director, West Valley Demonstration Project Office (WVDP)
Donald Metzler, Director, Moab Federal Project Office (MOAB)
Richard B. Provencher, Deputy Manager, Idaho Operations Office (ID)
Steve McCracken, Assistant Manager, Oak Ridge Office (OR)

QUALITY ASSURANCE (QA) FOR WORK AFFECTING NUCLEAR SAFETY

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

EM requires that American Society of Mechanical Engineers (ASME) NQA-1, 2004, *Quality Assurance Requirements for Nuclear Facility Applications*, and addenda through 2007 be implemented as part of the Contractor's QA Program for work affecting nuclear safety. The required portions of NQA-1 to be implemented include: Introduction, Part I, and as applicable portions of Part II. NQA-1 Parts III and IV are to be used as guidance for the Contractor's QAP and implementing procedures.

Contractors have three options for complying with this contract requirement:

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

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

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

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

The Contractor shall, at a minimum, annually review and update as appropriate, their QAP. The review and any changes shall be submitted to DOE for approval. Changes shall be approved before implementation by the Contractor.

Department of Energy
Washington, DC 20585

AUG 2 4 2009

MEMORANDUM FOR DISTRIBUTION

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

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

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

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

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

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

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

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

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

Attachment

cc:
I. Triay, EM-1
D. Chung, EM-2
C. Anderson, EM-2.1
J. Owendoff, EM-3
B. Smith, EM-3.2
D. Crouther, EM-3.3
J. Fiore, EM-5/6
F. Marcinowski, EM-10
M. Gilbertson, EM-20
M. Sykes, EM-30
D. Cochran, EM-40
J. Surash, EM-50
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Dennis Miotla, Acting Manager, Idaho Operations Office (ID)
Gerald Boyd, Manager, Oak Ridge Office (OR)

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

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

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