10TH EM QUALITY ASSURANCE CORPORATE BOARD MEETING

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10th EM QUALITY ASSURANCE CORPORATE BOARD MEETING (VIDEO CONFERENCE)

Meeting Location: ***U.S. Department of Energy – Washington DC, Forrestal Building Video Conference***		
Room: ***Video Conference with Site Offices***		
Agenda for July 21, 2011		
10 minutes	Welcome, Agenda and any High Priority Issues • Minutes from the Last Meeting • Outstanding Actions • Measurement Indicator for Goal #5 of the Journey to Excellence • Team leads for new Focus Areas on training resources	Jim Hutton (Acting EM-20) Larry Perkins (EM-23)
10 minutes	Issuance of DOE O 414.1D and how it affects our sites including any potential revision/modification to the corporate EM QAP (EM-QA-001)	Bob Murray (EM-23)
15 minutes	Presentation and Discussion on EM CGD Guidance Document deliverable from Focus Area #2	Pat Carier (ORP) Debbie Sparkman (CNS)
-----	Board Vote on endorsement of the guidance document	*Role Call*
15 minutes	Presentation and Discussion on Integration of QA in Design guidance document deliverable from Focus Area #4	Butch Huxford (EM-23)
-----	Board Vote on endorsement of the guidance document	*Role Call*
10 minutes	Discussion on revised QA contract language	All
-----	Board vote on revised QA contract language	*Role Call*
15 minutes	Operational Awareness - Basic QA Profile Associated with EM Hazard Category 2 and 3 Nuclear Operations	Bob Toro (EM-23)
15 minutes	Group Discussion of the EFCOG Current Efforts and Relationship to the EM QA Corporate Board Priorities and Focus Areas	Mike Mason (EFCOG)
-----	General Discussion Topics: • Next meeting • Others TBD	ALL

10TH EM QUALITY ASSURANCE CORPORATE BOARD MEETING

Presentations

10TH EM QUALITY ASSURANCE CORPORATE BOARD MEETING

U.S. DEPARTMENT OF ENERGY

10th EM QA Corporate Board Meeting

Introduction and High Priority Issues

Jim Hutton, Acting Deputy Assistant Secretary
Safety and Security Program, EM-20

and

Larry Perkins, Quality Assurance
Office of Standards and Quality Assurance, EM-23

July 21, 2011

EM Environmental Management
safety ❖ performance ❖ cleanup ❖ closure

FCOG *Energy Facility Contractors Group*

Agenda

- Welcome, Outstanding Actions, and other High Priority Issues
- Issuance of DOE O 414.1D - How it Affects EM Sites
- Commercial Grade Dedication Guidance Document
- Integration of QA in Design Guidance Document
- Draft Revision to the Standard QA Contract Language
- Operational Awareness – Basic QA Profile
- EFCOG Current Efforts & Relationship to the EM QA Corporate Board Priorities & Focus Areas
- General Discussion

Outstanding Actions

#	Action for Follow-Up	Individual Responsible	Current Status
1.	Provide a revised lesson learned document based on previous events surrounding Commercial Grade Dedication.	Linda Weir (BNI)	**Complete** Based on the information provided in the original lessons learned document, there does not appear to be a need to issue a revision. All of the relevant information was captured previously.
2.	Update the project plan to include new information.	Larry Perkins (EM-23)	**Complete** Project plan has been updated and ready for signature following the July 2011 meeting.
3.	Notify the EFCOG chair when the JSEP is ready to populate and the EFCOG chair will send a letter to member encouraging its use.	Christian Palay (EM-23) Joe Yanek (EFCOG)	**Pending** This action will follow the completion of the JSEP milestones.
4.	EM Corporate Board members should provide recommendations on how to report the status of the Goal #5 metrics in the Journey to Excellence.	EM Corporate Board Members	**Complete** A position/recommendation paper was developed in coordination with the field QA Managers. That paper has been provided for EM-20 review and submittal to EM-1/2/3.
5.	Provide the updated QA contract language for review/vote.	Bob Murray (EM-23)	**Complete – Vote Pending** Contract language has been revised to incorporate information from the electronics S/CI memorandum.

Outstanding Actions

#	Action for Follow-Up	Individual Responsible	Current Status
6.	Work with the sites to develop a summary report of recent assessments (e.g., last 6 months) to address flow-down	EM Corporate Board Members Bob Murray (EM-23)	**Complete** Information was provided from each site and reviewed by EM-23 staff. A discussion of that review was included in a recent letter to the DNFSB and the information will also be evaluated for future assessment schedules.
7.	Evaluate whether the EFCOG efforts on QA metrics can be combined with the needs of EM.	Larry Perkins (EM-23)	**Pending** EM-23 is working with HSS on a similar effort in the Quality Council and will discuss efforts with EFCOG team leads based on the presentations provided in the June 2011 meeting.
8.	Realign Focus Area #1 to investigate the integration of EM and NNSA efforts.	Mike Mason (BNI) Christian Palay (EM-23)	**Complete** Based on the last Board meeting, the focus of the team was adjusted. This is reflected in the update Project Plan.
9.	Provide a resolution to the comments on the CGD guidance.	Dennis Weaver (BNI) Pat Carier (ORP)	**Complete** Comments have been resolved and the guidance document is ready for distribution and Board vote.

Outstanding Actions

#	Action for Follow-Up	Individual Responsible	Current Status
10.	Change the CGD Guidance Task deliverable to a "Guide" and not a "Standard".	Pat Carier (ORP)	**Complete** The team has made the change in the document and it is reflected in the Project Plan.
11.	Base CGD guidance on NQA-1a-2009 with appropriate notations made where that version differs from NQA-1-2004 with addenda through 2007. Include a note that the basis for the guidance is not intended to alter any contractual requirements.	Dennis Weaver (BNI) Pat Carier (ORP)	**Complete** Comments have been resolved and the guidance document is ready for distribution and Board vote.
12.	Distribute the draft Design QA paper to the Corporate Board for review.	Butch Huxford (EM-23)	**Complete** Planned to be distributed as part of July 2011 meeting.
13.	Investigate EM participation on 413 development team.	Butch Huxford (EM-23)	**Complete** OECM is in the process of updating the DOE 413.3 series guides to conform with the issuance of DOE O 413.3B. EM-23 was provided an advance copy before entering the documents in REVCOM.
14.	Investigate the use of the lessons learned process with HSS or have the HSS website link to our QA website for distributing the corporate board deliverables.	Bob Murray (EM-23) Larry Perkins (EM-23)	**Complete** The EM QA website has been updated. Lessons learned from the QA Summit are posted on the website. The link from the HSS webpage is still being considered.

Outstanding Actions

#	Action for Follow-Up	Individual Responsible	Current Status
15.	Develop a Focus Area Team to address the September 13, 2010, commitment to the Board to develop a task team to determine if there is a shortage of QA/QC resources within EM (consider a follow up in 9 months).	TJ Jackson (EMCBC) Bob Murray (EM-23)	**Complete** Initial team has been developed and a team lead will be finalized in the July 2011 meeting.
16.	Develop a Focus Area Team to evaluate and assess the current strategy for EM QA/QC training and provide a recommended path forward.	TJ Jackson (EMCBC) Bob Murray (EM-23)	**Complete** Initial team has been developed and a team lead will be finalized in the July 2011 meeting.
17.	Distribute a copy of the most recent EM-23 assessment schedule.	Bob Toro (EM-23)	**Complete** This document has been provided to the sites via memo from EM-2.
18.	Provide a discussion at the next meeting of the latest list of issues that were prioritized for the Corporate Board.	Larry Perkins (EM-23)	**Complete** Included in the Corporate Board meeting materials for discussion.
19.	Ask HSS to provide a status of the DOE O 414.1D revision at the next meeting.	Bob Murray (EM-23)	**Complete** DOE O 414.1D presentation will be provided by EM-23 at the July 2011 meeting.
20.	Ask EFCOG to provide a status and list of issues they are currently working at the next meeting.	Larry Perkins (EM-23)	**Complete** Included in the Corporate Board meeting materials for discussion.

Journey to Excellence – Goal #5 Performance

- EM-2 Memorandum to the Site Managers on June 9, 2011
  - Measurement will only apply to Safety Class or Safety Significant systems (including software).
  - The performance element should be modified to the following: *Ensure that at least 95% of the safety class and safety significant equipment/software installed during the fiscal year is not defective, suspect, or counterfeit.*
  - The performance measurement for this goal can be measured using either of two measurement methods
- Site QA Managers should coordinate with EM-23 to ensure the monthly status reports for this measurement are up to date.
- An example calculation for the metric has been prepared by the Idaho office and distributed via email and the meeting materials.
- EM will re-evaluate the performance indicator at the end of the performance period to determine if any modifications are needed.

Focus Area #4 and Focus Area #5 Support

- EM Consolidated Business Center Staff have been working to begin the efforts for Focus Areas #4 and #5
- Team Leads have not been identified
- Focus Area #4 - Evaluation of QA/QC Resources
  - DOE Lead – *Needs to be identified today*
  - EFCOG Lead – Mike Nicol (Isotek)
- Focus Area #5 - Strategy for EM QA/QC Training
  - DOE Lead – *Needs to be identified today*
  - EFCOG Lead – *Needs to be identified today*

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Issuance of DOE O 414.1D
How it Affects EM Sites

Bob Murray, Office Director
Office of Standards and Quality Assurance, EM-23

July 21, 2011

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Implementation of DOE Order 414.1D

- Revision approved in April 2011
- Changes in the Order do not represent a material impact in the QA regulatory framework established as part of EM-QA-001
- Memorandum to the Field Offices from EM-2 will discuss the implementation of DOE O 414.1D within EM
  - Each Field Office is implementing a QA program approved by EM-1. Until EM-QA-001 is updated, the Field Office does not need to make any changes.
  - Once EM-QA-001 is updated, each EM Field Office should update their QAPs/QIPs as soon as reasonably possible.
  - For EM contractors, the issuance of this Order and the cancellation of the previous revision do not modify or otherwise affect an approved contractual or regulatory obligation.

Key Changes in DOE Order 414.1D

- HSS has provided a listing of key changes in the Order (see attachment to the EM-2 memorandum) and may be consulted regarding results of any gap analysis conducted

- Changes of specific interest to EM include:

  – For construction projects, continue to use the consensus standard cited in the current DOE-approved QA Program if Critical Decision-1 has already been achieved

  – For construction projects, implement NQA-1-2008 with the 2009 addenda (or a later edition) if Critical Decision-1 has not yet been achieved. Equivalent standards may be used if properly documented.

  – Once a construction project moves into the commissioning phase, re-evaluation of the standard referenced in the QAP against the Order will be conducted, addressing any gaps

Key Changes in DOE Order 414.1D *(continued)*

- Changes of specific interest to EM include: (continued)
  - For operating projects, work will continue to the Code of Record with any gaps between the existing QA Program and DOE Order O 414.1D documented.
  - Clarification was added that the requirements of NQA-1-2008 with the 2009 addenda (or later edition) should be used to acquire, develop, and implement safety software. There are no new safety software requirements in this Order for existing projects.
  - DOE-approved QAPs applicable to safety software based on requirements from DOE Order O 414.1C are acceptable.

Revision to EM-QA-001

- EM-QA-001 was issued in 2008
- Field Offices have completed implementation of the requirements and expectations of EM-QA-001 as evidenced by the Phase II self-assessments
- EM-HQ has completed implementation of the requirements and expectations of EM-QA-001 and is in the process of finalizing the Phase II self-assessment report
- Recommendation: EM QA Corporate Board charter a Focus Area to provide suggested changes to EM-QA-001 to ensure integration of DOE Order 414.1D

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Commercial Grade Items and Services Dedication

Pat Carier, Office of River Protection
Debbie Sparkman, Office of the Chief of Nuclear Safety

July 21, 2011

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Today's presentation

- Provide update on CGD activities since last meeting
  - CGD Training
  - Update to Training Material
  - CGD Guide revision to include dedication of software
  - Quality Council activities
- Request Vote on Revised Guide
- Update on CGD tasks.

CGD Training Provided

- Held three additional CGD training sessions
  - Trained a total of XXX Federal and Contractor Employees and issued certificates of completion
  - Training continues to be well received
  - Average scores from post course exam
  - Used revised training that included Software QA

CGD Training Material

- Incorporates Guide comment resolution
- Includes Software QA
- Includes lessons learned from teaching classes

CGD Guide Content Refresher

- The standard includes the following information:
  - Definitions
  - CGD Overview of the Generic Process
  - Technical Evaluation (content)
  - Four Methods of Acceptance
  - Sampling Plans and Lot Formation
  - Suitability
  - Oversight and Flow-down Expectations
  - Dedication Documentation
  - Model CGD Plan
  - Examples of Completed CGD Plans for items, services and Software

CGD Guide – What was added

- Resolution of comments (325 comments from Feds and Contractors)
- Amplifying text in the CGD process to describe how to deal with software
- Examples for CGD of software (Appendix D)

CGD Task Update

- Lost of Contractor co-lead (Dennis Weaver has left Bechtel Inc.)
- Lost ORP Contractor support. (Bill Smoot instructed over 90% of the classes taught in the DOE Complex)

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Integration of QA in Design Guidance Document

Butch Huxford, Quality Assurance Specialist
Office of Standards and Quality Assurance, EM-23

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Corporate Board Functional Area 3 Team

- William Huxford, EM-23 (co-lead)
- Robert Thompson, CWI (co-lead)
- Greg Hayward, DOE-ID, IWTU
- Robert Leugemors, DOE-SR, SWPF
- Ray Wood, Trinity Engineering
- Larry Zalants, DOE-SR, SWPF

Final Deliverable

- Focus Area 3 has completed the deliverable for QA during Design
- The final deliverable is included in the meeting materials provided the Board.
- Focus Area 4 recommends the deliverable be endorsed by the Board and the focus area be closed out as complete.

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Draft Revision to the Standard QA Contract Language

General Discussion

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Operational Awareness – Basic QA Profile Associated with EM Hazard Category 2 and 3 Nuclear Facilities

Bob Toro, Quality Assurance Specialist
Office of Standards and Quality Assurance, EM-23

July 21, 2011

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Background

- The major focus and programmatic priority for EM-23 has and continues to be improving quality performance at major design and construction projects

- There is continued corporate obligation and priority to ensure operational awareness of QA risk issues and sound QA performance across all EM high hazard nuclear operations

Objectives

Work thru the Corporate Board to initiate a low key operational awareness effort aimed at developing basic QA profile

- Initial effort focused on Hazard Category 2 and 3 nuclear facilities and operations - Information to be provided by sites
  - QAP/QIP status
  - QA performance trends
  - Known QA risks/issues (project/facility performance)
  - State of QA risk management/corrective action plan commitments
- Leverage information/data that is already available and collected
  - Do not add any burden to the field/contractors
- Analyze the information and formulate a cost-effective corporate strategy to collaboratively strengthen QA performance, as needed

Operational Awareness -Information Needs for Basic Facility-Specific QA Profile

EM Hazard Category 2 and 3 Nuclear Operations

Status of QAP/QIP

- Approval Date
- Last Field/Site Verification and Validation (V/V) date
- Risk significant QA Issues identified (if any)
- Status of QA risk management actions (if any)

Field/Site QA Oversight and Performance Monitoring

- # of and the scope of QA related assessments performed in FY 2011
- Risk significant QA issues identified- type and description (if any)
- status of progress of corrective action commitments, (if any)
- Contractual QA requirements (e.g., referenced DOE Directives and NQA-1 standard)

Contractor Assurance System

- # of and the scope of QA related assessments performed in FY 2011
- Risk significant QA issues identified- type and description (if any)
- status of progress of corrective action commitments, (if any)
- Trends associated with frequency and significance of QA related reportable events (e.g., ORPS, CAIRS)
- Known/significant issues associated with CGD, S/CI, flowdown, I&C, SQA (if any)

QA Manager (Federal and Contractor)

- Name
- Org
- Title
- Contact info
- QA related Certifications

Near-Term Steps

- EM-23 has prepared an initial list of site-specific EM HazCat 2 and 3 nuclear operations based on information reported to Safety Basis Information System (SBIS) at http://www.hss.doe.gov/nuclearsafety/ns/sbis/
- EM Corporate QA Board members facilitate receipt of site/facility-specific information:
  - Validate the accuracy and completeness of nuclear facility list
  - Provide the needed information by August 31, 2011
- EM-23 will prepare an initial analysis and assessment of the consolidated QA profile by October 1, 2011
  - Discussion topic for the Fall 2011 Corporate Board meeting

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EFCOG QA Sub-Group Tasks

Mike Mason, Deputy Corporate Quality Manager
Bechtel Group Inc.

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EFCOG QA – QC TASK TEAM

- Task: Apply a graded approach to the application of QC in Work Packages and CRAD development.
  - Developed in support of the Work Control Management Task Team
  - Drafted a “white paper” describing:
    - Critical characteristics which need to be addressed in work documents
    - Expectations of customers and specifications are included in work documents
    - QC documents – identified the QC elements that should be present in work documents
    - Verification – quantifies QC inspection activities
    - Records – provides guidance on the type of records generated and their retention span

EFCOG QA – QC TASK TEAM

- Task: Determine inspector qualification/certification processes used across the complex.
  - Questionnaire sent out to DOE complex
  - Results have been received and are currently being tabulated
  - The ultimate goal is to provide guidance to the complex on the acceptable practices being implemented

EFCOG QA – SUPPLY CHAIN TASK TEAM

- Task: Work with NNSA to determine the feasibility of joining resources for the development of a Joint Supplier Evaluation Program
  - Joint meeting between EM and NNSA held at the last EFCOG meeting (4/11)
  - Working 18 action items as a result of the meeting
  - Three teams comprised of members from EM and NNSA working the action items
    - Team 1 – resolve the issue of approved versus evaluated supplier and provide feedback on cost efficiencies using joint resources
    - Team 2 – define the differences in the IT databases used by EM and NNSA
    - Team 3 – develop a governance document for managing the process

EFCOG QA – SOFTWARE QA TASK TEAM

- Task: Commercial Grade Dedication of Software
  - Review current industry practices for dedication
  - Develop guidance on what constitutes an effective dedication program
- Task: Effective Graded Approach for Application on Software
  - Review current industry practices for grading
  - Develop guidance for defining the rigor applied to software
- Task: Computer Model Validation
  - Using GAO Report 11-143 as a basis the team will propose guidance on accepted/effective validation methods

Supplemental Information

The following slides provide current information and priorities that were presented and agreed to by the Board in 2010.

Status of Corporate Board Priorities

- Priority Areas were developed during a Corporate Board meeting in 2008 (~20 areas were identified)
- A number of priorities have been addressed in focus areas and have been closed out via the associated deliverables
- EM-23 solicited additional feedback for other priority areas in 2010 and discussed the priority areas at the meeting in February 2010
- The priority areas were separated into three areas
  - Current Focus Areas
  - Priority areas to be led by EM-23
  - Priority areas to be led by EFCOG/Site Offices

Current Corporate Board Focus Areas

- Adequate NQA-1 Suppliers
- Commercial Grade Item and Services Dedication
- Design Quality Assurance
- Evaluation of QA/QC Resources
- Strategy for EM QA/QC Training

Priorities Led by EM-23

- Resources (Federal)
- Identifying HQ requirements from memos and other correspondence beyond DOE orders
- Balancing inspection/field work control with HQ program audits and oversight reviews
- QAP/QIP Implementation/Clear Roles and Responsibilities
- ORPS reporting of S/CI Program

Priorities Led EFCOG/Site Offices

- Procedural compliance/execution/conduct of operations
- Effectiveness of corrective actions regarding human performance
- Vendor issues
- Supplier Quality Assurance
- Consistent application/interpretations of regulations/requirements
- Inspector training/mentoring and understanding expectations
- Improve understanding of expectations for safety software/software Quality Assurance
- Path forward for small contractors without rigorous NQA-1 programs
- Overseas suppliers

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General Discussion Topics

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Commercial Grade Dedication Guidance Document

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OFFICE OF ENVIRONMENTAL SAFETY AND QUALITY

GUIDANCE FOR COMMERCIAL GRADE DEDICATION
June 2011

FOREWORD

This U.S. Department of Energy (DOE), Office of Environmental Management (EM) guidance is approved for use by all DOE EM organizational units and contractors performing work for EM.

This Guide provides an acceptable process (Commercial Grade Dedication [CGD]) for EM facilities and projects to dedicate an item[1] or service that performs a nuclear safety function that was not manufactured, developed, or performed under a qualified American Society of Mechanical Engineers (ASME) NQA-1 Quality Assurance program. This Guide also provides guidance for the development of the associated documentation supporting the dedication activity.

CGD is an acceptance process performed in accordance with ASME NQA-1a-2009, Subpart 2.14 (ASME NQA-1) or ASME NQA-1-2004 with addenda through 2007, to provide reasonable assurance that an item or 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 ASME NQA-1.

The need for this Guide was recognized by EM-23, Office of Standards and Quality Assurance, following events at various EM facilities. Contractors across the EM complex have procedures or guidance documents on CGD based on ASME NQA-1 requirements and Electrical Power Research Institute guidelines. However, these documents vary widely from site to site. While the existing procedures and guidance documents are appropriate in some cases, individual prime contractors' or sub-tier supplier/fabricator/developers implementing procedures may not have all the attributes that EM Management considers important, including a reasonable degree of consistency or standardization. This Guide is a consolidation of the best existing practices from both the EM Complex and from the commercial nuclear industry and should be used as a companion document to the EM approved CGD training.

This Guide has been developed with a technical content and level of detail intended to be applicable to safety Structures, Systems, and Components, computer program(s) credited with safety functions, or safety computer program(s) at EM nuclear facilities and is approved for use by all DOE EM organizational units and contractors performing work for EM. This Guide should be applied in a manner that fits the specific procurement activity. This Guide can be applied either to new or existing facilities, systems, and activities.

It is the expectation of senior EM management that this Guide should be implemented for CGD. In the event that it is not, the burden of showing equivalency with the content of the Guide and implementation of ASME NQA-1 requirements thus ensuring proper dedication of procured services and items falls entirely on the procuring organization. This Guide discusses the preferred way to meet EM expectations and requirements. This

[1] DOE O 414.1C, 7.g, defines item to include software

Guide does not modify or create any new requirements; instead, it explains how to satisfy existing requirements.

Note: NQA-1a-2009 is used throughout this document. Reference to this version of NQA-1 does not constitute a change to any contractual requirements that specify earlier versions of NQA-1. Contractors will continue to implement the existing contractual requirements.

Definitions

These definitions are intended to provide a common set of terms for use in this Guide while retaining consistency of these terms with other standards and guidance currently used in nuclear applications. Where a definition is derived from an applicable consensus standard or other guidance document, the reference for the definition is provided in brackets.

Acceptance - The employment of methods to produce objective evidence that provides reasonable assurance that the Commercial Grade Item/Commercial Grade Services (as modified from source) received is the item specified. [EPRI NP-5652, "Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications (NCIG-07)"]

Acceptance Criteria - Specified limits placed on the performance, results, or other characteristics of an item, process, or service defined in codes, standards, or other requirement documents. [American Society of Mechanical Engineers NQA-1a-2009, "Quality Assurance Requirements for Nuclear Facility Applications"]

Approved Supplier - A supplier whose quality assurance system has been evaluated and found to meet the owner's quality assurance requirements for the item or service to be purchased. [IEEE STD-934]

Bounding Conditions - Parameters that envelop the normal, abnormal, and accidental environmental conditions an item is expected to meet during its lifetime in the plant (e.g., temperature, humidity, radiation, seismic response spectra). [EPRI Report NP-6046S, "Guidelines for Technical Evaluation of Replacement of Items in Nuclear Power Plants"]

Certificate of Conformance (C of C) - A document signed or otherwise authenticated by an authorized individual certifying the degree to which items or services meet specified requirements. [ASME NQA-1a-2009, "Quality Assurance Requirements for Nuclear Facility Applications"]

Certified Material Test Report (CMTR) - A document attesting that the materials are in accordance with specified requirements, including the actual results of all required chemical analyses, tests, and examinations. [EPRI Report TR-102260, "Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial Grade Items"]

Commercial Grade Item (CGI) - A structures, systems, and components, or part thereof that affects its safety function that was not designed and manufactured in accordance with the requirements of ASME NQA-1-2004. [ASME NQA-1-2004, "Quality Assurance Requirements for Nuclear Facility Applications"]

A structure, system, or component, or part thereof, that affects its safety function(s) that was not designed and manufactured in accordance with the requirements of this standard. [ASME NQA-1a-2009, Subpart 2.14]

Commercial Grade Services (CGS) - A service that is not provided in accordance with the requirements of ASME NQA-1-2004. [ASME NQA-1-2004, "Quality Assurance Requirements for Nuclear Facility Applications"]

A service that was not provided in accordance with the requirements of this Standard that affects the safety function(s) of a basic component. [ASME NQA-1a-2009, Subpart 2.14]

Commercial Grade Survey –Activities conducted by the purchaser or its agent to verify that a supplier of commercial grade items controls, through quality activities, the critical characteristics of specifically designated commercial grade items, as a method to accept those items for safety-related use. [EPRI NP-5652, "Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications (NCIG-07)"]

Note: This is not an ASME NQA-1 Supplier Qualification Audit

Commodity Item[2] - An item having a generic application that lends itself to bulk procurement (e.g., nuts, bolts, materials, o-rings, gaskets, indicator lights, fuses, relays, resistors). [EPRI Report TR-102260, "Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial Grade Items"]

Computer Program[3,4,5] - A combination of computer instructions and data definitions that enables computer hardware to perform computer hardware to perform computational or control functions. [ASME NQA-1a-2009]

Credible Failure Mechanism: - The manner by which an item may fail, degrading the item's ability to perform the component/system safety function under evaluation. [IEEE std. 500-1984,] [EPRI Report TR-102260, "Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial Grade Items"]

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. [ASME NQA-1a-2009, Subpart 2.14]

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[2] DOE O 414.1C includes software in its definition of item. That definition is used as a basis for this guide.

[3] Computer programs covered by this definition are those used for:

a) Design analysis
b) Operations or process control, or
c) Data base or document control registers when used as the controlled source of quality information for a) or b) above.

[4] This definition has been copied from ANSI/IEEE 610.12-1990, *Glossary of Software Engineering Terminology,* with the permission of IEEE.

[5] To the extent that computer programs are a physical part of plant systems (e.g., digital reactor protection system, digital instrumentation) they are included in the term item.

Critical Characteristics for Acceptance (CCFA) - Identifiable and measurable attributes of an item or service that, when verified, will provide reasonable assurance that the item/service received is the item specified. [EPRI Report NP-5652]

Critical Characteristics for Design (CCFD) - Those properties or attributes that are essential for the item's form, fit, and functional performance. Critical Characteristics for Design are the identifiable and/or measurable attributes of an item which provides assurance that the item will perform its design function. [EPRI Report NP-6406]

Dedication - An acceptance process performed in accordance with ASME NQA-1-2004 to provide reasonable assurance that an item or service will successfully perform its intended safety function and, in this respect, is deemed equivalent to an item or service provided by an ASME NQA-1 qualified vendor. This process includes the identification of Critical Characteristics for Acceptance and their verification by one or more of the dedication methods. [ASME NQA-1-2004, "Quality Assurance Requirements for Nuclear Facility Applications"]

An acceptance process performed in accordance with ASME NQA-1a-2009, Subpart 2.14 to provide reasonable assurance that a commercial grade item or service will perform its intended safety function and, in this respect, is deemed equivalent to an item or service designed and manufactured or provided under the requirements of ASME NQA-1a-2009, Subpart 2.14. This assurance is achieved by identifying the critical characteristics of the item and verifying their acceptability by inspections, tests, or analyses performed by the purchaser or third-party dedicating entity after delivery, supplemented as necessary by one or more of the following: commercial grade surveys; production inspections or witness at hold-points at the manufacturer's facility, and analysis of historical records for acceptable performance. In all cases, the dedication process must be conducted in accordance the applicable provisions of NQA-1a-2009, Part 1. [ASME NQA-1a-2009, Subpart 2.14]

Dedicating Entity - The organization performing the dedication process. [ASME NQA-1-2004, "Quality Assurance Requirements for Nuclear Facility Applications"]

The organization performing the dedication process. Dedication may be performed by the manufacturer of the item, a third-party dedicating entity, or by the facility. [ASME NQA-1a-2009, Subpart 2.14]

Equivalency evaluation – A technical evaluation performed to confirm that a replacement item (not identical to the original) can satisfactorily perform its intended functions, including its safety functions. [ASME NQA-1a-2009, Subpart 2.14]

Equivalent replacement – A replacement item not physically identical to the original. These replacement items require an equivalency evaluation to ensure that the intended functions, including its safety function, will be maintained. [ASME NQA-1a-2009, Subpart 2.14]

Identical item – An item that exhibits the same technical and physical characteristics (physically identical). [ASME NQA-1a-2009, Subpart 2.14]

Item – An all-inclusive term used in place of appurtenance, assembly, component, equipment, material, module, part, structure, product, computer program(s) (computer program; added by author), subassembly, subsystem, system, unit, or support systems. [DOE O 414.1C, "Quality Assurance"]

Like-for-Like Replacement – The replacement of an item with an item that is identical. [ASME NQA-1a-2009, Subpart 2.14]

Parts - Items from which a component is assembled, such as resistors, capacitors, wires, connectors, transistors, tubes, lubricants, O-rings, and springs. [EPRI Report TR-102260, "Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial Grade Items"]

Post-Installation Tests - Activities conducted after installation of a Commercial Grade Item to verify required Critical Characteristics for Acceptance prior to placement in operation. An element of the "Special Tests and Inspection" method to accept an item for use in safety functions. [EPRI Report TR-102260, "Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial Grade Items"]

Non-Complex Items - Items that can be procured by reference to national or international material specifications and/or a manufacturer's standard (commercial off the shelf). This can include items that require additional seismic and/or environmental qualifications. Non-complex items do not include computer program(s), services, skid mounted systems (including valves, pumps, piping, instrumentation), or items that cannot be procured on the basis of specifications set forth in a manufacturer's published product description.

Reasonable Assurance: - A justifiable level of confidence based on objective and measurable facts, actions, or observations which infer adequacy. [EPRI Report TR-102260, "Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial Grade Items"]

Safety and Hazard Analysis Design Software and Analysis Software - Software that is used to classify, design, or analyze nuclear facilities. This computer program(s) is not part of a structure, system, or component but helps to ensure the proper accident or hazards analysis of nuclear facilities or a structure, system, or component that performs a safety function. [DOE O 414.1C, "Quality Assurance"]

Safety-class structures, systems, and components (SC SSC). Structures, systems, or components, including portions of process systems, whose preventive and mitigative function is necessary to limit radioactive hazardous material exposure to the public, as determined from the safety analyses. [10 CFR 830]

Safety Function – The performance of an item or service necessary to achieve safe, reliable, and effective utilization of nuclear material processing. [ASME NQA-1a-2009, "Quality Assurance Requirements for Nuclear Facility Applications," (Modified for DOE EM use)]

Note: A function that is necessary to prevent or mitigate a release of radioactive material in an accident scenario as discussed in DOE-STD-3009-94, Revision 3.

Safety Management and Administrative Controls Software - Software that performs a hazard control function in support of nuclear facility or radiological safety management programs or technical safety requirements or other computer program(s) that performs a control function necessary to provide adequate protection from nuclear facility or radiological hazards. This computer program(s) supports eliminating, limiting, or mitigating nuclear hazards to workers, the public, or the environment as addressed in 10 CFR 830, 10 CFR 835, and the DEAR ISMS clause. [DOE O 414.1C, "Quality Assurance"]

Safety-significant structures, systems, and components (SS SSC). Structures, systems, and components which are not designated as safety-class SSCs but whose preventive or mitigative function is a major contributor to defense in depth and/or worker safety as determined from safety analyses. [10 CFR 830]

Safety Software – Safety system software, safety and hazard analysis software and design software, and safety management and administrative controls software. [DOE O 414.1C, "Quality Assurance"]

Safety Structure, System, or Component – Both safety class structures, systems, and components and safety significant structures, systems, and components. [10 CFR 830.3, "Nuclear Safety Rule, Sub-part A, Quality Assurance Requirements"]

Safety System Software – Software for a nuclear facility[2] that performs a safety function as part of a structure, system, or component and is cited in either (a) a DOE approved documented safety analysis or (b) an approved hazard analysis per DOE P 450.4, "Safety Management System Policy," dated October 15, 1996, and the DEAR clause. [DOE O 414.1C, "Quality Assurance"]

Sample - A sample consists of one or more units of product drawn from a lot with the units of the sample being selected at random without regard to their quality. The number of units of product in the sample is the sample size. [EPRI TR-017218-R1, "Guideline for Sampling in the Commercial-Grade Item Acceptance Process, January 1999"]

Sample Plan - A plan developed to determine the definition of appropriate lot and sample size(s) in order to achieve reasonable assurance that the sample size chosen provides an adequate representation of the item(s) quality. [EPRI TR-017218-R1, "Guideline for Sampling in the Commercial-Grade Item Acceptance Process, January 1999," Established from General Discussion]

Service - The performance of activities such as design, fabrication, inspection, nondestructive examination, repair, or installation. [ASME NQA-1-2004, "Quality Assurance Requirements for Nuclear Facility Applications"]

Source Verification - Activities are witnessed at the supplier's facilities by the Buyer, or its agent, to verify that a supplier of a Commercial Grade Item/Commercial Grade Service controls the critical characteristics. (Method 3) [EPRI NP-5652]

Special Tests and Inspections - Activities conducted during or after receipt of a Commercial Grade Item to verify one or more critical characteristics. (Method 1) [EPRI NP-5652]

Standard Receipt Inspection - Activities conducted upon receipt of items, including Commercial Grade Items, in accordance with ASME NQA-1a-2009 to check such elements as the quantity received, part number, general condition of items, and damage. [EPRI NP-5652 (Modified for DOE EM use)]

Supplier - An individual or organization who furnishes items or services in accordance with a procurement document. An all-inclusive term used in place of any of the following: vendor, seller, contractor, fabricator, consultant, and their sub-tier levels. [ASME NQA-1a-2009, "Quality Assurance Requirements for Nuclear Facility Applications"]

Technical Evaluation - An evaluation performed to assure that the correct technical requirements for an item are specified in a procurement document. [EPRI NP-5652]

Traceability - The ability to trace the history, application, or location of an item and like items and activities by means of recorded identification. [ASME NQA-1-2004, "Quality Assurance Requirements for Nuclear Facility Applications"]

1. INTRODUCTION

Over the past 20 years, accompanying the cessation of commercial utilities' nuclear construction activities, the number of suppliers maintaining a Quality Assurance (QA) program that meets the requirements of the American Society of Mechanical Engineers (ASME) NQA-1 has contracted severely. In many cases, suppliers/developers concluded that continuing business orders were inadequate to justify the costs associated with maintaining a strict QA program that met ASME NQA-1 requirements. Additionally, the use of digital technology has raised concerns over the potential for common cause failure resulting from computer program errors, the effects of Electromagnetic Interference on digital computer-based systems (e.g., different frequency ranges), and the use and control of equipment for configuring computer-based systems.

The U.S. Department of Energy (DOE), Office of Environmental Management (EM) has been pursuing construction of non-reactor nuclear facilities in order to perform the safe clean up of the EM Complex. These new nuclear facilities contain a subset of safety Systems Structures and Components (SSC) that are required to demonstrate that they can, with reasonable assurance, perform their safety functions on demand to either prevent or mitigate an accident condition.

DOE O 414.1C, "Quality Assurance," specifies that consensus standards be used for implementation of QA program requirements. It is EM policy[6] that ASME NQA-1-2004, "Quality Assurance for Nuclear Facility Applications" (including addenda through 2007) will be used to support EM nuclear facilities (allowing for variance requests to earlier versions of NQA-1). ASME NQA-1-2004, states that items or services that provide a safety function will be provided and/or performed under an ASME NQA-1 QA program or be commercial grade dedicated to ASME NQA-1 requirements.

On October 8, 2010, EM issued a memorandum[7] on the use of ASME NQA-1-2008 with the 2009 Addenda for issuance and implementation of the EM QA program. The memorandum stated that those sites that choose to implement the ASME NQA-1-2008 with the 2009 addenda as the basis for implementation of the EM Corporate QA Program are not required to obtain a variance or exemption. The review of the ASME NQA-1-2008 with the 2009 addenda concluded that the enhancements in the standard do not result in any additional risks to the quality of EM work, products or services. Information from ASME NQA-1-2008 with the 2009 Addenda has been used as the basis for this Guide.

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[6] The Office of Environmental Management (EM) Corporate Quality Assurance (QA) Program (EM-QA-001), issued in November 2008

[7] Dr. Steve Krahn, Deputy Assistant Secretary for Safety and Security Program Environmental Management, to Distribution, *Use of NQA-1-2009 Addenda for Issuance and Implementation of the Office of Environmental Management Quality Assurance Program,* Dated October 8, 2010.

As EM's construction of new non-reactor nuclear facilities increases with limited numbers of suppliers who have approved ASME NQA-1 programs, additional reliance is placed on Commercial Grade Dedication (CGD) to ensure parts and services can be procured that will have a reasonable assurance of meeting their safety function. These new non-reactor nuclear facilities are being designed using commercial computer program(s) applications with many of their safety functions controlled by Instrumentation and Control systems. Purchasing Commercial Grade Items (CGI) and services and verifying they are capable of performing specified safety functions (i.e., dedicating them – hence CGD) is one way of obtaining the needed items and services. Many contractors to the EM Complex have some mechanism that allows CGD to take place. The various processes are lacking in uniformity with regard to both classes of items and services allowed to be dedicated and methods for dedication. This Guide will establish consistency in the methods employed and the outcome of the process.

2. PROCESS DESCRIPTION

A facility procuring an item or service that supports a nuclear safety function has two options to procure the item or service. The item or service must be either procured or performed subject to the requirements of ASME NQA-1 (appropriate addenda) Part I and II or be commercial grade dedicated in accordance with the requirements of ASME NQA-1 (appropriate addenda). A dedication plan shall be developed for the item or service that identifies the critical characteristics for acceptance and dedication methods, including acceptance criteria. The dedication plan should be developed by engineering with input from QA regarding how selected critical characteristics should be verified. ASME NQA-1 requires that the technical evaluation be performed by engineering. Dedication plans may be developed for a specific item, service, or for a generic group of items or services. Dedication requirements shall be included in applicable procurement and technical documents as necessary to support the dedication.

Suitability of an item or service must be established before CGD of that item or service can be considered. Suitability is determined through the detailed design process where the design inputs and conditions are established and the appropriate item or service is selected. The process may require calculations, analyses, cost benefit evaluations, and other design activities. The design must consider all applicable design requirements including operability, maintainability, fit, form, function, process, interfaces, seismic, environmental, etc. If seismic or environmental qualification is required, it must be established as part of the design process. Only after suitability of a design has been established can the CGD process be implemented. Design verification, as addressed in ASME NQA-1, Requirement 3, is not part of the CGD process.

ASME NQA-1a-2009 states that to utilize a CGI or service, controls shall be implemented to provide reasonable assurance that the item or service will perform its intended safety function. CGD requires:

- A determination that the item or service performs a safety function;

- Confirmation that the item or service meets the applicable CGI definitions;

- A technical evaluation identifying the Critical Characteristics for Design (CCFD), selecting the Critical Characteristics for Acceptance (CCFA);

- Selecting one or more acceptance methods, including development of acceptance criteria, for each CCFA; and

- After acceptance criteria and acceptance methods have been established, the dedicator uses this information to evaluate the item or service to be dedicated.

The goal is to provide reasonable assurance that the CGI or service can perform its intended safety function and is the part or service specified in the procurement documents. Reasonable assurance is established by engineering judgment. That is, a process of reasoning that leads from a stated premise to a logical conclusion. This process should be supported by sufficient documentation to permit verification by a qualified individual.

The word "reasonable" connotes a level of confidence which is justifiable but not absolute. In the context of product or service quality, "reasonable assurance" of performance must be based on facts, actions, or observations (objective evidence). While these bases are objective and measureable, the inference of adequacy drawn from them – the decision that "reasonable assurance" has been attained – is inherently subjective and the judgment of reasonability may vary between different observers. These judgments are commonly referred to as "engineering judgment" and should be documented.[8]

Each element of CGD, including responsibilities for implementation, is addressed below in greater detail. Items or services that successfully complete the dedication process are subsequently subject to the controls of Part 1 and Part II of ASME NQA-1a-2009.

The performance of the CGD process shall be on a case-by-case basis. Prior to initiating the CGD process, an estimate of the cost to perform the CGD process should be completed. Then the cost-effectiveness of pursuing CGD as opposed to buying the device from a vendor with an ASME NQA-1 program can be determined. There are also tradeoffs involved in choosing between available commercial devices. It may be more cost effective to select a somewhat higher priced item if the vendor of that device has a better process and will require less costly and/or time consuming supplemental activities by the dedicating entity to dedicate the item.

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[8] EPRI Report TR-102260, *Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial Grade Items,* Section 2.1.2.2.3.

Applying expertise in the subject matter associated with the item is critical. Procurement personnel may not have this expertise for all items being dedicated. Procurement personnel may need to rely on personal in the design organization or outside sources for the requisite expertise. Many facilities have found that the procurement and design staffs must work hand-in-hand to reach sound decisions on applying the CGD process for safety applications.

Figure 1 and Appendix C provide an overview of the generic CGD process. These overviews demonstrate how the technical evaluation and acceptance process are applied to perform CGD. It should also be noted that the use of a supplier with an approved ASME NQA-1 program can still result in the need to perform CGD if items or services in support of the ASME NQA-1 procurement are provided by a commercial vendor/supplier. Documentation of the completion of the elements of CGD provides the quality record of the logic for selection of CC to be verified, verification of those CC's, and documentation of acceptance of the item or service.

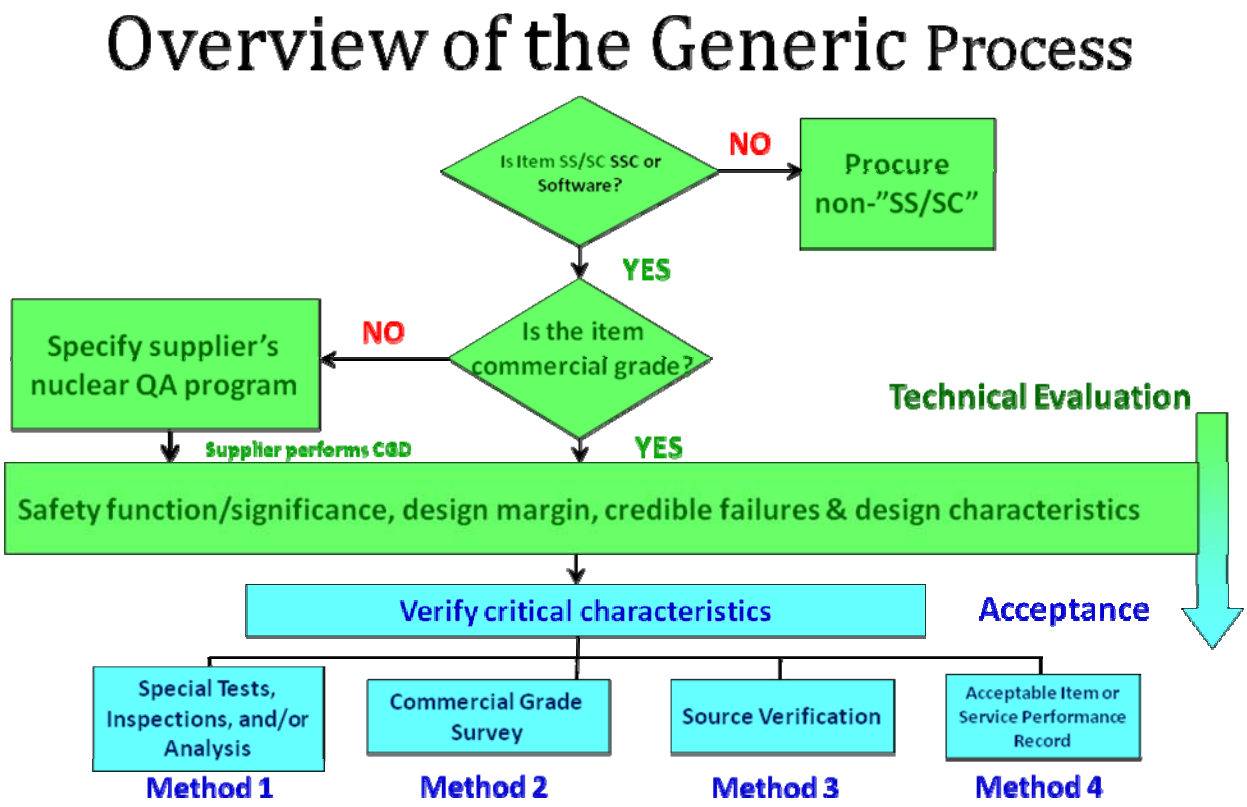

Figure 1: Overview of Generic Commercial Grade Dedication Process

2.1 Commercial Grade Dedication Plan

A CGD plan shall be established early in the CGD process to document the critical characteristics for acceptance, the methods for acceptance of the critical characteristics, and the acceptance criteria. Dedication plans may be developed for a specific item, service, or generic group of items or services. The CGD plan is based on the technical

evaluation. The dedication plan should be developed and approved by the Engineering organization responsible for the CGD with input from the QA organization that will be performing the acceptance activity. Actual implementation of this process should be included in the organization's CGD implementing procedures. Dedication requirements shall be included in applicable procurement and technical documents as necessary to support the dedication. Appendix C provides a process flow diagram of the CGD process from the technical evaluation through the development of a CGD plan. The following discussions are provided to assist the dedicator in the performance of the technical evaluation, the development of the CGD plan, and documentation of acceptance of a CGD item or service.

2.1.1 Technical Evaluation

The technical evaluation is the key to effective dedication. The technical evaluation shall be performed by engineering and used to identify and document the safety function of each item/service based on review of the approved safety analysis and supporting data.

Analysis of system and component level safety functions may be required to determine item level safety functions if not discussed in the safety basis. Components that perform a safety function can contain items that do not perform a safety function. Replacement items shall be evaluated to determine their individual safety function in relation to the component or equipment. The dedicator's technical evaluation should also result in an understanding of the overall safety function. Based on this evaluation, the engineer should be able to determine which items/services of the procurement must be procured to ASME NQA-1 requirements or dedicated and which items/services can be procured from a commercial vendor/supplier. EPRI 5652, Appendix B provides additional guidance on part classification that can result in a sub-part within a Safety Class (SC)/Safety Significant (SS) item not providing a safety function and as a result being procured commercially. For example, one could classify internal items such as a valve stem as general service if a valve, classified as SS, was passive and its only safety-related function was to maintain a pressure boundary. If the stem is not considered to be a pressure retaining piece, it would not be critical to the passive valve maintaining its pressure boundary.

The technical evaluation for a CGD item/service should also evaluate the scope and boundary for the item/service's use and whether or not the item is passive or active in performing the safety function. When an item has multiple uses in a facility, the dedicator's analysis should be based on the most severe use of the item or controls must be established to ensure that the dedicated item is only used for the evaluated scope.

CGD is performed only on those items that provide a safety function. Design output documents, supplier technical information, and other relevant industry technical and operating experience information, as appropriate, shall be utilized to prepare the technical evaluation. It should be noted that there may be instances in which implementation of a State's (e.g., State of Washington) requirement to implement

ASME NQA-1 on a non-safety related item such as an air permit or the implementation of the Quality Assurance Requirements Document for high level waste affecting items could also require performance of CGD. As such, the Critical Characteristics (CC) would be those that support the performance of the item to meet program requirements and not the SC/SS safety function.

It is critical to understand that the technical evaluation is based on approved design documents. In order to perform the technical evaluation, suitability activities discussed in Section 2.0 must be complete. For example, for new construction or modifications to facilities, seismic and environmental qualification must be complete in order to have an approved configuration on which to base selection of critical characteristics. A methodical approach to technical evaluations provides thorough, accurate and consistent results. The technical evaluation(s) shall be performed by the responsible engineering organization to:

- Determine the safety function(s) of the item or service;
- Identify performance requirements, the item functional classification, and applicable service/state conditions (seismic and/or environmental) including failure modes analysis;
- Confirm that the item or service meets the commercial grade definition criteria;
- Identify the critical characteristics, including acceptance criteria;
- Identify the dedication method(s) for verification of the acceptance criteria; and
- Determine if a replacement item is a like-for like or equivalent item.

The credible failure modes of an item in its operating environment and the effects of these failure modes on the safety function shall be considered in the technical evaluation for the selection of the critical characteristics. Services shall be evaluated to determine if the failure or improper performance of the service could have an adverse impact on the safety function of equipment, materials, or the facility operations.

If the design criteria for the CGI are known by the dedicating entity, then the item may be dedicated to these criteria in lieu of defining a specific safety function. In this case, consideration of failure modes is not required and the item's design parameters become the critical characteristics and acceptance criteria. This would be most appropriate when applied to a large number of simple commodity items.

ASME NQA-1 states that when evaluating a replacement item, if the design criteria or safety function of the original item have changed, the replacement item must meet the new design criteria and safety function. Like-for-like and equivalent items are not a design change subject to Part I, Requirement 3, Section 600, "Change Control."

2.1.1.1 Like-for-Like evaluation

The term like-for-like was used in Electrical Power Research Institute (EPRI) Report NP-5652 and EPRI Report NP-6406 to describe a procurement scenario in which a minimal technical evaluation is required for a replacement item. ASME NQA-1 defines like-for-like replacement as the replacement of an item with an item that is identical. It further defines "identical item" as an item that exhibits the same technical and physical characteristics (physically identical). If the design, materials, manufacturing processes, and end use of an item are identical to an item or service that has already been accepted and CGD performance issues have not been identified for that item, then ASME NQA-1 states that no further technical evaluation is required. The item must still meet CCFA acceptance criteria established by the initial CGD plan. The like-for-like evaluation is to determine if there is an existing technical evaluation for the item, not an evaluation to determine if an alternate item is acceptable for use in the design. The equivalency evaluation is discussed in Section 2.1.1.2. When considering a like-for-like procurement, the process of achieving a high confidence that the replacement is identical to the original or the process of establishing the degree of engineering evaluation deemed necessary should consider the following:

- Same Manufacturer;
- Complexity of the item;
- Same published product description of the item;
- Supplier performance;
- Adequate supplier design change process to ensure no changes have been made to the design;
- Adequate supplier controls of the manufacturing and procurement process; and
- Supplier reaffirms no changes in material, design, physical characteristics (fit, form), function or inter-changeability.

Items may be considered identical or like-for-like if one of the following applies:

- The item is provided from the original equipment manufacturer (successor companies that maintain equivalent quality controls are acceptable), and has not been subject to design, materials, manufacturing, or nomenclature changes;
- The item was purchased at the same time and from the same supplier, as determined by the purchase date, shipping date, date code, or batch/lot identification;
- Evaluation of the item confirms that no changes in the design, materials, or manufacturing process have occurred since the procurement of the original item.

A like-for-like determination shall not be based solely on the selection of a commercial-grade vendor with items manufactured to meet the same industry standards of the original item. Meeting the same industry standards may be a necessary condition, but is not sufficient condition for a like-for-like determination.

If the dedicating entity can demonstrate that the replacement item is identical, then the safety function, design requirements, and critical characteristics need not be re-determined. However, verification of the identified critical characteristics by an appropriate dedication method (s) is required to verify the acceptability of the replacement item.

Computer program(s), including programs embedded in digital equipment, do not wear-out. Generally they are only replaced if the computer program fails to perform as expected or is upgraded to include new functionality. Therefore, a computer program typically is not subject to like-for-like replacement.

2.1.1.2 Equivalent Items

When difference(s) exist from the original item, an equivalency evaluation is required to determine if any changes in design, material, manufacturing process, form, fit, or function could prevent the replacement item from being interchangeable under the design condition of the original items and performing its required safety function.

The equivalency evaluation shall be documented and include the following:

a) Identification of the change(s) in design, material, manufacturing process, computer program(s) development process, configuration, form, fit, or function of the replacement item that is different from the original item;

b) Evaluation of the change(s); and

c) Confirmation that the changes do not adversely affect the current design or safety function of the item.

If the change(s) adversely affects or is not bounded by the current approved design bases, the replacement item is not equivalent and must be rejected or processed as a design change in accordance with Part 1, Requirement 3, section 600, “Change Control.” Equivalency can be used for computer program(s) when the computer instructions associated with the safety function and any of the safety functions’ interfaces are not changed. This allows for independent non-safety functions to change or computer program(s) tools that assist in the creation of the computer program(s) item (e.g., compilers) to be changed.

Equivalency evaluations can determine the acceptability of the difference in the item to perform its safety function and identify critical characteristics for acceptance for the

replacement 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.

2.1.1.3 Item/Service Safety Functions

The CGI's specific safety function to be assured must be clearly identified. The safety function includes on-demand performance to prevent or mitigate a nuclear hazardous condition through correct design of safety SSC, proper analysis of credible accident scenarios, and automated management and administrative decisions impacting safety. The safety functions performed by the item or a host component in support of the overall safety function are described in the Documented Safety Analysis for an existing facility, the Preliminary Documented Safety Analysis for a facility under construction, or other safety basis documentation. For systems or complex components it may be that not all subcomponents would impact the safety function. If this is the case, the logic used by engineering to determine this must be documented.

The safety function is often a subset of the item function. For instance, the function of an instrument may be to maintain the pressure boundary of a pipe system and provide a flow signal, but the safety function may only be to maintain the pressure boundary. For computer program(s) that tracks surveillances of safety SSCs to meet the technical safety requirements, the portion of the computer program(s) that calculates dates based upon past surveillances completed and automatically notifies an engineer to schedule the surveillance would be the safety function, where as the portion of that same computer program(s) that stores the surveillance report may not be part of the safety function. If there is any question as to the safety function, the question should be raised to the responsible engineer to ensure the proper determination of safety function.

2.1.1.4 Environmental and Natural Phenomena Evaluation

The environmental conditions under which a safety function may need to perform over the life of the item, system, or complex component are established during design work and need to be evaluated during the technical evaluation. ASME NQA-1 states that CGI's designated for installation or installed in seismically or environmentally qualified equipment or in locations which require such qualification shall include the selection of appropriate critical characteristics required to maintain the qualification of the component or equipment. For example, environmental conditions such as the presence of high pH, and/or high radiation levels that would result in a negative impact on an item's material characteristics needs to be identified and verified. The expectation for long term performance of a valve seat in a high pH could require a specific material selection and subsequent CCFA. The need to preserve seismic qualifications could also impact material selection and CCFA to ensure that the item will perform as expected relative to the seismic event. Typically, computer programs, including program(s) embedded in digital equipment, do not require an environmental or natural phenomena evaluation. The computer hardware and other equipment where

the computer program(s) resides shall be evaluated for impacts from any environmental or natural phenomena condition.

EPRI TR-102260, Section 2.2.3.2, states that the CGD process as described in EPRI Report NP-5652 is the same when used to accept an item where the application has equipment qualification requirements as it is for applications which do not have equipment qualification requirements. The purpose of CGD acceptance is to provide reasonable assurance that an item meets specified requirements. Therefore, for applications which have equipment qualification requirements, these equipment qualification requirements simply become an input to the commercial grade acceptance process when the selection of critical characteristics for acceptance is performed. The critical characteristics for design which relate to the equipment qualification requirements should be weighted heavily when critical characteristics for acceptance are selected.

2.1.1.5 Item Characteristics

Item characteristics include product identification characteristics and other characteristics that are inherent to the item's design but are not required or used in the purchaser's application to support the safety function. Item characteristics may include characteristics such as;

- Item part number including revision number;
- Software/firmware revision number;
- Dimensions;
- Location of mounting holes or brackets; and
- Color.

2.1.1.6 Critical Characteristics for Design (CCFD)

The CCFD are those design characteristics that are important to the performance of the item which allows the item to perform its safety function and are a subset of item characteristics.

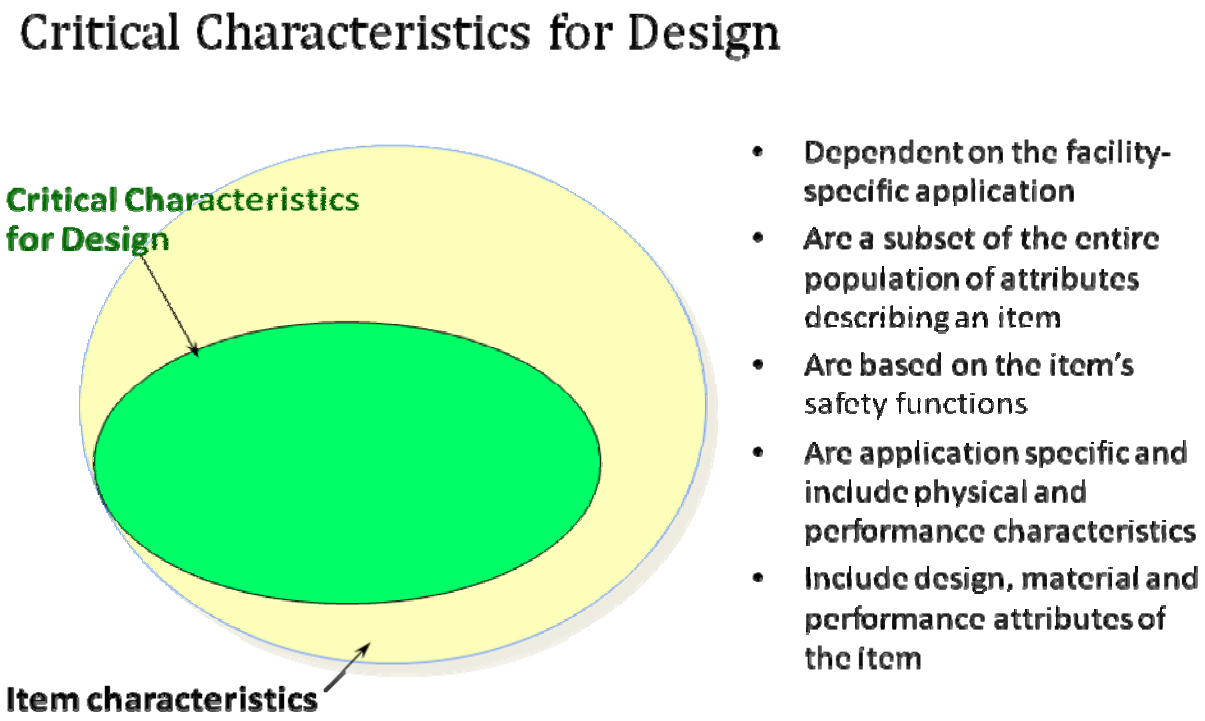

Figure 2: Critical Characteristics for Design

The CCFD normally ties back to the performance of the safety function. Physical or performance characteristics of the item that may have been specified in the original equipment specification and affect the item's safety-related functional performance should be considered as those selected for verification. Important performance characteristics that do not impact the safety function are also valid CCFD[9]. See Appendix A. In addition to specific design criteria, CCFD is also made up of critical characteristics dealing with performance, material, and reliability where applicable. Not all CCFD that support the safety function must be verified during the dedication process. The selection of CCFD supporting CCFA is discussed in more detail in Section 2.1.1.7 below. Examples of CCFD that could be selected as CCFA for hardware are listed in Appendix A and examples for CCFD that could be selected as CCFA for digital equipment and computer program(s) are listed in Appendix D, Table D-1.

A complete identification of specification is an important prerequisite for dedication of a CGI/Service. Examples of specification include instrumentation, equipment,

[9] EPRI NP 6406, *Guidelines for the Technical Evaluation of Replacement Items in Nuclear Power Plants*, December 1989.

computer hardware, computer program(s), human-machine interface, quality and reliability requirements. Experience has shown that many of the problems that occur in dedication are due to inadequate item specifications. This is especially true with computer program(s). The design requirements for the intended safety functions and anticipated failure modes factor heavily into ensuring the correct critical characteristics for acceptance are identified. For computer program(s), it is particularly important to identify specifications and design features that are related to unused, and unintended or prohibited functions.

Critical characteristics fall into the three categories: physical, performance, and dependability. Dependability is significant when dedicating digital equipment and computer program(s). The three categories are used to help the reader understand what types of attributes may represent critical characteristics. The names of the categories (physical, performance, and dependability) were selected from an EPRI Guide and chosen simply to be descriptive of the characteristics. The names have no formal significance in themselves.

Physical Characteristics

Physical characteristics include characteristics of the item such as mounting attributes, dimensions, computer file size, manufacturer's part number, and computer program(s)/firmware revision number. Most of these characteristics are verified using inspection and measurement, which fall under Method 1 (Tests and Inspections).

Performance Characteristics

The engineer should, as part of the technical evaluation, determine if there are specific performance expectations that must be met by the item or service to perform the safety function. Examples could include start up and loading time for an emergency diesel generator, closing time for an automatic closing damper, blow-down percent for a relief valve, or operation during normal service conditions. For computer program(s), performance could also include the functionality required of the device (the "must-do" functions) and performance related to this functionality (e.g., response time). Performance CCFD could also include environmental requirements related to the needed performance (e.g., meeting accuracy requirements over a specified range of ambient temperatures).

Performance characteristics also include characteristics related to failure management and "must-not-do" functions. Although applicable to mechanical and electrical systems, failure management is especially applicable to computer program(s). For example, based on a failure analysis, a required behavior of the item under certain abnormal or faulted conditions may be identified in the specifications. This behavior most likely is a critical characteristic that will require verification. Acceptance criteria might include items such as detection of failures, and "preferred" or fail-safe failure modes to be entered under prescribed circumstances. Verification methods may include testing and design reviews, supported by failure analysis and reviews of

operating history. These activities can involve Methods 1 (Tests and Inspections), 2 (Commercial Grade Survey), 3 (Source Verification), and 4 (Supplier/Item Performance Record).

Dependability[10] Characteristics

Dependability characteristics is the category in which dedication of computer program(s) differs from that of other types of items. Dependability addresses attributes that typically cannot be verified through inspection and testing alone and are generally affected by the process used to produce the item. A key issue is that mechanical and electrical item failures are typically associated with fabrication defects, aging and wear-out, but computer program(s) do not wear out. If there is a problem in the computer program(s) that degrades its dependability, this reflects a computer program(s) design defect that was built into the item, or a mismatch between the item specifications and its design.

In traditional dedications of mechanical and electrical equipment, dependability issues have been treated within the supplier's QA program and have been delineated in the commercial grade survey or source inspection plan. Due to the increased importance of the "built-in" attributes to computer program(s), this Guide has defined these attributes as critical characteristics to ensure that they are adequately addressed and documented during the dedication process. Although this may be viewed as a departure from traditional procurement and dedication practices, the end result is considered compatible with current industry practices.

Dependability attributes, such as reliability and built-in quality, are generally influenced by the process and personnel used by the supplier in the design, development, verification, and validation of the item. For computer program-based systems, high quality is best achieved by; building it in, following a systematic life cycle approach from requirements through implementation, with verification and validation steps, and appropriate documentation for each phase of the life cycle. Hence, understanding the vendor's development process can be very useful in developing confidence in the dependability of a product.

The dependability of an item can be heavily influenced by designed-in elements, including robustness of the computer hardware and computer program(s) architectures, self-checking features such as watchdog timers, and failure management schemes such as use of redundant processors with automatic fail-over capabilities. Evaluation of these attributes requires that the dedicator focus on more than just the development and QA processes. It may require gaining an understanding of the specific computer program(s) and computer hardware features embodied in the design, and ensuring that they are correct and appropriate in light of the requirements of the intended application.

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[10] The term "dependability" is used in various ways within the software and safety communities. In this document it is used broadly to include a number of characteristics of computer programs such as reliability, availability, built-in quality, and other related characteristics.

Accordingly, a survey team may need to include specialists who understand the computer program(s) and the system in which it will be applied in addition to QA and programmatic issues.

The dependability category captures those critical characteristics that must be evaluated to establish reasonable assurance regarding built-in quality of the item. It also includes characteristics related to problem reporting and configuration control. Verification of these characteristics typically involves a survey of the vendor's processes (Method 2), and review of the vendor performance record and product operating history (Method 4). Source inspections (Method 3) may be used to verity certain computer hardware quality characteristics during manufacture, or to ensure quality of changes made to computer program(s) as part of a particular procurement. Source inspections would not be used in verifying built-in quality of pre-existing computer program(s), because the computer program(s) development has already occurred.

The critical characteristics in the dependability category, including the "built-in quality" characteristic discussed in Appendix D, Table D-1, are somewhat different from those in the other categories because they are less tangible and quantifiable than a part number or a physical dimension. A commercial item may be judged to have sufficient quality, even if its development process lacked some of the rigorous steps of modern computer program(s) engineering and/or some formal documentation. Reaching a reasonable level of assurance of quality of a CGI typically involves making a judgment based on a combination of the item development process and its documentation, operating history, testing, review of design features such as failure management, and other factors noted in the critical characteristics.

The dedicator must determine what activities are appropriate to verify the built-in critical characteristics. In general, the choice and extent of activities undertaken to verify adequate quality, and the specific criteria applied in making the assessment, depend on the safety significance and complexity of the item.

2.1.1.7 Failure Modes Effect Analysis

Failure analysis provides information that assists in evaluating and verifying critical characteristics. It is important to understand the failure modes of the commercial device and their impact on the system failure modes. Failure analysis supports CGD as well as design. Consideration of potential failure modes and mechanisms helps to identify critical characteristics. Without an understanding of the item/service failure modes and the effects of failure in its operating environment it can be difficult to discern the impact of a failure on the safety function. ASME NQA-1 states in the technical evaluation general discussion that the credible failure modes of an item in its operating environment and the effects of these failure modes on the safety function shall be considered in the technical evaluation for the selection of the critical characteristics. Services shall be evaluated to determine if the failure or improper performance of the service could have an adverse impact on the safety function of equipment, materials, or the facility operations.

It is incumbent on the engineer to ensure that failure modes are properly developed and evaluated through a suitability review of the item's characteristics for design. Suitability reviews are discussed in Section 2.0. Some common failure modes are listed in Appendix B, Potential Failure Modes, "Examples of Creditable Failure Mechanisms."

2.1.1.8 Critical Characteristics for Acceptance

ASME NQA-1 states that the CCFA shall be identifiable and measureable attributes based on the complexity, application, function, and performance of the item or service for its intended safety function. The CCFA criteria shall include tolerances and computer data input ranges when appropriate. CCFA shall include the part number, computer program(s) version identifier, physical characteristics, identification markings, and performance characteristics, as appropriate. ASME NQA-1 also states that an item's part or catalog number shall be considered a critical characteristic if it provides a method to link the item with the manufacturer's product description and published data.

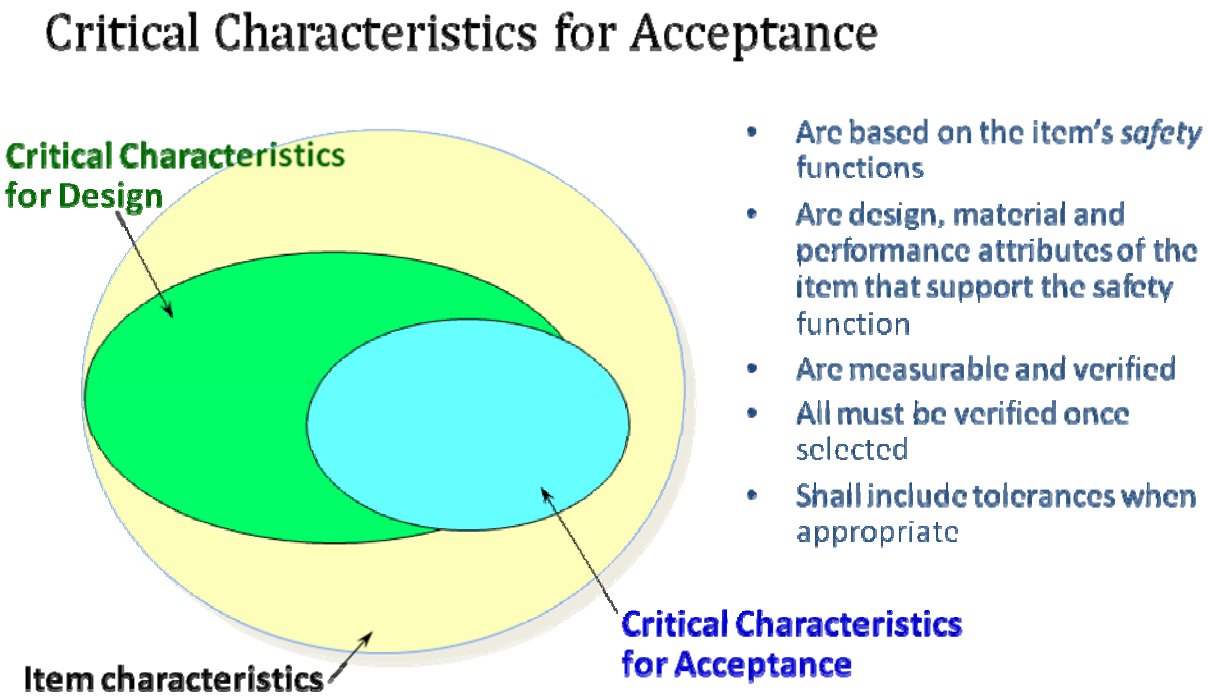

Figure 3: Critical Characteristics for Acceptance

The dedication process shall not rely on the part number or computer program(s) version identifier alone as the only critical characteristic to be verified. CGIs or services can have numerous characteristics that are related to composition, identification, or performance of the item or service. However, it is not normally

prudent or fiscally sound to verify all item characteristics and/or CCFD to provide reasonable assurance that the item or service will perform its intended safety function. The CCFA are those characteristics that one or more of the four acceptance methods discussed in Section 2.2 will be applied to in order to verify acceptability. Both the specific acceptance method and the acceptance criteria will be specified for each CCFA in the dedication package.

Reasonable assurance is considered to have been provided when, in the opinion of the responsible engineer, a sufficient number of CCFD and item characteristics have been verified and documented as CCFA to cause one to believe that the item will be capable of performing its safety function. The level of verification is expected to be graded. Items with less impact to safety or with large design margins may not need as many characteristics verified with as much rigor as items with critical safety importance and/or lower design margin. The following factors should be considered in determining the extent and type of verification to be applied:

- The consequences of malfunction, defect, or failure of the item;
- The complexity or uniqueness of the item;
- The need for special controls over process parameters and surveillance of equipment resulting from use of the item; and
- The degree of standardization of the item.

EPRI 102260 also states that when establishing reasonable assurance the engineer should consider; a) what is the degree of verification of any critical characteristic for acceptance; b) was an adequate sample of items chosen for verification; and c) were the proper critical characteristics for acceptance selected for verification?

Critical characteristics selected for acceptance shall be identifiable and measurable attributes based upon functional complexity and the application and performance of the item or service. Unless controls are in place to prevent usage in undesignated locations, include criteria related to the location/design basis conditions (or manufacturing design limits) of the item in the facility. For computer program(s) the location of the computer hardware and its computer configuration where the computer program(s) is installed may be a CCFA. For acceptance, not all CCFD need to be verified to provide reasonable assurance that the item or service will perform its intended safety function(s). This Guide does not require justification for failure to select a CCFD as a CCFA, however a clear understanding of why the set of CCFAs selected for verification was sufficient to provide reasonable assurance should be documented.

The vendor/supplier's published product description or additional technical information typically identifies technical criteria or performance characteristics inherent in the design and manufacturing or development of the item. The vendor/supplier can employ standard tests or inspections as part of the manufacturing or developing process and

utilize a quality program to assure that appropriate controls are applied. This type of information is an example to be considered in the selection of critical characteristics and the related acceptance criteria.

In cases where the CCFA criteria cannot be determined from the manufacturer's documentation or other documentation, the dedicating entity may perform an engineering evaluation, examination, or test (or any combination thereof) of the original item to develop the CCFA criteria.

2.2 Dedication

Engineering performs the selection of acceptance methods as part of the Technical Evaluation and documents the selection in the CGD Plan.

The selection of an acceptance method or combination of acceptance methods for the CCFA of a given CGI or Commercial Grade Services (CGS) should be based on factors such as the selected CCFA, available supplier information, supplier quality history, and degree of standardization.

The dedicating entity shall provide reasonable assurance that the item meets the acceptance criteria for the identified CCFA. The four methods that can be used are:

- Method 1 - Special Tests, Inspections, and/or Analyses;
- Method 2 - Commercial Grade Survey of Supplier;
- Method 3 - Source Verification; and
- Method 4 - Acceptable Supplier/Item Performance Record.

The four acceptance methods provide, either individually or in combination, a means to reasonably assure that the CGI/CGS meets the requirements that were specified. The justification for the method(s) selected and the results of employing each method must be documented in the CGD plan.

Prior to classifying the item or service as acceptable to perform its safety function, the dedicating entity shall determine if the following have been successfully performed:

- Damage was not sustained to the item during shipment;
- The item or service has satisfied the specified acceptance criteria for the identified critical characteristics; and
- Specified documentation was received and is acceptable.

The selection of acceptance method(s) shall be planned and based on the type of critical characteristics to be verified, available supplier information, quality history of the item and the supplier, and degree of standardization. If a critical characteristic cannot be verified by the selected dedication method, the dedication entity may select another or combination of dedication methods to verify the critical characteristics. The selection of another or combination of other dedication methods should be documented in a revision to the CGD Plan including justification for the revision.

The organization that performs or directs the dedication activity and determines the item or service has satisfactorily met the acceptance criteria for the selected critical characteristics is the dedicating entity. The dedicating entity can be the manufacturer/vendor/supplier, a third-party organization, the purchaser, or the nuclear facility organization. In some instances the responsibilities for the technical evaluation and performing the acceptance methods in accordance with the CGD Plan are performed by different organizations. For example, when the supplier does not have design responsibilities, the CCFA are provided by the purchaser/design authority. In this case the purchaser is directing the CGD activity and as such, is the dedicating entity. The ultimate responsibility for CGD is the owner who initiated the procurement.

2.2.1 Third Party Dedication

A third party dedicator is any company other than the original equipment manufacturer or buyer that procures and accepts commercial grade items and supplies the dedicated items as safety-related under their approved QA program[11]. The purchase order to a third party organization (TPO) from the buyer is a safety-related purchase order. As such, the TPO's ASME NQA-1 program should be evaluated and approved prior to performance of the dedication activity.

The TPO may establish a working or teaming relationship with the original equipment or part manufacturer. This allows the TPO to obtain information on design, technical requirements, and CC for design.

The Buyer can provide the TPO with the technical information needed to accept the commercial grade item. Where design information is not known, the TPO may assume item design responsibility. When the TPO is an authorized representative for a supplier and has access to the supplier's design information, the TPO may also be responsible for assuring the CGI is like-for-like. If the CGI is equalivent, the TPO can be assigned to assure the item will not degrade the seismic and/or environmental qualification of the host equipment. The TPO's responsibility for like-for-like or alternate evaluations needs to be clearly specified in the contract.

2.2.2 Method 1 – Special Tests, Inspections, or Analyses

[11] ERPR TR-102260, *Supplemental guidance for the Application of EPRI Report NP-5652*

Special test(s), inspection(s), or analyses either individually or in combination shall be conducted upon or after receipt of an item to verify conformance with the acceptance criteria for the identified critical characteristics. Use of Method 1 solely may be appropriate for the following:

- When the item is simple in design;
- When the computer program(s) does not include functionality beyond the safety functions;
- Commodity items;
- When critical characteristics are able to be verified with tests/inspections;
- Data to verify critical characteristics is available in existing documents such as specifications, drawings, computer program(s) life cycle documents, instruction manuals, bills of material and catalogs;
- Where multiple suppliers of the item exist;
- Items are purchased in small quantities or larger homogeneous lots where sampling can be applied; and
- Items on which post-installation tests can be conducted.

If Method 1 is not appropriate as the only method of acceptance, than it can be used in conjunction with Methods 2, 3, or 4.

Special tests, inspections, and/or analysis may be carried out by third parties (e.g., test labs or third party dedicator) provided they have been approved by the buyer as acceptable for use. Acceptance is either provided by an ASME NQA-1 evaluation and subsequent placement on an approved suppliers list or by survey if not part of an ASME NQA-1 program. In general, the services of an outside testing laboratory should be treated as any other service the user is procuring. Testing laboratories, as other types of suppliers, have a wide range of quality programs which may include 10 CFR 50, Appendix B. When outside services are utilized, the purchaser must have verified that the test laboratory has in place programs and procedures which ensure as a minimum:[12]

- Tests are conducted properly and to industry standards (American Society for Testing and Materials [ASTM], etc.);

[12] EPRI TR-102260, *Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial Grade Items*, Section 2.4.1.2

- Test equipment is calibrated and maintained in accordance with manufacturer recommendations;

- Accuracy of test equipment used is appropriate to the acceptance criteria and tolerances specified;

- Testing personnel are trained and qualified in the use of the test equipment and test methodologies; and

- Calibration standards are traceable to nationally recognized standards.

Some tests and inspections cannot be performed until after an item is installed. When post-installation test(s) are used to verify acceptance criteria for the critical characteristics, the CGI or CGS shall be identified and controlled to preclude inadvertent use prior to satisfactory completion of the dedication activities.

It is important to the process of implementing Method 1 to understand the difference between standard receipt inspections and/or simple computer program(s) installation checkouts and special tests and inspections performed after receipt. Even though receipt inspection and/or simple computer program(s) installation checkouts are important to the CGD process, they are not adequate on their own for CGD. With that said, it is recognized that while the part number or computer program(s) version identifier are attributes of a receipt inspection, they should also be part of the dedication process for the item. They can be verified during receipt inspection but should be listed as a CCFA.

ASME NQA-1 describes the standard receiving inspection as checking the quantity received, damage, general conditions of items, and part number. For computer program(s) receipt inspections are as simple as checking that the computer program(s) media has not been damaged and that the version identifier(s) are correct. Special tests and inspections go beyond the standard receiving inspection activities to verify that the CCFD selected as a CCFA are met. Example CCFD's that could be verified as CCFA include:

- Material type (chemical make-up);

- Material physical characteristics (e.g., Hardness, yield strength);

- Length;

- Open or closing time;

- Leak rate;

- Computer program(s) version identifier; and

- Computer program(s) application size (e.g., number of KB).

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, computer program(s) development organization, or a supplier engineering organization, depending on the item. Specific acceptance criteria from the item specifications, design documents, technical codes, or industry standards must be listed in the CGD plan for each CCFA when applicable. Experience has shown that Engineering and QA organizations should be working together during the development of acceptance criteria.

When evaluating the results of the test or inspection, all values tested or inspected must fall within the tolerance or data input range specified in the acceptance criteria. If one or more of the acceptance criteria is not met, the item is documented as nonconforming resulting in an engineering evaluation of the results of the test and/or inspection relative to the item being able to meet the safety function. Other like items should be evaluated to determine if they would exhibit the same nonconformance (i.e., extent of condition)

In addition to performance of a test or inspection by the dedicating entity or third party, the results of tests and inspections performed by the vendor/supplier may be reviewed to establish acceptability if sufficient confidence of the vendor/supplier's performance of the test or inspection is established. This is normally accomplished by performance of a vendor survey discussed in Section 2.2.2. The following approach may be used to prepare or review packages for items that are dedicated using Method 1:

- Perform receipt inspections to verify that the associated CCFA have been properly verified;

- Review receiving records and associated supplier tests and inspection results;

- Verify that the tests and inspections specified for acceptance using Method 1 will adequately verify the identified CCFA;

- Verify that sampling plans are controlled and have adequate technical basis, considering lot traceability and homogeneity, complexity of the item, and adequacy of supplied controls;

- Verify that the CGI receiving inspection activities are adequately controlled under a quality program regardless of whether the inspections are being performed in conjunction with other receipt inspection activities;

- Verify that receipt inspection activities establish and maintain traceability of CGIs by capturing and appropriately relating traceability documents through identification and monitoring of CGIs;

- Verify that measuring and test equipment were properly calibrated, that approved third party vendors were used to perform tests, and that personnel were qualified to perform the tests; and

- Ensure results of test performed are documented in test reports.

Where a number of identical items are being dedicated using Method 1, sampling[13] may be used for the performance of non-destructive and destructive testing to establish reasonable assurance that items received are the items ordered and that they perform their intended safety functions.

Sampling plans used to select items for special tests, inspections, and/or analysis shall have an adequate technical basis based on established standards that consider lot traceability, homogeneity, and complexity of the item. The approved sampling plan is part of an item's CGD package. EPRI Final Report TR-017218-R1, "Guideline for Sampling in the Commercial-Grade Item Acceptance Process," provides an enhanced methodology for the use of sampling in accepting and dedicating CGIs. Use of this EPRI guide provides useful information in establishing the basis for the sampling plan. Sampling plans are discussed in more detail in Section 4.

Services can result in a deliverable product that can be evaluated upon receipt or result in an activity that can be evaluated during or at the conclusion of its performance.

2.2.3 Method 2 – Commercial Grade Survey

The purpose of using a commercial grade survey of a supplier (Method 2) is to dedicate a CGI or CGS based on approval of a suppliers' implementing process and commercial controls as related to the items CCs when ASME NQA-1 is not invoked in the purchase order. The survey of the supplier must be performed and deemed acceptable prior to issuing the purchase order for the item or service. A survey of a supplier may be appropriate:

- When the supplier/manufacturer has implemented appropriate, documented commercial 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; and

- When critical characteristics are not easily verified after receipt[14].

[13] Sampling of software is only applicable for software embedded in digital equipment

[14] For CGD of computer programs, frequently, only Commercial Grade Survey can verify some of the critical characteristics. As such, this method will be used is most CGD of computer programs.

The basis of the commercial grade survey is to specifically identify the process controls and their controlling documents used or planned for use during the manufacture or development of the specific CGI. A commercial grade survey is a method to verify critical characteristics by evaluating the adequacy and effectiveness of the supplier/manufacture's commercial quality controls. A commercial grade survey is performed at the supplier/manufacture's facility using a checklist or survey plan developed by the dedicating entity. The survey shall address the following:

- Identification of the item(s), product line, or service included within the scope of the survey;
- Identification of the critical characteristics to be controlled by the supplier;
- Verification that the supplier's processes and quality program controls are effectively implemented for control of the critical characteristics;
- Identification of the survey methods or verification activities performed with results obtained; and
- Documentation of the adequacy of the supplier's processes and controls.

A commercial grade survey shall not be employed as a method for accepting CGIs or CGSs from suppliers with undocumented quality programs or with programs lacking effective implementation of the supplier's own specified processes and controls. After a supplier's specified processes and controls have been determined to be adequate, the dedicating entity shall invoke or reference the verified processes and controls, including revision level, as a part of the purchase order or control requirements for the CGI or CGS and then require the supplier to provide a Certificate of Conformance (C of C) attesting to the implementation of the identified processes and controls. Reliance is placed on the supplier/manufacturer to verify critical characteristics during the fabrication process. Commercial grade surveys do not qualify a commercial vendor to ASME NQA-1 requirements.

The following approach shall be used to prepare or review packages for items that are dedicated using Method 2:

- When a CCFA is based on certified material test reports or C of C, the criteria of ASME NQA-1a-2009, Part I, Requirement7, Section 503 shall be met. Specifically,

  a) The certificate shall identify the purchased material or equipment.
  b) The certificate shall identify the specific procurement requirements met by the purchased material or equipment, such as codes, standards, and other specifications. This may be accomplished by including a list of the specific

requirements or by providing, onsite, a copy of the purchase order and the procurement specifications or drawings, together with a suitable certificate. The procurement requirements identified shall include any approved changes, waivers, or deviations applicable to the subject material or equipment.

c) The certificate shall identify any procurement requirements that have not been met, together with an explanation and the means for resolving the nonconformance.
d) The certificate shall be signed or authenticated by a person who is responsible for this QA function and whose function and position are described in the Purchaser's or Supplier's QA program.
e) The certification system including the procedures to be followed in filling out a certificate and the administrative procedures for review and approval of the certificate shall be described in the Purchaser's or Supplier's QA program.
f) Means shall be provided to verify the validity of Supplier certificates and the effectiveness of the certification system such as during the performance of audits of the Supplier or independent inspection or test of the items. Such verification shall be conducted by the Purchaser at intervals commensurate with the Supplier's past quality performance.

- Surveys shall not be employed as a method for accepting items from distributors unless the survey includes the manufacturer/developer of the item and the survey confirms adequate processes and controls by both the distributor and the manufacturer/developer. A survey of the distributor may not be necessary if:

  a) The distributor acts only as a broker and does not store or repackage the items.
  b) In cases where traceability of the item(s) can be established by other means such as verification of the manufacturer's markings or shipping records.

- Surveys performed by organizations other than the dedicating entity may be used as a basis for acceptance if the survey results of the critical characteristics, survey scope, supplier's processes and controls, and acceptance criteria are evaluated by the dedicating entity to be acceptable and consistent with the dedicating entity's dedication requirements. The dedicating entity should also establish a basis on which to accept performance of a survey from another organization. One method to accomplish this would be for dedicating entities to consider partnering with other prime contractors to perform surveys together on the same supplier resulting in more efficient vendor oversight. The scope of the survey should be similar with each dedicating entity responsible to ensure that their CCFA are appropriately evaluated.

- The scope of the survey shall be determined by the dedicating entity based upon the item or service and critical characteristics to be verified. The survey shall be specific to the scope of the CGI or CGS being procured. When several items or services are purchased from a supplier, a survey of representative groups of CGIs or

CGSs can be sufficient to demonstrate that adequate processes and controls exist. The survey report shall provide objective evidence that the critical characteristics are verified and controlled by the supplier.

- If the scope of the survey cannot verify a designated critical characteristic due to controls by the supplier's sub-supplier(s), the dedicating entity shall extend the survey to the sub-supplier(s) or select another dedication method(s) to verify the critical characteristic.

- Organizations performing surveys shall develop criteria for the personnel qualifications and processes used to perform surveys.

- The survey documentation shall provide objective evidence that the processes and controls for the identified critical characteristics were observed and evaluated for acceptance. Deficiencies identified in the supplier's process or controls shall be corrected, if the survey is used for acceptance of the identified critical characteristic(s).

- If items are to be procured over time or the manufacture and/or development of the item occurs over a period of time, the dedicating entity shall establish a survey frequency to ensure that process controls applicable to the critical characteristics of the item or service procured continue to be effectively implemented. Factors to be considered in determining the frequency of commercial grade surveys include:

  a) The complexity of the item or service, frequency of procurement, receipt inspection, performance history, and knowledge of changes in the supplier's process and controls.
  b) The survey frequency interval may be the same used for supplier audits, but shall not exceed the frequency interval for supplier audits.

The following additional items may be used to prepare or review packages for items that are dedicated using Method 2:

- Determine if supplier documentation (e.g., production and quality records) relied on in the dedication of the item, is verified during the survey;

- Determine if surveys of a CGI vendor are performance-based as opposed to compliance-based or programmatic. Specifically, verify that the critical characteristics for the CGIs being surveyed are controlled by the vendor's quality control activities;

- If a potential supplier has multiple fabrication facilities, verify that the facility surveyed is the one providing the CGI or CGS;

- Determine if survey teams include technical and quality personnel, as appropriate, that are knowledgeable in the operation and safety function of the item(s) and the

associated CCFA to be verified, including any special processes such as welding, computer program(s) development, and heat treatment that are specific to the critical characteristics;

- Determine if the control of sub-vendors is adequately addressed by the surveys so that the vendor has an adequate basis to accept test results and certifications (e.g. Certified Material Test Reports) from their sub-vendor;

- Determine if pertinent information about a vendor or its products is used to plan, conduct, and report results of surveys and source verifications. (Such information could have been available from source verifications, receiving inspections, the dedication process, supplier/product performance history, or other sources [e.g., from DOE, or other government agencies (e.g., Nuclear Regulatory Commission {NRC}, Environmental Protection Agency, National Institute of Standards and Technology), information notices and bulletins, nuclear plant reliability data system reports, or Nuclear Utility Procurement Issues Committee commercial grade survey reports];

- Confirm that: a) the documented commercial quality program was effectively implemented; and b) the surveys were conducted at the location necessary to verify that adequate controls were exercised on distributors as well as manufacturers;

- Ensure the persons who perform vendor surveys are knowledgeable in: a) the use of performance-based surveys; and b) screening third-party surveys. The allowance for use of third-part surveys including guidance is discussed in Section 2.2.1 above.

- Determine if a previously performed survey is being used to establish the acceptability of a vendor or supplier's commercial quality program. If so, verify that for each procurement, the program requirements necessary to ensure that a CGI or CGS will perform its safety function are the same. Determine if the surveys have been updated on a regular basis to support dedication;

- Evaluate adverse findings resulting from the review of third party surveys to ascertain if those findings affect CGIs already received.

The dedicating agency shall complete the commercial grade survey, review the survey report and determine the extent to which the vendor's controls were found adequate. Then the dedicating agency will make a final determination of which critical characteristics are to be accepted using Method 2 alone and document the basis in the technical evaluation.

The dedicating agency should also ensure that the procurement documents specify that the vendor/fabricator/supplier or sub-tier supplier will provide a certificate of conformance attesting to the fact that the item was fabricated or the service was performed to the requirements of the procurement contract. The procurement contract

should invoke or reference the verified processes and controls including revision level for the CGI or CGS.

2.2.4 Method 3 – Source Verification

Source verification is a method of acceptance conducted at the supplier's facility or other applicable location to verify conformance with the identified critical characteristics and acceptance criteria during the fabrication/development process. The scope of the source verifications shall include activities such as witnessing the fabrication and assembly processes, computer program(s) development, non-destructive examinations, performance tests, computer program(s) performance tests, or final inspections, as applicable. It shall also include verification of the supplier's design, procurement, calibration, and material process and control methods employed for the particular commercial grade item or service being purchased, as applicable to the identified critical characteristics. For example a requirement to perform an inspection of a welding activity would also expect that an evaluation of welder qualification, rod control, and the weld procedure would be performed.

Organizations performing source verification shall develop criteria for the personnel qualifications and processes used to perform source verification. Source verification documentation shall provide objective evidence that the supplier's activities for the identified characteristics were observed and evaluated for acceptance.

Source verification is only applicable to the actual item(s) or services(s) that are verified at the supplier's facility or other applicable location. Source verification shall be performed in accordance with a checklist or plan with the documented evidence of the source verification furnished to the dedicating entity for approval and shall include or address the following:

a) Identification of the items(s) or service(s) included within the scope of the source verification.
b) Identification of the critical characteristics, including acceptance criteria being controlled by the supplier.
c) Verification that the supplier's processes and controls are effectively implemented for the identified critical characteristics.
d) Identification of the activities witnessed during the source verification and the results obtained.
e) Identification of mandatory hold points to verify critical characteristics during manufacture, development, and/or testing for those characteristics that cannot be verified by evaluation of the completed item.
f) Documentation of the adequacy of the supplier's processes and controls associated with the critical characteristics and acceptance criteria.

When using source verification, critical characteristics are verified by witnessing the quality activities of the supplier specific to the item being dedicated before an item is released for shipment to the Purchaser.

It may be appropriate to use Method 3 if the following conditions exist:

- 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 supplier's QA program/procedures;
- Buyer schedule demands;
- Single supplier of the item;
- Item purchased infrequently;
- Manufacture, computer program(s) development or fabrication requires a significant amount of time; and
- Item being procured is the first of its kind being manufactured, developed or fabricated.

The requirements for CGIs are defined in the purchase order which includes supporting technical documents. The documents include the identification of witness and hold points during the development of or fabrication of a CGI for performance of a CGS. The source verifier may be an auditor, inspector, engineer, Subject Matter Expert consultant or combination thereof.

Source verification activities may include witnessing a test such as:

- Material hardness;
- Nondestructive examinations;
- Tensile test;
- Hydrostatic test;
- Leak rate test;
- Material type (chemical analysis);
- Calibration;
- Operability;

- Electrical continuity;
- Insulation resistance;
- Pressurization; and
- Computer program(s) module functionality.

Witnessing an inspection:

- Dimensional;
- Configuration;
- Coating thickness;
- Weld;
- Non-destructive examination; and
- Computer code.

Observing a process:

- Welding;
- Assembly;
- Insulating;
- Coating;
- Heat treatment;
- Machining;
- Testing;
- Reviewing of computer program(s) specifications; and
- Reviewing of computer program(s) design.

The following approach may be used to prepare or review packages for items that are dedicated using Method 3:

- Determine what critical characteristics can be best verified during the manufacturing, development, or fabrication activities at the vendor's location;

- Determine and define the necessary witness or hold points to allow proper verification activities of CCFA during the fabrication process. Include the required inspection/verification points in the order to the sub-supplier to ensure notification of the dedicating entity; and

- Verify and document the acceptance of the critical characteristics selected for source verification in the CGD package.

In the application of this method proper care should be exercised to ensure that the data used is directly applicable to the verification of critical characteristics specific to the intended application of the item being dedicated.

2.2.5 Method 4 – Acceptable Supplier Item or Service Performance Record

Before using Method 4 as a means to justify that an item or service can demonstrate an acceptable CGD process, the dedicating entity needs to understand that EM considers this method very difficult to implement as a stand-a-lone method of acceptance. Method 4 should not be used unless it is in conjunction with Methods 1, 2, and/or 3.

This method of acceptance is based upon the documented, demonstrated past performance of the supplied item over a period of time for identical or similar items and/or services. The method can be applied best when the historical performance results can be compiled using: a) industry product tests; b) national codes and standards (ASME, ASTM, International Electrical and Electronics Engineers, etc.); c) monitored performance of the item installed and operated in a similar environment as the intended facility; d) industry data bases (Institute of Nuclear Power Operations [INPO], EPRI, Aerospace, Military etc.) or performance data resulting from use of Methods 1, 2, or 3.

Method 4 is a valuable means to assist in accepting CGI/CGS since it relies on documented historical performance and may not require costly and time-consuming inspection and auditing activities. However, Method 4 should only be used when a large dataset of successful historical performance for the item is available. The supplier item or service performance record or data shall be from the condition of service, environmental condition, failure mode, maintenance program, testing, or other conditions equivalent to the intended application of the CGI or CGS. Method 4 cannot be used if the only history available is with the purchaser.

Use of Method 4 allows the purchaser to accept CGIs based upon a confidence in the supplied item achieved through proven performance of identical or similar items or services. The method allows the purchaser to take credit for item performance based upon the historical performance and the records of the successful utilization of Methods 1, 2, or 3. In the application of this method proper care should be exercised to

ensure that the performance data used is directly applicable to the verification of critical characteristics specific to the intended application.

The basis of this acceptance should include the following as applicable:

- 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 an acceptable supplier/item performance record;
- 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;
- Shall not be a single source of information; and
- Should not be used as the sole method of acceptance.

An acceptable supplier item or service performance record shall include the following:

- Identification of the supplier item or service being evaluated;
- Identification of previously established critical characteristics specific to the item or supplier;
- Identification of utility/industry data examined to evaluate the supplier/item;
- Basis for determining that industry data substantiates acceptability of the supplier/item;

- Documentation of the adequacy and acceptance of the supplier/item/service performance record; and

- Statement of the purchaser attesting to the acceptability of the supplier/item.

An acceptable item or service performance record shall not be employed alone as a method of acceptance unless:

a) The established historical record is based on industry-wide performance data that is directly applicable to the critical characteristics and the intended facility application. Single sources of information are not adequate to demonstrate satisfactory performance.
b) The manufacturer's measures for the control of applicable design, process, and material change have been accepted by the dedicating entity, as verified by survey.

Continued application of an acceptable supplier/item/service performance record as a method of acceptance shall include a documented periodic update and review to assure the supplier/item/service maintains an acceptable performance record.

3. SAMPLING PLANS AND LOT FORMATION[15]

When sampling is required as a part of the acceptance process, the selection of the appropriate sampling plan complements the critical characteristic selection. Because of numerous procurement qualitative factors, it is normally not necessary to perform 100 percent tests or inspections to obtain reasonable assurance. Nuclear Facility procurements usually involve quantities that are small relative to large production lots unless new facility construction or modification is involved. Just as in the selection of critical characteristics, sound engineering judgment in the selection of sampling size is a key factor. The basis of the acceptability of random sample selection is that each item in the lot has an equal opportunity of being selected as part of the sample. Acceptance of the lot is then based on the sample results. If the sample results are acceptable then there is reasonable assurance that the remainder of the lot is acceptable.

Sampling plans used to select the number of items for special tests, inspections, and/or analysis should have an adequate technical basis using established standards that consider lot traceability, homogeneity, and complexity of the item. EPRI Final Report TR-07218-R1, "Guideline for Sampling in the Commercial-Grade Item Acceptance Process," provides an enhanced methodology for the use of sampling in accepting and dedicating CGIs.

Verify lot homogeneity when it is relied upon to apply a sample plan. The extent to which lot homogeneity must be verified is a factor of the safety significance of the item, the method of

[15] Sampling of computer programs is only applicable for computer programs embedded in digital equipment. It should be noted that in most instances the quantity of the same digital equipment item is small, requiring 100% sampling because of the small lot size.

testing selected, whether verification technique is destructive or non-destructive, the number of critical characteristics being verified, the cost effectiveness of the test or inspection and the correlation between the destructive and non-destructive testing. Objective evidence of the supplier's ability to provide acceptable items through its manufacturing product controls is a key factor. It is important to recognize that heat number, manufacturer lot number or other manufacturing identification intended to demonstrate traceability to common production cannot be used unless the traceability can be verified back to the source of manufacture. Groups of components or commodities obtained through a distribution chain without traceability control established through QA audit or commercial survey cannot be considered homogenous.

After the lot has been established, the EPRI report listed above can be used as a guide in determining the sample size. The results of the above evaluation should be used to develop the sampling plan. Selection of the appropriate sampling plan should also consider the additional level of confidence considered necessary. For a given CGI dedication, different CCFA can have different sampling plans. Sampling plans for non-destructive testing can be normal sampling plans, tightened sampling plans, or reduced sampling plans depending on lot formation. Development of sampling size for destructive and non-destructive testing based on lot homogeneity is discussed in detail in EPRI Final Report TR-07218-R1 and should be used by the dedicating entity when developing the specific sampling plan for a CGI. Guidance for determining an acceptable sample size may also be found in ANSI/ASQ Z1.4, "Sampling Procedures and Tables for Inspection by Attributes," and ANSI/ASQ Z1.9, "Sampling Procedures and Tables for Inspection by Variables for Percent Nonconforming." There may be cases where more or less than the recommended sample size should be tested based on specific details of the procurement. The basis for definition of the lot and sample size should be documented.

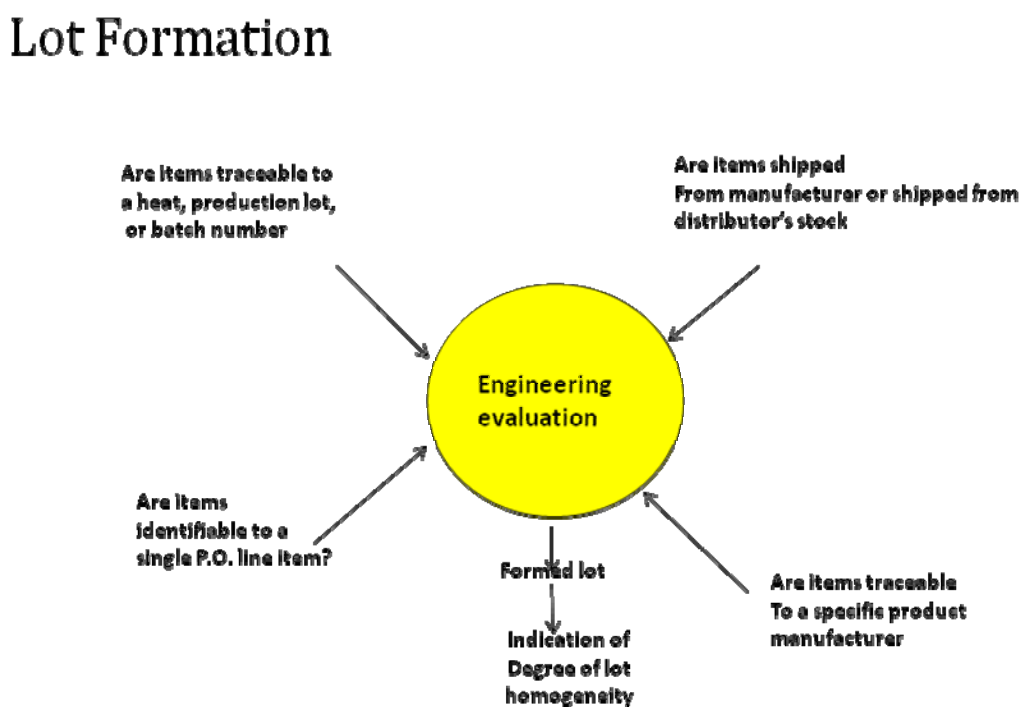

Figure 4: Lot Formation

4. OVERSIGHT AND FLOW-DOWN EXPECTATIONS

Each ASME NQA-1 supplier must be qualified by audit under the DOE contractor's QA program and placed on their approved supplier list. Periodic re-audits must be conducted as required by the DOE contractor's QA program for the vendor to remain a ASME NQA-1 qualified supplier and hence, remain on the Approved Supplier List.

Each sub-vendor to an ASME NQA-1 qualified supplier (vendor) that provides safety items or services under their own QA program must be audited and qualified in accordance with the vendor's QA program for the scope of supply and placed on the vendor's approved supplier list. If an approved vendor will have design responsibility, the DOE contractor or the vendor must specify the safety function based on the DOE approved safety analysis. If the sub-tier supplier with design responsibility is expected to perform CGD of items and/or services, than the CGD aspect of their ASME NQA-1 program must be evaluated and accepted as part of their approved program. If the vendor will not have design responsibility, then it is the DOE Contractor's/buyer's responsibility to perform a technical evaluation of the safety function, design, environmental conditions, failure modes analysis and significance of the item/services' safety function. Based on the technical evaluation, the DOE Contractor will provide the CCFA and acceptance criteria to the sub-supplier. The same logic applies to an approved sub-tier supplier with design and CGD responsibility that is receiving

material from supplier/fabricator that is not on their approved supplier list (based on an approved ASME NQA-1 program).

The above expectation should be included in procurement contract language to a company's ASME NQA-1 qualified vendors along with instructions for them to further promulgate the guidance to any of their ASME NQA-1 qualified vendors. However, even after having flowed down this guidance, the responsibility for the competent performance of CGD activities remains with the DOE contractor placing the procurement. Therefore, it is important that the DOE contractor maintain oversight of the entire supply chain where dedication activities could be performed.

4.1 Supplier Deficiency Correction

Deficiencies with the supplier's processes and controls identified by the acceptance method(s) shall be corrected by the supplier if it affects the acceptance criteria for critical characteristic(s) utilized for CGD. Corrective actions shall be evaluated for acceptability by the dedicating entity. Uncorrected deficiencies in processes or controls may result in the selection of another dedication method for determining acceptance or rejection of the item.

5. DOCUMENTATION

Documentation of the CGD process of an item or service shall be traceable to the item, group of items, or services and shall contain the following types of documents, depending on the applicable dedication method:

- Dedication plans or procedures including the essential elements of the dedication process;
- CGI or CGS procurement documents;
- Facility commercial grade definition criteria;
- Technical evaluations;
- Critical characteristic identification and acceptance criteria, including or referencing design documents and failure mode analysis;
- Test reports or results, inspection reports, analysis reports;
- Commercial grade survey reports;
- Source verification reports;
- Historical performance information; and

- Dedication report containing sufficient data to accept the item or service.

6. REFERENCES AND READING LIST

6.1 Codes and Standards

ANSI/ASQ Z1.4	"Sampling Procedures and Tables for Inspection by Attributes"
ANSI/ASQ Z1.9	"Sampling Procedures and Tables for Inspection by Variables for Percent Nonconforming"
ANSI N45.2.13	"Quality Assurance Requirements for Control of Procurement of Items and Services for a Nuclear Power Plant"
ASME B&PV Code, Section III	"Rules for Construction of Nuclear Facility Components"
ASME NQA-1-2004, and Addenda through 2007	"Quality Assurance Requirements for Nuclear Facility Application"
ASME NQA-1a-2009, Sub-Part 2.14	"Quality Assurance Requirements for Nuclear Facility Application"
DOE G 414.1-2	"Quality Assurance Management System Guide for use with 10 CFR 830.120, and DOE 0 414.1 C, Quality Assurance"
DOE/RW-0333P	"Quality Assurance Requirements and Description"

6.2 Industry References

EPRI NP-5652 (1998)	"Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications (NCIG-07)"
EPRI NP-6406 (1989)	"Guidelines for Technical Evaluation of Replacement of Items in Nuclear Power Plants"
EPRI Report TR-017218 (Rev 1)	"Guideline for Sampling in the Commercial-Grade Item Acceptance Process"
EPRI Report TR-102260 (1994)	"Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial Grade Items"

EPRI Report TR-106439 (1996)	"Guideline on Evaluation and Acceptance of Commercial Grade Digital Equipment for Nuclear Safety Applications"
NRC Generic Letter 89-02	"Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products"
NRC Generic Letter 91-05	"Licensee Commercial-Grade Procurement and Dedication Programs"
NRC IP 38703 (1996)	"Commercial Grade Dedication"
NRC IP 43004 (2007)	"Inspection of Commercial Grade Dedication Programs"
NRC IN 2011-01	"Commercial Grade Dedication Issues Identified During NRC Inspections"

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APPENDIX A
Examples of Critical Characteristics for Design

Table 1 - Examples of Critical Characteristics for Design

Identification	
Color coding Display type (scale, graduations) Enclosure type	Industry Standard Markings Part Number / Unique Identifier Nameplate Data
Physical Characteristics	
Balance Capacitance Cloud point Coating Color Composite material hardness Concentration Conductivity Continuity Density/Specific Gravity Dielectric strength Dimensions (to within manufacturers tolerance) Drop point Ductility Durometer Hardness Elasticity Fatigue resistance Flammability Flashpoint General Configuration of Shape Homogeneity Inductance	Leachable Halogen Luminescence Material hardness Material chemistry Oil/water separation Permeability Plating Polarity Pour point Purity Resilience Resistance Rockwell Hardness Surface Finish Solubility Spring constant Surface finish Surface hardness Tensile Strength Torque Total chloride content Viscosity Weight Yield Strength
Performance Characteristics	
Accuracy Burn-in endurance Chatter Current Rating Cycle Time Dead-band width Flow rate Gain Horsepower Input/output voltage Interrupt rating Interrupting current Leakage Load rating Open/closure time Operability (fail, open/close, stroke)	Operating range Performance during under voltage conditions Pickup & Drop-out voltage Power rating Pressure Drop Pressure Rating Pressure Test Repeatability Ride out Rotational Direction Set point stability (no drift) Speed Time/current response Voltage rating

APPENDIX A
Examples of Critical Characteristics for Design

Table 2 – Examples of Item Critical Characteristics for Design

Commercial Grade Item (Example) [(1)]	Critical Characteristics [(2)]
Anchor Bolt (Seismically Qualified Concrete Anchors)	Configuration, dimensions, material, wedge hardness, pitch
Control Switch (Reactor Building Sump Reset)	General configuration, contact configuration, voltage rating, current rating, materials, dimensions, operability
Crane Wheel Axle (Spent Fuel Bridge Crane)	Configuration, dimension, material, tensile strength, hardness, finish
Filter Regulator Assembly (High Pressure Control Valve, seismically qualified)	Configuration, dimensions, materials, flow rate, pressure range, pressure rating, temperature rating, filter micron size
Globe Valve, Seismically and Environmentally Qualified	Ductility, finish, markings, hardness
Impeller Key (Auxiliary Feed Water Pump)	Configuration, dimensions, material, hardness
Integrated Circuit (Reactor Protection System)	Configuration, gain, input/output impedance, frequency responses, operability
Limit Switch (Electric motor operator for a gate valve, seismically and environmentally qualified)	Configuration, dimensions, materials (metallic and nonmetallic), markings, operability, voltage rating, current rating
Motor (Cooling Room Fan)	Nameplate data (horsepower, speed), insulation class, frame size, materials, weight, shaft type, coupling type, bearing types
Nonmetallic Diaphragm (Air operator for a globe valve, seismically and environmentally qualified)	Configuration, dimensions, material, durometer hardness, reinforced material
Pinion Gear (Spent Fuel Bridge Crane Hoist)	Configuration, dimensions, material, hardness, pitch
Pressure Transmitter (Main Steam Isolation Valve Air Accumulator)	Configuration, voltage rating, current output, pressure rating, materials, accuracy
Pump Impeller (Make-up Water Transfer Pump)	Configuration, dimensions, material, hardness, balance, flow rate
Pump Mechanical Seal Assembly (Service Water Booster Pump)	Configuration (completeness of assembly), materials, finish, leakage, leachable halogen content, dimensions
Shaft Coupling (Diesel Generator)	Configuration, dimensions, materials, hardness
Solenoid Valve (Torus vacuum breaker)	Configuration, size, pressure rating, materials, voltage rating, current rating, coil class, open/closure time

Table 3 – Examples of Item Critical Characteristics for Design (continued)

Commercial Grade Item (Example) (1)	Critical Characteristics (2)
Spring (Pressure relief valve, seismically qualified)	Configuration, dimensions, (free length, coil diameter), spring rate, finish
Torque Switch (Operator for globe valve, seismically and environmentally qualified)	Configuration, dimensions, materials (metallic and nonmetallic), operability
Transistor (Uninterrupted Power Supply)	Markings, gain, input/output impedance, current rating, voltage rating, operability
Valve Packing Gland (Active control valve, seismically qualified)	Configuration, dimensions, material, tensile strength, hardness, finish
Valve Seal Ring (Emergency Closed Cooling System Globe Valve)	Configuration, material, dimensions, finish leakage
Valve Body	Configuration, material,
(1) Seismic and environmental qualification pertains to the parent component. (2) Part Number is a critical characteristic for each item.	

Table 4 – Examples of Bulk Item Critical Characteristics for Design

Commercial Grade Item	Critical Characteristics[16]
Bearing	Configuration, dimensions, load rating, material, model number
Bolting (Nuts, Bolts, Studs, etc.)	Configuration, dimensions, pitch, material, tensile strength, hardness, plating
Cotter Pin	Configuration (point type), dimensions, material, finish, hardness
Crimped Terminal Connector	Configuration, material, dimensions (wire size, ring tong size), voltage rating, continuity, tensile pullout strength, color
Drive Belt	Dimensions, cross-sectional shape, hideout, fatigue resistance, load rating, material, tensile strength
Fitting	Marking, material, dimensions
Flange	Marking, material, dimensions, sealing surface flatness and finish, bolting arrangement
Framing Device	Configuration, shape, dimensions, material, tensile strength, coating
Fuel Oil	Density, flash point, cloud point, pour point, kinematic viscosity, chemical composition, BTU rating viscosity, chemical composition,
Fuse	Configuration, current rating, interrupt rating, time/current response, dimensions
Lubricating Grease/Oil	Color, specific gravity, viscosity, drop point, cone penetration, pour

[16] Part number is a critical characteristic for each item.

	point, chemical composition, cloud point
Structural Material (e.g., Plate, Bar, Rod, etc)	Dimensions, shape, material, tensile strength, hardness, ductility, markings, coating
O-ring	Dimensions, material, durometer hardness, elongation, leachable halogens
Pipe	Marking, material, dimensions
Relay	Configuration, pick-up/drop out voltage, voltage rating, current rating, chatter, response time
Resistor	Configuration, markings, resistance, power rating
Spiral Wound Gasket	Configuration, dimensions, markings, style number, materials (filler and windings), pressure rating, leachable chlorides, spiral density
Temperature Switch	Configuration, dimensions, material, voltage rating, response time, accuracy, nameplate data, temperature range, wire rating, enclosure type dielectric strength (insulation), dead band width
Terminal Block	Configuration, voltage rating, current rating, materials, dielectric strength
Digital Valve	Product/Part Identifier, Computer program Version Identifier, Size of executable code, Receipt Media (embedded), Software Life Cycle Documentation (software specification, tests performed and results, user/configuration manual, maintenance manual), input signal, power, EMI, loss of signal, loss of power, operating history, response to abnormal conditions and events, configuration control, problem reporting, reliability
Seismic Design Standalone Application	Computer program version identifier, identification of all associated databases and data input files, size of executable code, size of all associated data input files, receipt media type, output file format, User interface functionality, cyber security functions, response to abnormal conditions and events, accuracy of results, isolation of safety functions, maintainability, quality of design, software life cycle documentation, problem reporting, requirements completeness and correction, design completeness and traceability, implementation completeness and traceability, configuration control, change control process, internal reviews and verifications, thoroughness of computer program testing.

APPENDIX B
Examples of Creditable Failure Mechanisms

B.1 Typical Credible Failure Mechanisms (CFM)

Blockage
Corrosion
Ductile fracture
Erosion
Excess strain
Fracture
Loss of properties
Mechanical creep
Open circuit
Seizure
Short circuit
Unacceptable vibration
Unresponsive computer program
Computer program exception encountered
Computer program crash

B.2 Potential Failures in the Performance of Services

Repair Services

- Use of unacceptable replacement part
- Improper welding or soldering
- Improper assembly
- Component functional requirement not being met after repair

Testing

- Use of un-calibrated testing equipment
- Technical inadequacies in performing the test
- Improper test specimen preparation
- Improper calculation of test results

Fabrication/Machining/Cleaning/Unique Manufacturing Processes

- Failure to meet dimensional requirements
- Material contamination

Training

- Errors in instructional materials used by trainees to perform a safety-related activity

Engineering / Technical Services

- Incorrect voltage drop calculations
- Failure to confirm initial assumptions

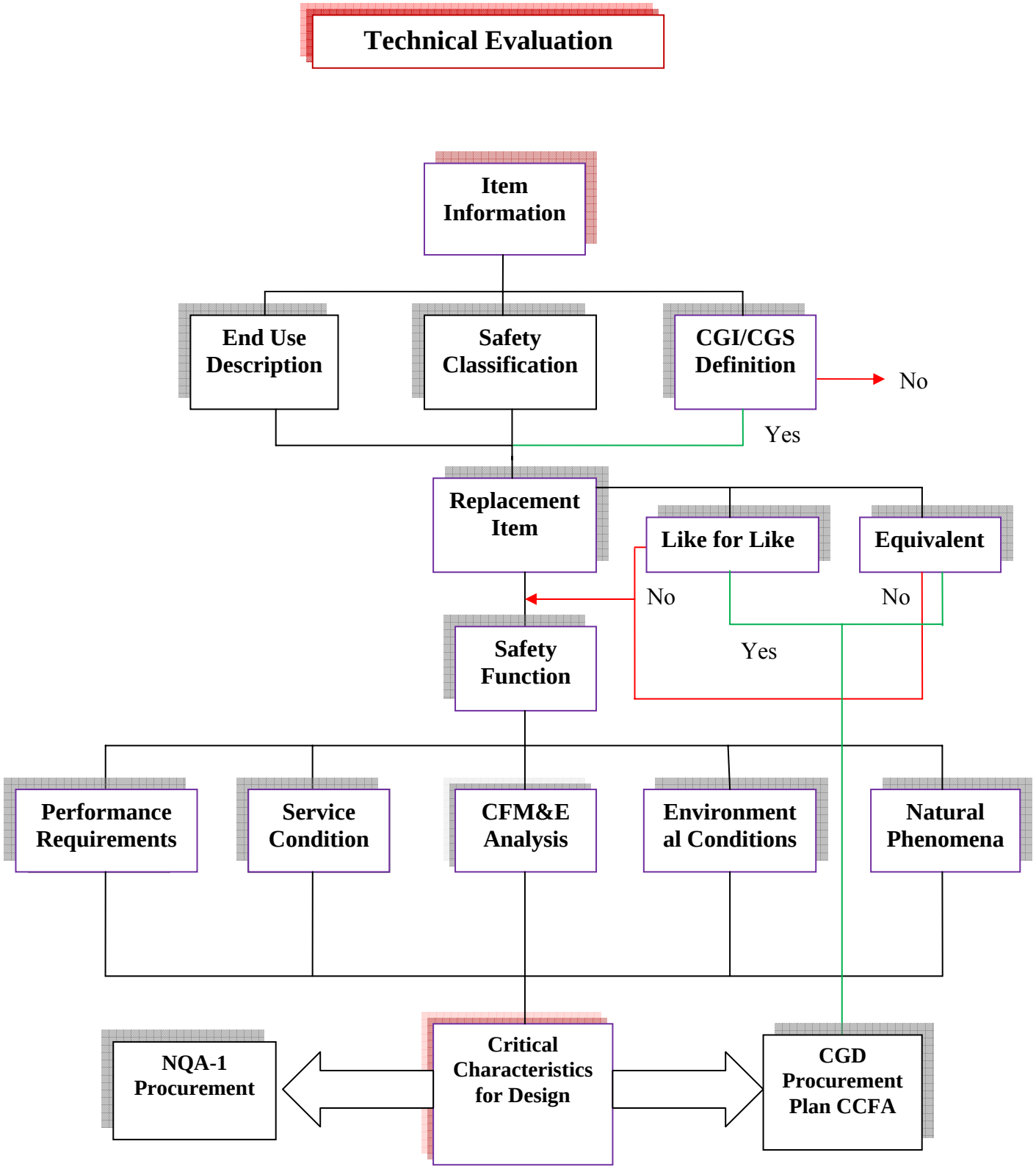
Calibration

- Equipment is out of calibration causing failure to accurately measure or actuate at the proper time
- Plant equipment is calibrated incorrectly by maintenance because the measuring and testing equipment has not been properly calibrated

APPENDIX C

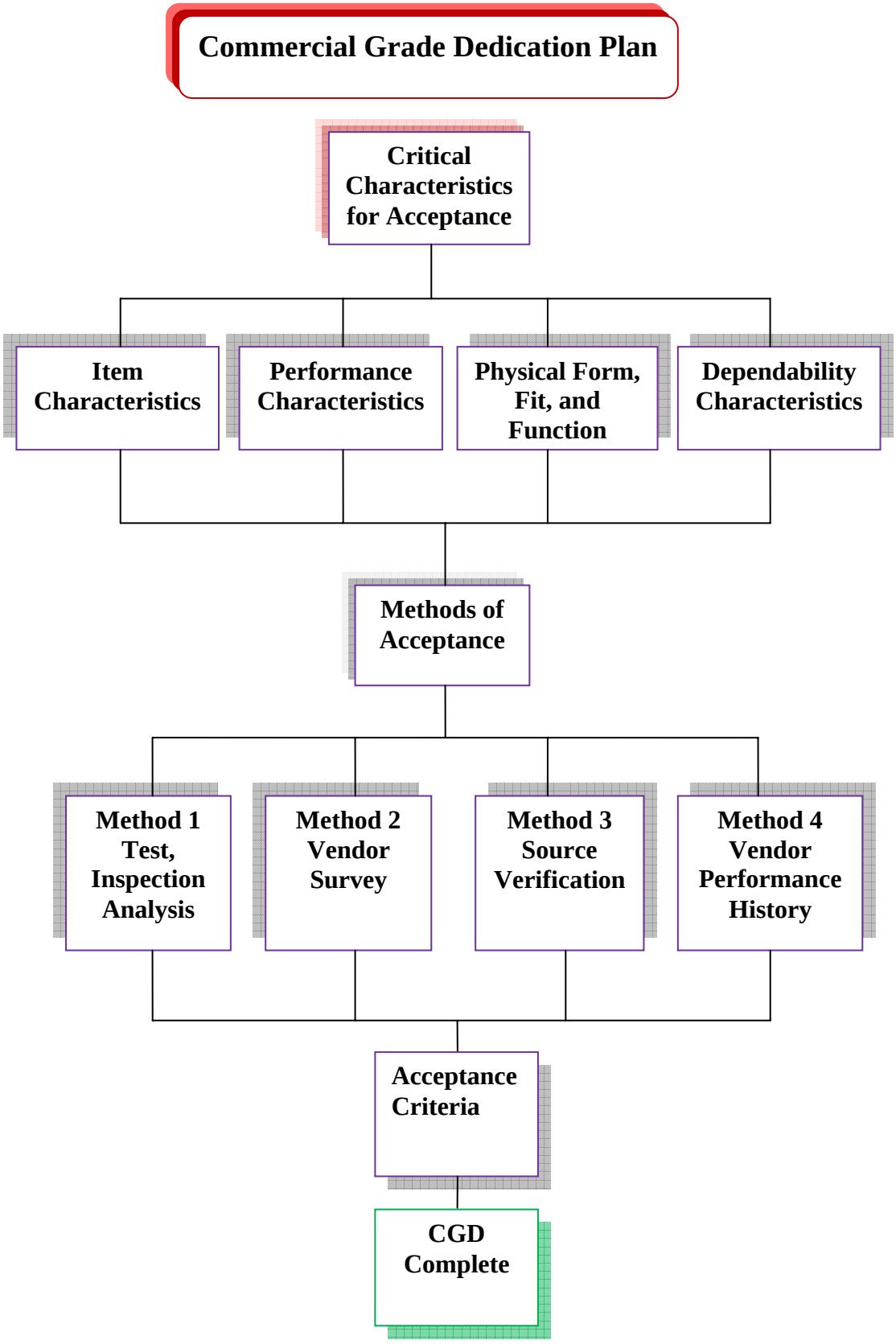
Example Commercial Grade Dedication Activity Flow Chart

COMMERCIAL GRADE DEDICATON ACTIVITY PROCESS FLOW CHART



APPENDIX C

Example Commercial Grade Dedication Activity Flow Chart



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APPENDIX D
Critical Characteristic Development for Digital Equipment and Software

Table D
Critical Characteristics for Digital Equipment, Embedded Computer program(s), Off-The-Shelf Computer program(s) and Stand Alone Computer program(s)

Identification CC:

CC	*Description*	*Acceptance Criteria*	*Method of Verification*
Host computer operating environment	The manufacture and model number of the host assembly or computer hardware computer program is intended to reside. This critical characteristic is applicable to all computer programs.	Host computer operating environment criteria must match the purchase specification. This should include the manufacturer name and model from a supplier's catalog. (e.g., Dell PowerEdge T110 Tower Server, IBM AIX & System, and Dell Precision T3500 Workstation, Siemens Simatic S7-400)	Verified through one or more of the following: o Inspection of receipt inspection documentation (Method 1) o Inspection of test system operating system identifiers. (Method 1)
Host computer operating system identifier	Vendor name, operating system version, service packs or patch identifiers that are needed for the computer to be executed. This critical characteristic is applicable to all computer programs.	Host computer operating system identifier must match the identifier in the vendor product list (e.g., Microsoft Windows 7, UNIX Operating System Version 5.1, B-5, and Yokogawa Pro-Safe-RS R2.01.00)	Verified through one or more of the following: o Inspection of receipt inspection documentation (Method 1) o Inspection of test system operating system identifiers. (Method 1)
Computer program(s) Name	The full name of the computer program(s). It should be the same identifier as used for during the procurement/acquisition process. This critical characteristic is applicable to all computer programs.	Computer program(s) name must match the product name from vendor catalog. (e.g., CFAST, Wolfram Mathematica 8, Monte Carlo N-Particle Transport Code System (MCNP5), Emerson valve Link, and Organic Concatenater)	Verified through one or more of the following: o Inspection of receipt inspection documentation (Method 1) o Inspection of test system operating system identifiers. (Method 1)
Computer program(s) Version Identifier	The complete version identifier including any patches. This critical characteristic is applicable to all computer programs.	Computer program(s) version identifier must match the product identifier from the vendor catalog the includes computer program(s) name-major functional version.minor functional version.	Verified through one or more of the following: o Inspection of receipt inspection documentation (Method 1) o Inspection of test system

		corrective revision (e.g., CFAST-05.00.01, Hotspot-02.07.01, Emerson valve Link-02.04-13, and Organic Concatenater-3.1b)	operating system identifiers. (Method 1)
Support Tools Name(s) and Identifier(s)	The complete name, including version identifier of all support tools that are used during the CGD process to assist in performing special tests or other support tools used in the operations environment. These tools, such as PLC test simulator tools and database management systems, could impact the correct operation of the safety functions performed by the computer program during special tests or operations.	Support tool name and identifier must match the product identifier from the vendor catalog or specification.	Verified through one or more of the following: o Inspection of receipt inspection documentation (Method 1) o Inspection of test system operating system identifiers. (Method 1)

Physical CC:

CC	***Description***	***Acceptance Criteria***	***Method of Verification***
Interfaces: User Interface	The computer program user interface design that provides consistency in design, including the use of symbols, notations, terminology, conventions, and layout that are important to the safety function. Although applicable to all computer programs, this critical characteristic may be more important for computer programs that have multiple users, used in control rooms or used by safety component maintenance staff.	User interface can be expressed by how well the user interface that is related to the safety function meets company HMI designs (e.g., 100&% of UI meets Americans with Disability Act requirements)	Verified through: o Review of computer program inspection reports against industry interface standards. (Method 1)
Receipt Media	The physical object or distribution media received from the supplier that contains the computer program. This critical characteristic is applicable to all computer programs.	Receipt media criteria is expressed as the method in which the computer program is distributed to the dedicating entity (e.g., CD, embedded, and downloadable.)	Verified through: o Inspection of media (Method 1)
Size (lines of code, function points)	The size of the computer program. This can be the quantity of folders received, the size in Kb of the executable(s), number of function points, or other physical means of measuring the size of the	Size criteria can be expressed in terms several different methods of measurement (e.g., 500K source lines of code (SLOC), number of data functions,	Verified through one or more of the following: o Review of design documentation (Method

	computer program. This critical characteristic can be important for embedded computer programs that must operate in processors with limited memory or storage or standalone computer programs that must execute with limited memory or storage.	and number of transactional functions)	2) o Execution of support tools that measure size (e.g., function points, SLOC) (Method 1)
Life Cycle Documentation	The documentation that is produced during all phases of the software life cycle. Documentation is evidence of the activities being performed. Documentation from multiple life cycle phases may be combined into one or more physical documents.	Life cycle document include separate or combined documents that include: Software Requirements Specification, Requirements traceability matrix, Design documentation, Architecture views, Design description document, Interface Documentation, Test Plans, Test Reports, and User Documentation.	Verified through: o Inspection of life cycle documents (Method 1)

Performance/Functional CC

CC	***Description***	***Acceptance Criteria***	***Method of Verification***
Abnormal Behavior: Response to Abnormal Conditions and Events	Action(s) or behavior which the computer program detects and responds to invalid inputs, erroneous states, and abnormal conditions. This critical characteristic is important to identify risks of the computer program failing to execute its safety functions.	As described in computer program requirements or procurement specification documentation. The criteria can be expressed as actions to the operations console when a warning event occurs (e.g., alarm on low power signal, entry of erroneous data input, entry of erroneous data sets, or initiation of data backups).	Verified through a combination of one or more: o Inspection and Testing (Method 1) o Review of design (Method 2) o Observation of development (Method 3) o Review the installed base to determine performance history (Method 4)
Accuracy/Precision/Tolerance Outputs	For accuracy the degree in which there is a close correlation with the expected or desired outcome. For precision the degree of repeatability or degree of measure. For Tolerance the allowable possible error in measurement.	As described in computer program requirements or vendor specification documentation. Criteria may be: accuracy- +- 1%; precision +- 0.0001; tolerance +- 0.00001.	Verified through a combination of one or more: o Observation and review of design (Method 3) o Inspection and Testing (Method 1)

CC	*Description*	*Acceptance Criteria*	*Method of Verification*
			o Review the installed base to determine performance history (Method 4)
Environmental Compatibility: Portability	The measure of the effort required to migrate the computer program to a different hardware platform, component or environment. This critical characteristic may only be important for computer programs that are expected to be executed in a different environment.	As described in computer program requirements or vendor specification documentation. Portability criteria can be expressed as a unit of time (e.g., 16 hours or 15 days).	Verified through: o Performing migration to one or more environments equivalent to the dedicating entities. (Method 1)
Functionality: Completeness	The measure of the extent the computer program design and implementation has satisfied the allocated safety requirements. This critical characteristic is important to identify risks of the computer program failing to execute its safety functions.	Functionality completeness is based upon how many of the computer program's requirements have been verified to be successfully implemented. Functional completeness can be expressed as a percentage of requirements implemented (e.g., 100% of allocated safety requirements are met.)	Verified through a one of the following: o Performing a review of the functional requirements traceability to test cases and verification that those test cases were successfully executed. (Method 2) o If requirements traceability is unavailable, the dedicating entity can develop the traceability matrix from the computer program's requirements or procurement specifications and test cases performed. (Method 2)
Functionality: Consistency with appropriate engineering/scientific	The degree in which the computer program's sample or complete data sets of results correlate with experimental data, expected data results or	and professional technical approaches is based upon peer reviewed published technical papers or industry accepted	Verified through a combination of one or more; o A comparison of peer

CC	*Description*	*Acceptance Criteria*	*Method of Verification*
research and professional technical approaches	professional analyses and any erroneous data sets do not correlate with the experimental data or professional analyses. This critical characteristic most likely is important to computer programs used to perform analysis of accident and structural integrity analyses for determining proper design of safety components.	computer programs performing a similar function. The output of the computer program can be viewed as how closely the computer program's output matches the technical report or baseline computer program output (e.g., computer program output correlates with experimental data to +/- 3σ.)	reviewed technical publication detail results against the computer program's output for a similar problem being solved. (Method 1) o A comparison of the baseline computer output against the computer program's output that is being dedicated. The baseline computer program must solve the same or closely similar physical problem as the dedicating computer program. (Method 1) o A review of the computer program's current user base and its applicability to the intended use by the dedicating entity. (Method 4)
Functionality: Correctness (correctness, proof of correctness)	The degree to which the computer program is free from errors, meets the specified requirements, and meets the user's needs. Correctness differs from completeness in that the number of requirements implemented is not considered. Formal techniques may be used to mathematically prove that the computer program satisfies its specified requirements. This critical characteristic is important to identify risks of the computer program failing to execute its safety functions.	Correctness may be expressed as the how well the computer program satisfies its requirements. The number of errors identified for each requirement can be an indicator as to the correctness. The severity or impact on performing the safety function correctly should be a factor in determining correctness. (e.g., 0 major errors reported, 5 minor errors reported, and 3 minor errors repaired and being tested	Verified through the following: o A review of the test results error categorization. (Method 2)
Functionality: Security	The protections included in the computer	As described in computer program	Verified through a combination of

CC	*Description*	*Acceptance Criteria*	*Method of Verification*
functions	program and operating environment which provide access to authorized users or which eliminate or mitigate unwanted access or unintended modification or the computer program. This critical characteristic may be important for computer programs that are executed on computer networks that are used by multiple individuals or are susceptible to intrusions.	requirements, procurement specification documentation and/or compliance standards. The criteria can be expressed as the presence of strong passwords, or biometric access, and network design including firewalls.	one or more: o Observation and review of design (Method 3) o Inspection and Testing (Method 1) o Review the installed base to determine performance history
Functionality: Interface Communications (usability, interoperability, communicativeness)	The measure to which the computer program operates properly and shares resources with other computer program or hardware operating in the same environment, the ease in which the various components of the system communicate with each other and external entities, to which the complexity of the interfaces is minimized. This critical characteristic may be important to standalone computer programs that are part of a complex analysis or component design and for many operator controlled devices such as digital cranes.	Interface communication may be expressed as how the computer program uses standardized or industry approaches in its design and implementation. These interfaces identify how well the computer program accepts input from or can send output to other systems (e.g., # of manual process steps to transfer the computer program output to be used as input to another computer program), uses industry and accepted port assignments (e.g., controller output port 3 is used to communicate with operator console) and ease in which operator controls are received by the computer program (e.g., all operator controls are via haptic devices such as joysticks).	Verified through one or more of; o Observation of computer program execution to assure interface standards are met. o Review of computer network design drawings. o Execution or observation of tests that exercise the external interfaces. (Method 1) o Inspect the user manual content that describes the process to receive or send electronic information to or from the computer program. (Method 1).
Functionality: Specific safety functions and algorithms	The critical functions or calculations that are performed. This includes time dependent functions. This critical characteristic is most likely is important to verify for all computer programs being dedicated.	As described in computer program requirements or procurement specification documentation. Functionality criteria may be similar to: given detector signal, close valve or given source input data, calculate dose exposure at 10 meters and 0 receptor height.	Verified through a combination of one or more: o Observation and review of design (Method 3) o Inspection and Testing (Method 1) o Review the installed base to determine

CC	*Description*	*Acceptance Criteria*	*Method of Verification*
			performance history (Method 4)
Interfaces: Critical input parameters and valid ranges	The set of input parameters that are used in the critical functions of the computer program and the range of their valid values. This critical characteristic is important to all computer program types to ensure that the computer program will function properly for all possible operational inputs.	As described in computer program requirements or procurement specification documentation. This criteria may be input voltage (e.g., 1.5 to 2.8 ohms), deposition receptor height (e.g. 0 to 1 ft), time: (dd/mm/yyyy hh:mm:ss); and length (1.00 to 5.00 meters).	Verified through a combination of one or more: o Observation and review of design and or implementation (Method 3) o Inspection and Testing (Method 1) o Inspection of user's manual (Method 1) o Review the installed base to determine performance history (Method 4)
Interfaces: Outputs parameters	The characteristics of the critical output parameters. The characteristics of the critical output parameters include file formats, signal specification, mathematical notations type, signal strength, signal type. This critical characteristic is important to all computer program types to ensure the computer program output is in the expected format or units of measure.	As described in computer program requirements or procurement specification documentation. This criteria can be specification of output filename (e.g., 28 characters, case insensitive with a file extension of pdf), output format specification (e.g., comma delimited) and units of measure (e.g., ohms, 1.0E-24, bams)	Verified through a combination of one or more: o Observation and review of design (Method 3) o Inspection and Testing (Method 1) o Inspection of user's manual (Method 1) o Review the installed base to determine performance history (Method 4)
Response Time	The time in which it takes the computer program to execute a specific action. This critical characteristic may be important to digital equipment that must perform an action within a specific period of time. Rarely is response time important to stand alone computer program applications.	Response time can be expressed in terms of time in days, minutes, seconds or milliseconds (e.g., the alarm is reported to the console 3 seconds after detection and calculation results are completed within 20 minutes.)	Verified through: o Observation or execution of functional test that is timed. (Method 1)
Throughput	The measure of the amount of work performed by	Throughput can be expressed in terms of	Verified through:

CC	*Description*	*Acceptance Criteria*	*Method of Verification*
	a computer program system over a period of time. This critical characteristic would rarely be important for digital equipment that performs on demand safety functions. This critical characteristic may be of best use for large analytical computer programs that require several hours to perform calculations.	completing a specified quantity of an object over a period of time (e.g., number of millions of instructions per second, and number of bits per second)	o Observation or execution of functional test that is timed. (Method 1)
Reliability	The extent to which the computer program can perform its critical functions without failure for a specified period of time under specified conditions. This critical characteristic more likely to be important for dedication of digital equipment. However, it can be used to for standalone computer programs used in design or analyses.	Reliability is typically expressed in terms of number of failures over a period of time (e.g., 1 failure per year in high radiation environment.) or number of failures for any given of executions of the computer program (e.g., 3 failures for every 100 computer runs).	Verified through: o Observation or execution of functional test that is timed or otherwise uses a counting attribute. (Method 1)

Dependability CC

CC	*Description*	*Acceptance Criteria*	*Method of Verification*
Built-in Quality: Existence of QA Program	A QA program that includes documented procedures or process controls. QA Program generally complies with a recognized standard (e.g. ISO 9000, ASME NQA-1). This critical characteristic can be used to determine if the foundation of a QA Program exists.	QA Program criteria are based upon the vendor's procedural compliance to a recognized standard that addresses development and quality assurance for computer programs. This criteria can be expressed in terms of the number of significant findings from a compliance audit against the chosen recognized standard, or achievement of certification for the chosen recognized standard.	Verified through one or more of the following: o Inspection of evidence of any 3rd party certification. (Method 1) o Review internal or external audit reports. (Method 2) o Performance of a survey against the chosen recognized standard. (Method 2)
Built-in Quality: Training, knowledge and proficiency of personnel performing the work	Staff training, knowledge and proficiency associated with the design, development, testing, oversight of the computer program, experience in similar projects, and familiarity with specific	Staff training, knowledge and proficiency criteria may include how well the specific staff member satisfies the vendor's qualification requirements	Verified through: o Review of objective evidence of attendance at courses, staff resumes,

CC	*Description*	*Acceptance Criteria*	*Method of Verification*
	tools, languages used in design and implementation. This critical characteristic can be used to provide an indicator of the errors remaining in the computer program.	for the position held. The criteria can be the percentage of qualification requirements met.	and on the job training against the vendor qualification requirements to determine how well the staff member satisfies the requirements. (Method 2)
Built-in Quality: Adherence to coding practices	The degree to which the computer program complies with the approved coding standards, use of code libraries, or automated configuration management tool. This critical characteristic can be used to provide an indicator of the errors remaining in the computer program.	Coding practice criteria can be a percentage (e.g., 90%) of the vendor coding standards met, and where appropriate 100% of possible code library modules are used instead of recoding.	Verified through: o Review of code inspection reports or other vendor evidence that included reviews of coding practice for the subject code modules. The dedicating entity during a survey may also review the code module(s) compliance with the vendor's documented coding practices. (Method 2)
Built-in Quality: Code Structure (complexity, conciseness)	The measure in which the computer program is legible, complexity is minimized, code length is minimized. This critical characteristic can be used to provide an indicator as to the difficulty to verify through reviews and testing that the code will perform as expected.	Code structure criteria can be quantitative through the use of static analysis tools or qualitative through reviews of the documented design or inspection of the code. Code structure criteria may take the form of number of internal subroutine interfaces, number of do-loops, numbers of exits from a module, straightforward flow of logic in code module, and code module depth and breath.	Verified through: o Review of vendor documented evidence from the use of a static analysis tool or the dedicating entity performing an inspection and manual analysis of the documented design or computer program code. (Method 2)
Built-in Quality: Error Minimization (defect density, defect containment	The degree in which errors are minimized. Indicators include defect density, effectiveness of error detection techniques to keep errors from	Error minimization criteria can include quantitative and qualitative measures. The acceptance criteria selected should	Verified through: o The review of vendor tracked errors detected

CC	*Description*	*Acceptance Criteria*	*Method of Verification*
effectiveness, defect severity)	entering the next software life cycle phase, and severity of the errors detected. This critical characteristic can be used to provide an indicator of the errors remaining in the computer program.	be appropriate for the computer language or code generation tool used to create the computer code. Error minimization criteria may be the number of errors detected per lines of code (e.g. 5 errors per 100 lines of code), number of errors per pre- and post release (5 major and 10 minor errors), and number of errors per software lifecycle phase (7 errors in requirements phase).	during reviews and inspections during the development and testing of the computer program. The dedicating entity may through the inspection of the vendor's documented reviews develop the values associated with the acceptance criteria. (Method 2)
Built-in Quality: Internal reviews and verifications	The degree in which static analysis methods (e.g. peer reviews) are performed during the computer program's development to identify errors and non-compliance to vendor procedures and standards.	Criteria for internal reviews and verifications effectiveness is based upon the ratio of errors identified during the review/verification and the number of errors that are discovered in the next life cycle phase. (e.g., ratio of the number of requirements errors identified during requirements review and the number of error detected during the design phase).	Verified through: o Inspection and analysis of results from reviews or verification activities performed in two or more adjacent life cycle phases. (Method 2 and/or Method 3).
Built-in Quality: Maintainability	The computer program design that provides for ease in performing modifications to the computer program. This critical characteristic may be more appropriate for computer programs whose failure could result in few or no alternatives should the computer program be unusable.	Maintainability criteria are based upon the time required to change the computer program. This criterion can be expressed as mean time to change or mean time to fix.	Verification through: o Review of vendor metrics associated with the length of time to evaluate the change/error correction, made the code change/correction, test the change/correction, update all computer program documentation, and release the change. (Method 2).
Built-in Quality: Process Effectiveness	A measure of how well the Vendor's QA process meets its purpose and objectives. This critical	Process effectiveness criteria are based upon the degree in which 3rd party	Verified through one or more of the following:

CC	*Description*	*Acceptance Criteria*	*Method of Verification*
	characteristic can be used to provide an indicator of the errors remaining in the computer program.	certification/recertification programs are achieved (e.g., 90% of achievement of compliance to CMMI SEI maturity level 4 or achieved ISO 9000) or by qualitative measures of conformance to the vendor procedures (e.g., 75% of vendor computer program procedures are met).	o Inspection of the proof of 3rd party certification (Method 1) o Review of vendor procedures and objective evidence that processes performed to produce the computer program is complaint with those procedures. (Method 2)
Built-in Quality: Testability	The measure of the effort required to perform computer program verification, validation, and installation testing. This critical characteristic may be appropriate to use when assurance is needed that reviews and tests were adequately performed.	Testability criteria are based on the ease or difficulty in conducting verification and validation activities. Testability criteria may include: # of hours to perform peer reviews, # of hours to pretest a module, and # of hours to develop test cases.	Verified through: o Inspection of documented review reports and test records that include the time spent to prepare, conduct, and perform post review or test activities. (Method 1)
Built-in Quality: Thoroughness of computer program testing	A measure of the completeness of the computer program testing to ensure that the computer program correct and complete. This critical characteristic may be appropriate to use for ensuring that tests were adequate to provide the reasonable assurance that the safety functions can be performed satisfactorily.	Thoroughness of computer program testing criteria can be measures that identify the quantity of errors discovered during the various testing activities (e.g., trend analysis of errors per module, comparison of pre- and post release errors) and traceability of tests performed to the safety requirements for the computer program (e.g., 95% of the requirements were tested).	Verified through: o Review of the objective evidence of the errors identified during the testing processes or traceability of safety requirements to tests completed. If objective evidence is not available, the dedicating entity may be able to create the traceability of the safety requirements to tests performed from the computer program's documented requirements and test

CC	*Description*	*Acceptance Criteria*	*Method of Verification*
			reports. (Method 2)
Configuration Control: Control of enhancements	The computer program improvements are controlled, approved, and necessary. Requirements churn is minimized but not zero. Control of enhancements minimizes unintended or prohibited functions. This critical characteristic may be appropriate to use when the stability of the computer program is important. This critical characteristic can provide an indicator as to the number of errors inserted into the computer program during the change process.	Control of enhancements criteria can be obtained from configuration control board statistics. These statistics may include number of enhancements (e.g., 15 changes/last year), and number of approved enhancements (e.g., 7 changes/last year), and number of completed enhancements (e.g., 3 changes/last year).	Verified through: o Review of meeting minutes of a configuration control board, data from change logs and release notes. (Method 2)
Failure Management: Isolation of safety functions	The computer program design implements methods of cohesion, reduces coupling, and promotes modularity. Cohesion is a module or routine that performs a single task or function. Modularity or decoupling is a module or routine that performs an independent task or function. Nominally, this is a qualitative measure. This critical characteristic provides an indicator to determine how much of the non-safety portions of the computer program must be included in the CGD process to provide the reasonable assurance that the failure of non-safety functions will not impact the proper execution of the safety functions.	Isolation of safety functions criteria can be the total number of computer program modules that perform safety and non-safety functions, there is no sharing of logic between safety and non-safety modules, and non-safety modules or routines may only read output of safety modules or routines.	Verified through: o Review of the computer program design or source code. (Method 2)
Failure Management: Redundancy	The computer program design to implement duplication of critical components with the intention of increasing reliability. This critical characteristic may be important when the failure of the safety function can lead to severe consequences that harm the individuals or the environment. This critical characteristic may be more applicable to computer program that controls instrumentation.	Redundancy criteria may include the existence of back-up critical hardware computing systems, multiple computer program development teams, information redundancy, multiple controllers, and dual processors.	Verified through: o Review of the computer program design, computer processor specifications, and computer system drawings. (Method 2)
Problem Reporting:	Notification by the vendor to customers of	Notification to Customers criteria may	Verified through:

CC	*Description*	*Acceptance Criteria*	*Method of Verification*
Notification to Customers	potential computer program errors or weaknesses.	be the presence and use of a problem reporting system, use of problem reporting metrics, and number of notifications to the users over time.	o Notification to Customers criteria verification is performed by reviewing communications of errors with users, review of any web site or other form of communicating with the vendor, and review of a log of communications. (Method 2)
Supportability	The ability for the vendor to continue support for the computer program over the life of its use. This critical characteristic is important for because of the difficulty to ensure the computer program is free of all errors. This critical characteristic should be considered when alternative computer programs are not easily obtained or where financially not feasible.	Supportability criteria can be the stability of the vendor based upon longevity of business (e.g. 20 years in business), size of customer base (e.g. 1000 customers world-wide), planned future product releases (e.g. vendor R&D has updates scheduled for next 3 years), and vendor history of discontinuing products (e.g., cancelled 3 product lines over past 2 years).	Verified through: o Review of the vendor history for the specific computer program as well as their history in supporting similar computer programs or products. (Method 4)
Build In Quality: Conformance to national codes and standards	The computer program's compliance to applicable national codes and standards.	Conformance criteria can be a measure of well the computer program meets industry accepted practices that provide a qualitative pedigree of the computer program.	Verified through: o Inspection of vendor performed assessments of the computer program against the national code or standard (Method 1) o Review of computer program documentation and artifacts against the selected national code or standard (Method 2)

Integration of QA in Design Guidance Document

U.S. DEPARTMENT OF ENERGY

OFFICE OF ENVIRONMENTAL MANAGEMENT

GUIDANCE FOR INTEGRATION OF QUALITY ASSURANCE IN DESIGN

July 2011

FOREWORD

This Department of Energy (DOE) Environmental Management (EM) guide is approved for use by all DOE EM organizational units and contractors performing work for EM.

A project's Quality Assurance Program assigns responsibilities and authorities, defines policies and requirements, and provides for the performance and assessment of work that provides confidence that required level of quality is achieved, commensurate with the various project requirements.

This guide offers for evaluation, by project personnel from EM and contractor organizations, activities and approaches to be considered as projects establish QA requirements to be used throughout the lifecycle of the project.

The need for this guide was recognized by the EM Quality Assurance Corporate Board as the membership was questioned regarding gaps in existing program support literature to be used on EM projects.

This guide should be considered throughout the lifecycle of project related activity and applied in a manner that fits the specific conditions applicable to the project.

Existence of a guide does not mandate its use. However, it is the expectation of senior EM management that this guide will be considered for implementation locally as conditions warrant. This guide details considerations that should be evaluated in establishing Quality Assurance Programs on EM Projects in fulfilling the requirements of 10 CFR 830 and DOE Order 414.1, Quality Assurance. This Guide does not modify or create any new requirements; instead, it explains how to satisfy existing requirements. As such, no contract requirements are altered by use of the guide.

Within this guide, any use of the term "shall" designates requirements contained in 10 CFR 830 or DOE Order 414.1, Quality Assurance, and "should" designates recommendations to meet EM expectations. Compliance with the standard is achieved by adherence to its requirements and consideration of its recommendations.

ACRONYMS

A/E	Architect/Engineering firm, external entity providing of professional design service support
ACI	American Concrete Institute
AISC	American Institute of Steel Construction
ASL	Approved Supplier List
ASME	American Society of Mechanical Engineers
ASNT	American Society for Nondestructive Testing
ASTM	American Society of Testing Materials
CD	Critical Decision
CFR	Code of Federal Regulations
CGD	Commercial Grade Dedication
CMTR	Certified Material Test Report
CoC	Certificate of Conformance
CRA	Contractor Readiness Assessment
DOE	US Department of Energy
DSA	Documented Safety Analysis
EFCOG	Energy Facility Contractors Group
EM	Environmental Management
EPC	Engineering, Procuring and Constructing Contractor
FPD	Federal Project Director
HVAC	Heating, Ventilation and Air Conditioning
M&O/I	Managing and Operating/Integrating Contractor
M&TE	Material and Test Equipment
MSA	Management Self-Assessment
NCA-xxxx	Series of ASME Requirements, a subsection to Section III of the Boiler and Pressure Vessel Code
NDE	Nondestructive Examination
NQA-1	Nuclear Quality Assurance-1, ASME's Quality Assurance national consensus code for nuclear activities
O&M	Operating and Maintaining
ORR	Operational Readiness Review
QA	Quality Assurance
QC	Quality Control
QSL	Qualified Supplier List
RT	Radiographic (volumetric) Examination
S/CI	Suspect/Counterfeit Items
SC	Safety Class
SS	Safety Significant
SSC	Systems, Structures and Components
TSR	Technical Safety Requirements
UT	Ultrasonic (volumetric) Examination

1. INTRODUCTION

This document will examine the roles and responsibilities of the Quality Assurance (QA) organization during the life cycle of projects. As a result, this paper will draw closely upon DOE Order 413.3A, *PROGRAM AND PROJECT MANAGEMENT FOR THE ACQUISITION OF CAPITAL ASSETS* and associated guides, since those documents define how DOE manages projects. The capital project "critical decision" defined phases will provide the framework for this guide's discussions regarding the involvement of the QA program and will address considerations that local project teams (DOE and contractors) will use in devising/tailoring their project's Quality Assurance Program throughout the project's life.

It is the intent of this paper to provide guidance to two audiences; DOE project personnel who are planning and overseeing projects within Environmental Management (EM), and contractor personnel who will be responsible for executing project QA activities. Also, the paper will examine the evolution of the QA program as different acquisition strategies (including Engineering, Procuring, Constructing (EPC), Architect/Engineer (A/E), and Management and Operating/Integrating (M&O/I) options) are considered.

This paper will also discuss the concept of an assurance system where quality is expressed as a project value that is shared in by all personnel assigned to the project throughout its life. Noteworthy practices that have been identified during audits and assessments of EM activities will be highlighted where appropriate.

In accordance with the project stages defined in DOE Order 413.3A, the discussions in this paper will generally align as follows:

- CD-0, Approve Mission Need
- CD-1, Approve Preliminary Baseline Range
- CD-2, Approve Performance Baseline
- CD-3, Approve Start of Construction; and
- CD-4, Approve Start of Operations or Project Closeout

Projects often evolve from ongoing program funded activities where mission needs are understood and possible approaches to meeting those newly identified needs begin their evolutionary development process.

2. ACTIVITIES UNDERWAY SUPPORTING CD-0, APPROVE MISSION NEED

- Conceptual design activities
- Request PED funding
- Justification of mission need document

- Acquisition Strategy
- Pre-conceptual planning
- Mission Need Independent Project Review

General Discussion:

During the CD-0 time frame, EM needs to focus on developing a project quality system that assures early activities are performed in a manner that provides information of sufficient quality to support subsequent tasks. Putting the project QA framework in place at the outset will also institute the type of quality environment necessary for delivering a project that meets all the performance requirements needed to fulfill the mission.

The EM staff managing the early phases of major projects must ensure that the overall quality requirements for the project are communicated to and understood by all organizations and personnel involved with the project. Understanding and communicating expectations that define the quality requirements and goals of the project are a key consideration. Although the final project contractual structure may be nebulous at this early point in the project, the approach to be used for including EM quality expectations into the project should be part of the project execution planning activities. This early planning should include items such as:

- What will be the overall quality program requirements?
- How will EM ensure that these requirements (and any other quality expectations) are communicated to prospective project organizations?
- Is preliminary work to support the project being performed, and is this work subject to EM's quality expectations? (one example might be early phase R&D and pilot/prototype activities needed to support project design activities).
- Are persons familiar with the EM quality systems part of the early phase project planning teams?
- When will certain quality oversight activities be implemented for the project?

In summary, at this early stage of the project when the executing organization may be somewhat unclear in terms of the level of involvement the M&O/I organizations will have (leading or supporting), whether or not A&E specialty contractors will be relied upon for design services, or if the project will be acquired thru the services of an EPC contractor, QA needs should be understood and accounted for either in existing M&O/I contracts or through independently developed A&E/EPC contracts and other related documents that will be defining EM's expectations for the execution of the project. Building an effective quality environment early in the project is essential. As has been noted, projects are evolutionary in nature and the establishment of clear QA requirements and expectations early will ensure reliable data is developed. Establishing appropriate and clearly communicated Quality Assurance requirements

and expectation will ensure the reliability of early efforts later in the project lifecycle, minimizing the need for the project to regress.

The goal of early phase project quality activities is to build an organization that understands EM's quality expectations and communicates to all project personnel that *Quality is bigger than QA***.** Regardless of the acquisition strategy selected, the Federal Project Director (FPD) should be focused on instituting a "project assurance" mentality within the executing organization(s) whereby all project personnel understand that the responsibility for achieving quality resides at the level where work is being performed. Individuals and organizations must be focused on delivering quality products that contribute directly towards mission success (e.g., programs, procedures, calculations, designs, drawings, specifications, plans, etc.).

When acquisition strategies identify the use of A&E/EPC contractors, the FPD will need to assure those contracts fully describe the expectations for Quality Assurance activities under the contract. Assurance requirements will need to fully describe, not only lifecycle QA expectations, but also how EM expects the oversight of early research, development, and design related activities to be performed.

It is not unusual that during this time, process flow sheets are leading to preliminary calculations and design products used to describe early concepts associated with the project (pre-conceptual design documents). The project quality system must ensure that the quality status of such early work is identified to personnel who will subsequently be using this information as sources of design inputs or safety analyses. Concurrently, the FPD needs to understand where his project is headed in terms of new construction or modification of existing facilities, purchase of services, and what safety significant/safety class systems the FPD anticipates being needed. These and other considerations will play heavily on the project's QA requirements as well as the structure of the FPD's assurance team.

The contractor's assurance system must provide for clear definition of interfaces between the varying disciplines involved in design and provide for a process of cross-checking of deliverables at those interface points by the involved organizations. The system needs a strong and independently functioning Quality Assurance organization performing oversight of critical activities such as long lead-time procurements and the design activities producing the specifications for these items. The contractor's assurance system also needs a strong management review process wherein senior leadership of the organization evaluates the performance of their organization and takes effective corrective actions where their oversight identifies deficiencies. The FPD may also decide it is important to establish expectations within the contract requiring the parent corporation to periodically review the work of the local entity and identify weaknesses and initiate improvement.

The efforts included within the CD-0 time frame are largely engineering and design support functions, and the need for a significant QA organization independently overseeing these

activities is to be determined by the FPD. This is a prime example where an assurance system that places responsibility for quality at the point where work is performed adds tremendous value. Introducing quality assurance concepts, even at this early stage of the project, creates a project culture that allows the continued evolution of assurance to proceed and develop as project conditions warrant.

As the project progresses, the activities being performed will transition to those necessary for executing the CD-1 project phase.

3. ACTIVITIES SUPPORTING CD-1, APPROVE PRELIMINARY BASELINE RANGE

- Allow expenditure of PED funds for design
- Acquisition Plan
- Conceptual Design Report
- Code of Record
- Preliminary Project Execution Plan and baseline range
- Project Data Sheet for design
- Verification of mission need
- Preliminary Hazard Analysis Report
- Process Related Studies such as Material Balance and Process Flowsheets associated with facility mission

General Discussion

Generally, M&O/I contractors will be supporting EM as directed in developing the pre-conceptual design information as well as other documents that support the decision related processes.

In cases where the acquisition decision defines the M&O/I contractor organization as the executing organization, understanding how that contractor's quality processes will be engaged early needs to be considered. Contractors should examine the applicability of their quality system to any project tasks assigned to their organization.

EM and any project contractors will also need to begin defining the project Code of Record. The Code of Record work should identify those upper-tier design basis documents that will apply to the project. Also, the method for configuration management of the Code of Record as well as products extending from their use, from a project perspective, must be developed.

Specific Considerations:

- Ensure that contract procurement documents include the requirements communicated within the EM Quality Assurance Program (EM-QA-001).

- Where appropriate, incorporate the standard Quality Assurance Clause as communicated via Memorandum of August 21, 2009 into the prime contract responsible for executing the project. (available online at www.em.doe.gov/Pages/QABoard Meetings.aspx#feb2010)
- Cross reference existing M&O/I Quality Programs to the requirements in EM-QA-001 to assure existing program scopes adequately address the projects anticipated needs.
- Begin defining the Code of Record and institute configuration management.
- Verify that project-related research and development work is proceeding under acceptable quality assurance requirements.

4. ACTIVITIES SUPPORTING CD-2, APPROVE PERFORMANCE BASELINE

- Establish baseline budget for construction
- Continue design development
- Request construction funding
- Preliminary design
- Process Related Studies: Material Balance and Process Flowsheet associated with facility mission
- Review of contractor project management system
- Final Project Execution Plan and performance baseline
- Independent cost estimate
- NEPA documentation
- Project Execution Planning (PEP)
- Project Control System Descriptions
- Project Data Sheet for construction
- Draft Preliminary Safety Analysis Report
- Performance Baseline External Independent Design Review reports and other Technical Baseline Documents
- Geotechnical/seismic investigations, studies, and reports
- Optimization/Value Engineering Studies
- Design Reviews
- Modeling/prototyping
- Testing programs (demonstrating technologies or material sufficiency)
- Analytical Laboratory Design Requirements
- Technology Readiness Reviews
- Final Design, Updated PDSA, and CD-3 Package
- Process Flow Diagrams

Project Related Quality Activities:

The following are activities projects will be engaging as they marshal project documentation in preparation for CD-2.

- Supporting Design processes and review of design deliverables:
    - Develop and implement procedures for reviewing:
        - Specifications
        - Drawings
        - Calculations
        - Design reviews
        - Design interfaces
        - Design changes
    - Provide oversight of configuration management program for control of upper tier design requirements such as design inputs and design criteria
    - Provide oversight of design change control process
    - Assist engineering in developing commercial grade dedication process
- Supporting Procurement Processes:
    - Develop comprehensive quality related procurement subcontract clauses to be flowed to applicable subcontractors, suppliers and vendors addressing:
        - NQA-1 related expectations and requirements
        - Suspect/Counterfeit Item (S/CI) program requirements
        - Commercial Grade/Item Dedication (CGD) requirements
        - Software QA requirements
        - Flow-down of requirements to lower level suppliers
    - Institute grading process for requirements identification and flow-down in subcontracts
    - Define and implement a comprehensive process for qualifying subcontractors, suppliers and other vendors
    - Identify long-lead procurements and ensure the capability to provide required QC/QA oversight is available
    - Develop receiving processes in conjunction with the engineering organization addressing normal receipt inspection activities as well as CGD capabilities and S/CI evaluation processes
- Implement Software Quality Assurance program for applicable design and analysis activities including modeling codes and calculations.
- Develop Quality Control (QC) program plans and procedures
- Develop training and indoctrination plans and procedures for project participants
- Early Procurements: Ensure QA/QC capabilities to oversee those early activities are available (CD-3x requests: project specific as the project employs the approach)

General Discussion

Progress on the project will begin to pick up momentum during the period leading to CD-2. Testing and/or modeling programs are normally nearing completion during the phase which allows process definition to mature. As that maturation process continues, material selections based on process parameters will be made. Drawings and specifications, as well as the calculations supporting those designs, will be underway. Geotechnical investigations will likely be in the field gathering fundamental data to support resolution of soil/structure interactions as well as seismic conditions that will play into the civil/structural design of the building(s) that will house the process. As process definition matures, the ancillary supporting processes and perhaps the facilities where they will be housed will be defined. As stated initially, a tremendous amount of activity will be performed by the technical organizations.

The contractor QA organization will be busy confirming the bases for engineering decisions are well executed as data and calculations are translated into plans, designs, specifications, etc. Particular care needs to be paid to ensure adequate and appropriate QA requirements are defined within those specifications. NQA-1, Part II contains insight within the amplified requirements that the project should consider.

The QA organization must also ensure the contractor QC programs and procedures are appropriate to measure those characteristics that will define the quality of an item being installed. The codes and standards defined by the code of record and referenced in the various design documents will define attributes that must be achieved to assure that Structures, Systems, and Components (SSCs) will perform as expected. Procedure authors must consider all these requirements and devise a set of procedures that ensures data is collected and retained that demonstrates reasonable assurance the SSC will perform as required.

For example, QC inspection procedures must confirm that fit-up requirements defined within Weld Process Specifications (WPS) are accurately used by crafts performing welding of pipe, accurately referenced and used by the QC personnel at all organizations including fabrication related suppliers or field personnel, etc. Another example is drawn from structural steel erection. The American Institute of Steel Construction (AISC) provides a Specification of Structural Joints Using ASTM A325 and A490 Bolts. Therein it discusses acceptable fastening processes for the various kinds of joining operations associated with bolted connections. QC procedures should address specific fastening processes selected by the designer and collect information as necessary to substantiate fastening of the structural components to achieve the design expectations.

Also during this phase, the QA organization must verify that all appropriate organizational interfaces have been defined and understood. In particular, lines of communication and organizational responsibilities for activities specified in project execution plans must be clearly defined in interface documents and understood by the appropriate project personnel. For example, close coordination of procurement and fabrication organizations with design personnel

is required so that QC and QA procedures accurately plan for the collection of the right information that verifies the design intent is actually achieved. The specific responsibilities for design and fabrication activities by all involved organizations, including contractors and EM organizations, should be defined in interface control documents or other project plans, procedures and subcontracts, where applicable. The design authority and design agency functions should be included in these interface definitions.

Specific Considerations:

Early Procurements:

As projects develop, the need for specialty services, such as geotechnical/seismic engineering services and/or soil sampling/testing capabilities to support in-house engineering activities may be identified. Also, it is often appropriate for early CD3x authorities to be granted to address long lead procurements or site development needs. These are business decisions and will be tailored to the particular project based on their needs to move in an orderly fashion to executing the full CD-3 scope.

The FPD and contractor will be working closely to identify those strategies that are appropriate for their particular project. When such authority is granted, special care must be taken to ensure the QA/QC requirements and programs/procedures supporting those scopes are well developed and adequate to assess those early activities. That may require expediting development of these kinds of documents, particularly in the case of EPC managed projects, to ensure the early work is performed in a competent manner. Procedures controlling Supplier Qualification Audits as well as those needed to provide oversight of suppliers/subcontractors must be available when executing early work.

FPDs should have resources associated with the oversight of the contractor's early services subcontracts, as well as any subcontracts related to early CD3x activities, identified, available, and deployable as the authority is conveyed and work moves to execution. Further, the FPD should carefully examine how the contractor is overseeing both in-house and subcontracted work to help identify weaknesses and correct them before full CD-3 construction authorities are granted.

Supplier Qualification:

Experience suggests supplier evaluation/qualification is a very important process and weak processes may allow problem suppliers onto project approved supplier lists (ASLs/QSLs). Both EM and EFCOG have concluded that diverse audit teams, representing QA and technical organizations are best to effectively evaluate supplier capabilities.

EM's experience has shown there are suppliers with effective QA programs predicated on NQA-1, which appear competent based upon initial reviews. However, some suppliers have been ineffective in operating those programs as the work is performed. This forces EM's prime contractor to dedicate additional resources to assure the adequacy of supplier performed work. This experience is primarily in heavy industries engaged in ASME related activities (vessels/piping) and needs to be evaluated based on the scope of the project and market surveys completed by the contractor in ascertaining potential participants in subcontracts.

EM has a collective wealth of experience with numerous suppliers and regularly observes that suppliers are contracted to multiple projects. Contractors should engage other EM/DOE contractors within the complex as these kinds of decisions are being made. The FPD may need to facilitate those discussions.

The project may experience poorly implemented QA programs within some supplier shops. Projects will have to be ready to focus additional resources to assure the quality of the items being fabricated in that supplier's shop meet the project's design expectations. A best practice observed in the EM complex is to assemble teams of QA and select technical personnel that bring the requisite skills to the problem and deploy them to the problem shop to supplement supplier resources and perform additional assurance functions as required. These are often diverse teams involving both QC, NDE, welding and QA expertise. Depending on the nature of the engineered equipment being fabricated and observed performance issues, these teams may be deployed for extended periods. EM has observed skills possessed by the NDE and welding engineering personnel are not needed on a daily basis in the supplier shops. They normally rotate thru the supplier's shops as suppliers perform radiographic/ultrasonic examinations (RTs) or qualify welders.

Welding engineers may need to pay additional attention as suppliers introduce new welding processes into the work or begin welding under different WPS to ensure the supplier's qualified welders possess the appropriate skills for the work. The welding engineers should review the supplier's welder qualification processes to ensure they are adequate.

There have been instances where skill of supplier's NDE interpreters has been less effective than necessary. In these instances, prime contractors have bolstered their Level III interpretation resources and periodically deploy them to perform oversight of this crucial process. The NDE skills, particularly of RT examiners may also rotate thru shops as the work necessitates.

These decisions will be considered in the context of the problems being encountered and the need for compensatory oversight plans to address the unique weaknesses discovered within the supplier's organization.

Software Quality Assurance:

The EM contractor requirements for software quality assurance are defined in Attachment 2 Section 5 and Attachment 5 of DOE Order 414.1d. Guidance on implementing a software quality assurance program that meets EM expectations is provided in DOE Guide 414.1-4. Early establishment of a software quality program is essential to providing confidence in the quality of design results because many design activities are now performed using computer codes and models. Additionally, the proficiency of today's engineers in writing software and developing spreadsheet models virtually ensures that such personally-developed calculation routines will be part of the design process. The quality assurance program must include persons with knowledge of software quality assurance early on and must develop procedures for identifying and controlling software used in design activities, research, or development work that develops design inputs.

Many of EM facilities are reliant on distributive control systems to operate facilities. Computer software used to automate Safety Instrument Systems and Balance of Plant DCS systems require special care. EM observations are that it is crucial to develop clear and concise technical requirements to all procurements, but perhaps the best example is with DCS related equipment and software.

QA Organization and Budgeting:

Special care must be taken when building budgets in support of construction oversight by the QA organization. There are times contractor's present these costs as Level of Effort (LOE) activities and this approach is routinely suspicious by those tasked with assuring budgetary requests are reasonable. Contractors should consider directly linking QA/QC activities to specific work activities within resource loaded project schedules. This approach represents a clearly correlating link between the work being overseen and the resource(s) needed to perform its oversight. It is recognized that all oversight, particularly that of other LOE activities in project budgets, isn't practical. In those instances, contractors need to pay careful attention to documenting the scopes included in the LOE and making the clearest possible link to those LOE activities being performed by other organizations. It may best serve the QA Organizations' interests to use the WBS dictionary descriptors as it develops these narratives and expand on the nature of the oversight attributable to discrete WBS entries rather than attempting to generate overarching discussions to justify resource requirements grouped together. The former should result in a clearer case for the resource allocations being requested within the CD-3 budget request.

When allocating risks within the project baseline, the contractor and FPD should work closely together to understand the nature of the work, the nature of the supplier pool likely assisting the project, and evaluate risk appropriately. FPDs observing contractors planning minimal oversight of suppliers should enter discussions with the contractor to understand their basis for this decision and determine if their approach for identifying project risks is reasonable. FPDs should

ensure their contractor is adequately examining the risks associated with subcontractor/supplier performance and, when appropriate, addressing those risks within the project's risk management/mitigation planning.

Commercial Item Dedication:

The project will likely be engaged in the dedication of commercially available items. Requirement 7 of NQA-1 should provide the basis for project programs and procedures involving the dedication process. The project personnel responsible for establishing Commercial Item Dedication requirements/programs should consult a document entitled Guidance for Commercial Grade Dedication, published July 2011 and may be found at: http://www.em.doe.gov/Pages/QACorporateBoard.aspx.

QA will have a role in the dedication activities; however, their responsibilities should be generally limited to performing the tasks associated with item acceptance, as identified by engineering. Therefore, engineering must have the lead in identifying the required dedication activities.

Commercial Item/Service Dedication must:

- Clearly identify the item/service
- 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
- Fully document the basis for all decisions associated with the dedication of an item or service

QA and Engineering will also have important duties for suppliers performing dedication activities. Validating the effectiveness of dedication actions down in the supplier's supply chain is essential to understanding how dedicated components get assembled into larger assemblies and eventually accepted for use in the project/facility. Lessons learned by EM projects suggest the lower tier suppliers often don't understand the dedication process or how to implement it with the level of rigor required to adequately demonstrate the item/material/service will perform its

intended function. Contractor specifications need to thoroughly address the expectations associated with commercial item/service dedication and establish requirements within prime-subcontracts that the requirement be passed down to subordinate subcontractors.

The contractor must review each dedication plan developed by prime-subcontractors and their subordinates to ensure the lower level dedications are performed effectively and do not introduce unresolved quality issues as the eventual item or service is delivered to the facility. Although the engineering organization will have the lead, QA has a role in supporting the validation of subsupplier dedication activities.

In order that these reviews are performed correctly and consistently, project QA programs must address oversight of supplier dedication activities. Particular care needs to be paid, in plan approval, to supplier's technical evaluations to assure the item or service will perform as intended. Close communication may be required to adequately convey the functional requirements associated with the item or service so those responsible for identifying critical characteristics associated for the item or service are effective. The project may see the need to have review/approval of this process so engineering organizations are assured the communications leading to the identification of those critical characteristics, and eventually the selection of those key characteristics for acceptance by suppliers, will be effective.

Material Verifications:

The project needs to identify, within its procedures, the methods to be employed for verifying materials by both self-performed activities as well as those activities performed by suppliers. The project should identify sources of specialized laboratory support in performing chemical and physical properties testing. QA will need to qualify laboratories in terms of adequate procedures, appropriately qualified personnel, and the adequacy of equipment to perform against the various consensus standards controlling the properties of the material. Similar considerations will be needed by suppliers, depending on the approach to material verification they will use.

EM contractors are widely using Positive Material Identification (PMI) techniques in validating material. Project engineering personnel need to consider the convenience and limitations of the available equipment. Particular care needs to be taken in describing, in project procedures, the expectations regarding verifying certified material test reports (CMTRs) for all metals. Depending on the materials identified within the design, engineering may need to identify additional controls that are needed when examining exotic metals, particularly those low-carbon alloys with chemical makeup beyond the limits of PMI equipment or other alloying materials not measured by PMI equipment. Recognizing its limitations, PMI should NOT be viewed as an independent analysis of alloying ingredient content. Rather, PMI provides a degree of confidence that the material is accurately represented by the accompanying CMTR; that no mix-up has occurred during procurement and storage. If the chemical and physical properties of the material must be independently tested, or the content of light elements such as carbon and

nitrogen must be verified, then a sample should be sent to a qualified laboratory for the appropriate analyses.

The project needs to address, if it selects to utilize PMI in material validation, how it relies on PMI-obtained chemical properties in accepting physical properties (tensile and yield strength, hardness, ductility, etc.) data found on CMTRs and CoCs. ASME Code Case N-483 entitled *Alternative Rules to the Provisions of NCA-3800, Requirements for Purchase of Material Section III, Divisions 1 and 3,* is an instance where that code body has devised a methodical approach to using alternative data to validate vessel material. Engineering must identify the bounds within which PMI can be used and define where it may not.

Inspection and Testing Support:

In general, NQA-1, Part I, Requirement 10 states within 100 Basic "Inspections required to verify conformance of an item or activity to specified requirements or continued acceptability of items in service shall be planned and executed." Identifying those attributes of an item or activity that are essential and are to be documented will require close coordination and identification/agreement of the engineer designing the item or specifying the activity.

The requirements continue by emphasizing "Characteristics subject to inspection and inspection methods shall be specified. Inspection results shall be documented." This is where QA/QC procedures will clearly layout the expectations and preferably the actual requirements associated with the work being executed. At a minimum, the QA/QC procedures must define where inspection requirements or acceptance criteria is found, such as concrete specifications (compressive strength, slump/air content, temperatures, truck revolutions, etc.), Weld Process Specifications [fit-up requirements (gap, land, bevel, preheat, post-weld heat treatment, etc.)], etc. are to be found.

Project QA personnel need to plan for specialized testing services that may be needed to support QA and QC activities. These services may be obtained via staff augmentation or may take the form of specialty subcontracts where services are needed to perform supporting activities like concrete testing, radiographic examinations, material testing, etc.

These services will either be obtained from organizations with existing and effective NQA-1 QA programs or from service suppliers with QA programs finding their basis in some other standard, and dedicated (CGD) by the project. The decision regarding the method the project will use will likely be driven by commercial conditions that will only be known as the procurement is processed. As a result, it is recommended these services be procured at the appropriate time, such that the services are available when needed to support the work.

The project, if it involves concrete, needs to be mindful of the storage requirements for test specimen that will be generated as construction proceeds. ASTM C31 will normally be the

standard that establishes the storage requirements for freshly molded concrete test specimen. It establishes the physical requirements as well as temperature limitations associated with temporary storage of the specimen. Potential difficulties associated with temperature extremes need to be understood and planning effective in assuring cylinders do not exceed the limits established within the standard. Other controlling codes or standards to a project need to be understood and similar considerations recognized and planned to avoid disruptions.

Nondestructive Examination (NDE):

Engineering needs to define the requirements associated with NDE as it pertains to the various materials to be used within the project. In the case of weld examination for process piping systems, ASME B31.3 establishes visual examination as well as other examinations required under the code. In the case of Normal Fluid Service piping, Section 341.4 requires at least 5% of circumferential butt and miter groove welds be examined fully by random radiography. The code goes on to provide some cautionary statements associated with the RT examination frequency. The code body advises:

> *Random or spot examination will not ensure a fabrication product of a prescribed quality level throughout. Items not examined in a lot of piping represented by such examination may contain defects which further examination could disclose. Specifically, if all radiographically disclosable weld defects must be eliminated from a lot of piping, 100% radiographic examination must be specified.*

This advice needs to be considered by engineering as they are determining the NDE requirements for the systems they are designing. If the service of the piping, or other welded components, mandates the potential presence of a weld defect could compromise the integrity of the system and that compromise would result in an unacceptable consequence, then the NDE requirements associated with that work needs to be commensurate.

EM has observed piping that underwent 5% random sampling within the initial inspections, actually contained ~30% defects. Engineering needs to be mindful of this potential as it establishes NDE requirements for piping, vessels and similar components.

EM's experience has shown instances where 100% radiographic examination of piping or vessel components is appropriate. In instances where components are destined for areas of the facility that, due to design considerations, repairs are impossible or otherwise inconceivable, (e.g., embedded within concrete structures) an increased radiographic examination is warranted. These considerations will not only effect QA inspection plans but also will effect specifications of procured engineered equipment destined for these areas. Fabricated components (i.e., spool pieces) performed via subcontract agreements will also be included.

Another consideration engineering needs to define as it prepares its specifications is how piping "lots" will be managed within the context of the NDE examination processes. ASME B31.3 states:

> *A designated lot is that quantity of piping to be considered in applying the requirements for examination in this Code. The quantity or extent of a designated lot should be established by agreement between the contracting parties before the start of work. More than one kind of designated lot may be established for different kinds of piping work.*

It may be in the project's interest to manage piping lots around those components shipped concurrently. This allows for a simplistic approach to the transfer of QA supporting document that may benefit the project. By defining shipped quantities as lots where possible, all QA records, including radiographic or other NDE examination records, may accompany the shipment, making records management more simple. This approach may be particularly helpful when subcontracting for large quantities of spool pieces or other similar fabricated items with NDE associated with the item's production. Similarly, defining lots for internally produced spool pieces will make NDE, particularly when predicated on sampling approaches, more manageable and defensible as reviews of QA documents take place.

Although it is recommended specifications establish lot designations, it is not imperative. As advised by ASME, there needs to be agreement between the parties before the start of work. Since the lot designation process has the potential to effect the amount of NDE performed as the items are fabricated, it is recommended that subcontract documents clearly establish the expectations so that suppliers may appropriately plan and bid the work.

Lastly, Engineering needs to define those processes, acceptable under the various codes, that are deemed acceptable processes to be used on the project. For example, ASME allows volumetric examination using ultrasonic (UT) as well as radiographic (RT) processes. Engineering needs to evaluate the pros and cons as they define the project NDE requirements. There are instances where geometry limitations restrict RT. There are other instances where interferences restrict UT. When Phased Array UT is contemplated, the limitations and difficulties associated with the approach need to be understood and planned. Digital RT also involves considerations that need to be understood and planned by the project. These processes need to be considered and any project specific expectations addressed within specifications for engineered equipment or other items fabricated by suppliers.

Material and Test Equipment:

The project will need material and test equipment (M&TE) in validating the work performed. Planning must also address the calibration capabilities that will support the confirmatory process associated with M&TE. Understanding the design associated with the various SSCs found within

the project will aid in understanding the nature of the M&TE inventory needed to support the project. Ensuring these items are available when needed is essential to ensure work is not delayed.

Qualifying QC personnel:

ASME NQA-1 Requirement 10 establishes “Inspection for acceptance shall be performed by qualified persons other than those who performed or directly supervised the work being inspected.” Accordingly, testing procedures must require that QC/QA personnel divorce themselves from the performance of work in order to maintain their independence and objectivity when performing their duties. QA/QC programs and procedures must establish minimum qualifications for personnel performing tests and inspections and should likely reference the recommended practices found within the ASNT SNT-TC-1A. SNT-TC-1A provides guidance concerning the qualification of personnel performing the various NDE testing methods typically relied on by EM projects and operating facilities. Contractor qualification processes are to conform to the contract requirements concerning QA, but at a minimum should be relying on processes described in SNT-TC-1A.

Note to FPD’s:

In preparing prime contract QA requirements, it is suggested that consideration be paid to elevating the “recommended practices” found within American Society for Nondestructive Testing, Inc.’s (ASNT) SNT-TC-1A and convey the qualification process as the minimum requirement for qualifying QA/QC personnel. The SNT-TC-1A requirements associated with Written Practices (Ref. Chapter 2) should also be required within the contract. The FPD should convey the expectation that these requirements be flowed into appropriate subcontracts where applicable work is to be performed, including, but not limited to, any procurement for engineered equipment or other items where fabrication activities requiring NDE to validate the acceptable nature of the work is to be performed.

EM personnel:

The FPD will continue assembling his integrated project team (IPT) adding different talents as the project moves from design to construction. During CD-2, the IPT will be reviewing contractor originated programs, plans and procedures that will define the QA program and activities used throughout the duration of the project. These reviews will be focused on adequacy to provide the required oversight of the project. Planning for the availability of personnel with the skill sets required within the scope is necessary as the FPD puts together the oversight team. In scopes where considerable welding of piping systems and vessels are included, it is recommended the FPD obtain the services of personnel with experience in the appropriate ASME codes. It is also recommended, since many EM projects have considerable civil/structural features, that personnel experienced in the American Concrete Institute (ACI) and American

Institute of Steel Construction (AISC) be integrated into the staff. Electrical, HVAC, instrument and controls, and radiological controls are skills that will be needed to support final design and installation.

The FPD will need to understand how to obtain these resources and plan accordingly. Often time, these skills may not exist within DOE employees and will have to be obtained thru contract support instruments. As the FPD develops the budget for the DOE related costs associated with the project, the planning needs to not only provide for the employment related costs associated with these resources, but for the travel and perhaps equipment and other supplies required to support oversight of contractor and supplier quality processes.

The Quality Assurance program developed during the CD-2 phase will then be implemented across a wide range of activities during the CD-3 project phase.

5. ACTIVITIES SUPPORTING CD-3, APPROVE START OF CONSTRUCTION:

- Approve expenditure of funds for Construction
- Update Project Execution Plan and performance baseline
- Final design and procurement packages
- Verification of mission need
- Budget and congressional authorization and appropriation enacted
- Approval of Safety Basis documentation
- Execution Readiness Independent Review
- Operations Assessment (HAZOPS Review)
- Operations Requirements Document
- Site Layout Drawings
- Construction, Procurement, and Acceptance Testing Planning
- Procurement System
    - Qualifying suppliers of SS/SC SSCs and other critical procurements
    - Supplier oversight
    - NDE/QC presence when appropriate
    - Acceptance of supplier delivered items
    - CGD oversight of supplier and subsupplier organizations
    - Receipt Inspection Plans
- Construction Work Packages
- QA/QC programs
    - Audits and assessments
    - Acceptance Testing Program of Constructed SSCs
    - NDE/Destructive testing
    - Inspection in the field/supplier shops
    - Accepting work

    - Record generation and retention
    - Inspection Guides/Plans
- S/CI
- CGD
- SQA
- Start-Up/Commissioning Plans
- System Operational Tests/Integrated System Operational Tests

General Discussion

The Quality Assurance organization is entering the project period during which it will be processing numerous quality related activities concurrently. The organization will have to be staffed and organized in order to meet the challenges. The work will not only be at the project site, but will likely begin to accelerate in supplier shops as engineered equipment and other items are being fabricated for the project.

At this point in the project, the QA organization's procedures must be mature and ready to support construction. An important part of supporting the project involves remaining cognizant of those activities being performed as well as those upcoming. The schedule is an important tool in remaining aware, but involvement in the construction organization's internal meetings is also needed. Plan of the Day meetings and the like should be attended so emerging events are understood and planning for effective and timely oversight may be accomplished.

Generally, Civil/Structural activities will be the early focus although other discipline activities may be underway depending on the project's use of early construction authorities. Receipt inspection activities, as raw commodities are delivered, will be numerous. Inspection plans that cover installation, as well as the receipt of materials, need to be available as these activities occur. If the execution strategy is to utilize M&O/I contractors to deliver the project, the QA/QC procedures, Receipt Inspection Plans, etc. will likely be already developed. If the execution strategy is to use an EPC contractor, these plans may not exist immediately prior to the inspection activity. Regardless, inspection procedures need to thoroughly document the quality requirements identified by design that are essential to the performance of the item and capture the details to be documented as the item is inspected.

Specific Considerations

Appropriately qualified personnel must perform inspections.

The QA staffing level will be influenced by several decisions by the EPC Contractor. One model in use today places responsibility for the achievement of quality with the work crews and assigned Field Engineers. The FEs provide crucial guidance to the crafts in understanding the design, and FEs also help communications (interface) with Engineering, QA and other

organizations. If the EPC contractor elects to not assign sufficient FEs, then QA and QC personnel, of necessity, will fill the vacuum. The same is true for Field Welding Engineers.

ASNDT SNT-TC-1A provides guidance concerning the qualification of personnel performing the various NDE testing methods typically relied on by EM projects. This document should provide the basis for prime contractor, subordinate subcontractor, and supplier qualification programs. QA personnel assigned to oversee supplier operations will be reviewing the qualifications of personnel performing various inspections within those shops. It is imperative that the suppliers' qualification processes effectively demonstrate the abilities of the NDE personnel and other inspectors, as well as the welders when necessary, within the scope of work assigned. Equally important are the inspection procedures, written practices, etc. these personnel will be using as they perform inspections. Weld Process Specifications (WPS) will communicate both the fit-up requirements to the welder and the same information becomes acceptance criteria for the QC personnel as they inspect that work. The inspector will utilize written practices in defining the steps to be used while performing those inspections. Written practices are particularly important to nondestructive examiners (NDE) personnel. Whether the examination uses dye penetrant testing, ultrasonic tests, radiographic tests, etc., those practices are of critical importance. The written practice must faithfully implement the applicable standard controlling the work and be followed closely by the NDE personnel. Prime contractor surveillance of supplier performed inspections should regularly focus on the adherence of the inspection to the written practice covering it.

Quality Assurance and Quality Control (QA/QC) personnel must be thoroughly familiar with all the provisions of the documents that describe the work, including submittals and other documents pertinent to the work (design changes, requests for information, etc.). The inspections are to be directly relatable to plans and specifications, including all revisions, changes, and amendments.

Records:

The Quality Assurance organization of the prime contractor and suppliers' organizations will generate numerous records that provide documentary evidence that items or activities meet specified quality requirements. These records will fall into two broad categories:

- Lifetime records: Those records that meet one or more of the following criteria:
    - Would be of significant value in demonstrating capability for safe operations,
    - Would be of significant value in maintaining, reworking, repairing, replacing or modifying an item,
    - Would be of significant value in determining the cause of an accident or malfunction of an item.

Lifetime records are required to be maintained for the life of the particular item while it is installed in the plant or stored for future use.

- Nonpermanent Records:
    - Those records required to show evidence that an activity was performed in accordance with the applicable requirements but need not be retained for the life of the item because they do not meet the criteria for lifetime records.

Nonpermanent records shall be maintained for the retention period identified by project procedures or as identified in applicable national code or standard.

Part II of NQA-1 contains additional guidance on the records normally required. NQA-1 integrates national consensus code requirements associated with record retention into the record retention requirements. Part II subparts typically end with a Records Section that requires:

> *Record copies of procedures, reports, required qualification records, test equipment calibration records, test deviation or exception records, and inspection, examination, and check records shall be prepared. These records shall be retained with other project records as required by code, standard, specification, or project procedures.*

Additional records requirements may be defined in design codes or standards specified in the project Code of Record. ASME B31.3, *Process Piping*, for example, is a code typically used in EM projects. Chapter VI entitled Inspection, Examination, and Testing establishes the requirements associated with the QC/QA activities for Process Piping. Section 346 specifically discusses the minimum records required under the code and should provide the basis for the project's determinations associated with lifetime and nonpermanent records. As the design work proceeds, the project may decide other tests are required to confirm the acceptability of the component to perform the design intent. Records associated with those additional tests will be generated and retained as indicated by project procedures. These additional records will be additive to those identified by the national code or consensus standard upon which the design is predicated since the code or standard identifies those minimum tests required.

Other codes will similarly be used as the record determinations are made, acceptance criteria are identified, testing and inspection activities are developed and performed, and QA documents are prepared and accepted into the project's document control system. Procured items require special care when reviewing deliverables that accompany the item. Quality documentation will be retained by the project, some are lifetime while others are not. Radiographic film requires extraordinary care. Project design and QA personnel will need to ensure procurement requirements associated with vessel weld radiographs are addressed in a manner consistent with project's QA and records-retention needs. Many projects identify vessel RTs as Life-Time Records under one or more of the criteria associated with its definition. The code is requiring the

fabricator retain RT films. The project may decide to require vessel fabricators (and perhaps others) to prepare double cassettes when radiographing welds. This will allow the fabricator to remain compliant with the code requirements and the project to possess a lifetime record of the vessel installed in the facility.

As preparation for operation begins, the quality assurance organization must transition its activities and staff to support an operating facility.

6. ACTIVITIES SUPPORTING CD-4, APPROVE START OF OPERATIONS OR PROJECT CLOSEOUT

The tasks that involve quality assurance include:

- Final Safety Analysis Report
- Cold Commissioning Process Verification Report
- Design Capacity Performance Tests
- Off-standard Operational Testing
- Cold Commissioning Results
- Certification of Completion of Cold Commissioning
- Final Documented Safety Analyses
- Readiness for Hot Operations
- Hot Commissioning Start
- Environment Performance Test
- Hot Commissioning Results
- Documents Attesting to Completion of Hot Commissioning
- Project Closure Package
- Facility Turnover
- As-built drawings
- Document close-out
- Start-up Plan

General Discussion

There are several tasks within CD-4 (Approval of Start of Operations and Project Completion) that the Contractor quality assurance organization completes or supports to assist the project. These activities generally 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.

Also, the quality organization must verify that design processes are implemented which provide appropriate control of design inputs, outputs, verification, configuration and design changes, and technical and administrative interfaces. These processes include configuration management activities pertaining to operations and maintenance and transition of the design authority role to cognizant individuals within the operating facility organization.

Specific Considerations

The following discussion provides insight into specific items needed within the general tasks mentioned above.

Checkout, Testing, and Commissioning Plan

QA should review all associated documents and records to assure that processes for preparation, review, approval, issuance, use, and revision of the plan are implemented and that the plan addresses the QA requirements of the operating organization. This should include inspection and acceptance testing to assure that performance expectations, acceptance criteria, inspections and tests, and calibration of M&TE are adequately addressed. Some of the documents that QA should be monitoring may include: Test instructions (TI), Grooming Packages (or other packages that may be used locally to establish prerequisites for system testing), Test procedures, Test Deficiency reports, Test Directives and Procedure Change Requests

Allow start of operations or project close-out including document closeout

As construction work is completed, the work control documents are reviewed for closeout. If the construction was performed by a subcontractor with responsibility for the cold/hot testing, then the work control document closeout may be a subcontractor responsibility with final acceptance by the Contractor as vendor data. Alternately, if the construction was performed by the Contractor, then the Contractor would be responsible to review and close the work control documents. In either case, QA should review the documents ensuring the necessary signatures, dates and inspection reports were completed. In addition, QA should review any nonconformances or deficiency reports related to the work control document ensuring those reports were closed. If there is a transition between construction work control and operations work control processes, the QA organization should be engaged in this transition and turnover process to assure QA requirements for documentation and work control are effective. This includes verification 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 assure that actions are planned and carried out by qualified personnel, using approved procedures, instructions, and equipment under administrative, technical, and environmental controls. QA will verify that design processes, which provide appropriate control of design inputs and outputs, verification, configuration and design changes, and technical and administrative interfaces, are implemented.

Operational Readiness Review and acceptance report

QA is an integral part of testing and commissioning. The QA tasks include test plans and procedure reviews ensuring adequate acceptance criteria are cited, verifications during the testing phase that acceptance criteria are met, and review of the test reports for completeness. Testing would include the design capacity tests, hot and cold commissioning tests, environmental performance test, component tests, and integration tests. As part of the testing process, QA would complete surveillances of testing operations ensuring procedure compliance. QA also is responsible for the quality control and inspection activities that support the testing and commissioning activities. This includes completing and validating inspection reports, pressure tests, and other hold points as called out in design and work control documents.

There is also a need for QA to assure that processes are in place to identify, control, and correct items, services, and processes. If the processes do not meet established requirements, then corrective actions are developed and implemented to preclude recurrence.

It is also critical for QA to review work control and work documentation to assure that the planned scope of work demonstrates that work prerequisites have been satisfied, personnel have been suitably trained and qualified, and detailed implementing documents and management controls are available and approved.

Project transition to operations plan/report

QA is responsible to assist operations and construction organizations in preparation and implementation of processes that assure quality management approaches are established and implemented for preparation, review, approval, issuance, use, and revision of the transition plans.

Final Documented Safety Analyses

During the final Documented Safety Analysis preparation, QA reviews the QA chapter to ensure the information is up-to-date. During subsequent operating procedure reviews, QA determines if the appropriate QA requirements are included in the procedures and helps assure that processes for preparation, review, approval, issuance, use, and revision of the DSA and TSR documents are implemented to assure that applicable design inputs are controlled and configuration management requirements are met.

As-Built Drawings

QA may provide several services during the as-built drawing phase including, some field verification of the drawings, review and approval of the final drawings, and confirmation that the drawings have been properly reviewed, approved, and placed in document control. Another QA activity is the verification that a key or essential drawing list has been established for operations

and that those drawings have been as-built and released for use. The as-built process is part of the overall facility turnover activity.

Facility Turnover

When the facility is ready for turnover or partial turnover, a punch list of items is normally generated between the constructor and the facility owner. Those punch list items are remaining work that either must be done before the constructor leaves or items the owner agrees to finish. Many times the QA organization helps develop and verify the punch list items. As a minimum, QA ensures there is a defined process for the turnover process including the use of punch lists. The facility owner may decide to use a corrective action system to track the punch list items. In which case, QA will have to factor those action items from the corrective action system into the close out verification before operations start.

O&M Manuals

The facility owner will have to ensure that all the needed O&M Manuals are obtained from the constructor. Those manuals should have been transmitted via a vendor data system during construction turnover. However, a review of the vendor data system by the appropriate system engineers is necessary to ensure all needed vendor data, including the O&M Manuals are present.

Management Self-Assessment

During management self-assessments (MSA) the project determines their readiness for an independent review, usually an ORR. QA evaluates the existing QA program at the project level to determine adequacy for operations. QA also reviews QA training records to ensure required QA pre-operational training is completed. If the QA staff supporting operations must complete some operations-related training (i.e., DSA training) this verification would include evaluating completion of that training. In addition, a review of open nonconformance and deficiency reports is completed and a list provided to project management. Project management then determines the priority of open issues as either pre-start or post-start issues. QA provides support to the project during MSA, ORR, CRA, etc. preparation and performance. The QA support during MSA, ORR, and other internal or external reviews is to assist with the preparation of objective evidence files, providing status on nonconformance and/or deficiency reports, verification that the as-built drawings and other operational documents are approved and released, and close-out of construction work control documents.

Oversight Plan

Another QA task during CD-4 is preparation of an oversight plan or strategy for the upcoming operations phase of the project. QA may periodically complete surveillance on various operations to verify procedure compliance and identify opportunities for improvement. The

schedule or strategy is coordinated with the operations staff to ensure the surveillances focus on important operational activities.

Final Project Closeout Report

QA is also tasked with helping assure that project has established, implemented, and documented processes to detect and prevent quality problems and that problems have been corrected and documented.

7. CLOSING THOUGHTS

As communicated within the body of this guide, establishing a comprehensive QA program appropriate for the project scope requires considerable investment in understanding the work to be performed by all parties involved. There is no “model” that may be applied to individual projects that shortens this process.

This guide would be remiss if it weren’t to reference the vast number of tools for EM projects to consider as projects are managed, and particularly as those projects’ QA Programs are developed. These tools include the Standard Review Plan Modules, which are available on the EM Website (http://www.em.doe.gov/Pages/qualityassurance.aspx). DOE personnel should consider the content of these modules when considering what particular requirements and expectations are being developed. The lines of inquiry should point out to contractors what elements need to be addressed within quality programs and procedures.

Draft Revision to Standard QA Contract Language

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. However, EM also allows for the use of NQA-1-2008 and addenda through 2011. 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). Specifically, the contractor's QAP shall also describe the supply chain for electronic subcomponents, require procurement of sub-components only from original equipment manufacturers or original equipment manufacturer authorized distributors, and require electronic subcomponents be procured from vendors with a documented successful history with the supplier.

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.

Status of Actions from the February 2011 Board Meeting

Status of Actions from the EM Corporate Quality Assurance Board Meeting in February 2011

SUMMARY OF ACTION ITEMS			
#	**Action for Follow-Up**	**Individual Responsible**	**Current Status**
1.	Provide a revised lesson learned document based on previous events surrounding Commercial Grade Dedication.	Linda Weir (BNI)	**Complete** Based on the information provided in the original lessons learned document, there does not appear to be a need to issue a revision. All of the relevant information was captured previously.
2.	Update the project plan to include new information.	Larry Perkins (EM-23)	**Complete** Project plan has been updated and ready for signature following the July 2011 meeting.
3.	Notify the EFCOG chair when the JSEP is ready to populate and the EFCOG chair will send a letter to member encouraging its use.	Christian Palay (EM-23) Joe Yanek (EFCOG)	**Pending** This action will follow the completion of the JSEP milestones.
4.	EM Corporate Board members should provide recommendations on how to report the status of the Goal #5 metrics in the Journey to Excellence.	EM Corporate Board Members	**Complete** A position/recommendation paper was developed in coordination with the field QA Managers. That paper has been provided for EM-20 review and submittal to EM-1/2/3.
5.	Provide the updated QA contract language for review/vote.	Bob Murray (EM-23)	**Complete – Vote Pending** Contract language has been revised to incorporate information from the electronics S/CI memorandum.
6.	Work with the sites to develop a summary report of recent assessments (e.g., last 6 months) to address flow-down	EM Corporate Board Members Bob Murray (EM-23)	**Complete** Information was provided from each site and reviewed by EM-23 staff. A discussion of that review was included in a recent letter to the DNFSB and the information will also be evaluated for future assessment schedules.
7.	Evaluate whether the EFCOG efforts on QA metrics can be combined with the needs of EM.	Larry Perkins (EM-23)	**Pending** EM-23 is working with HSS on a similar effort in the Quality Council and will discuss efforts with EFCOG team leads based on the presentations provided in the June 2011 meeting.
8.	Realign Focus Area #1 to investigate the integration of EM and NNSA efforts.	Mike Mason (BNI) Christian Palay (EM-23)	**Complete** Based on the last Board meeting, the focus of the team was adjusted. This is reflected in the update Project Plan.

SUMMARY OF ACTION ITEMS			
#	**Action for Follow-Up**	**Individual Responsible**	**Current Status**
9.	Provide a resolution to the comments on the CGD guidance.	Dennis Weaver (BNI) Pat Carier (ORP)	**Complete** Comments have been resolved and the guidance document is ready for distribution and Board vote.
10.	Change the CGD Guidance Task deliverable to a "Guide" and not a "Standard".	Dennis Weaver (BNI) Pat Carier (ORP)	**Complete** The team has made the change in the document and it is reflected in the Project Plan.
11.	Base CGD guidance on NQA-1a-2009 with appropriate notations made where that version differs from NQA-1-2004 with addenda through 2007. Include a note that the basis for the guidance is not intended to alter any contractual requirements.	Dennis Weaver (BNI) Pat Carier (ORP)	**Complete** Comments have been resolved and the guidance document is ready for distribution and Board vote.
12.	Distribute the draft Design QA paper to the Corporate Board for review.	Butch Huxford (EM-23)	**Complete** Planned to be distributed as part of July 2011 meeting.
13.	Investigate EM participation on 413 development team.	Butch Huxford (EM-23)	**Complete** OECM is in the process of updating the DOE 413.3 series guides to conform with the issuance of DOE O 413.3B. EM-23 was provided an advance copy before entering the documents in REVCOM.
14.	Investigate the use of the lessons learned process with HSS or have the HSS website link to our QA website for distributing the corporate board deliverables.	Bob Murray (EM-23) Larry Perkins (EM-23)	**Complete** The EM QA website has been updated. Lessons learned from the QA Summit are posted on the website. The link from the HSS webpage is still being considered.
15.	Develop a Focus Area Team to address the September 13, 2010, commitment to the Board to develop a task team to determine if there is a shortage of QA/QC resources within EM (consider a follow up in 9 months).	TJ Jackson (EMCBC) Bob Murray (EM-23)	**Complete** Initial team has been developed and a team lead will be finalized in the July 2011 meeting.
16.	Develop a Focus Area Team to evaluate and assess the current strategy for EM QA/QC training and provide a recommended path forward.	TJ Jackson (EMCBC) Bob Murray (EM-23)	**Complete** Initial team has been developed and a team lead will be finalized in the July 2011 meeting.
17.	Distribute a copy of the most recent EM-23 assessment schedule.	Bob Toro (EM-23)	**Complete** This document has been provided to the sites via memo from EM-2.

Status of Actions from the EM Corporate Quality Assurance Board Meeting in February 2011

SUMMARY OF ACTION ITEMS			
#	**Action for Follow-Up**	**Individual Responsible**	**Current Status**
18.	Provide a discussion at the next meeting of the latest list of issues that were prioritized for the Corporate Board.	Larry Perkins (EM-23)	**Complete** Included in the Corporate Board meeting materials for discussion.
19.	Ask HSS to provide a status of the DOE O 414.1D revision at the next meeting.	Bob Murray (EM-23)	**Complete** DOE O 414.1D presentation will be provided by EM-23 at the July 2011 meeting.
20.	Ask EFCOG to provide a status and list of issues they are currently working at the next meeting.	Larry Perkins (EM-23)	**Complete** Included in the Corporate Board meeting materials for discussion.

EM-2 Memorandum for Goal #5 of the EM Journey to Excellence

Department of Energy
Washington, DC 20585

June 9, 2011

MEMORANDUM FOR DISTRIBUTION

FROM: DAE Y. CHUNG
PRINCIPAL DEPUTY ASSISTANT SECRETARY
FOR ENVIRONMENTAL MANAGEMENT

SUBJECT: Clarification of Performance Indicator to Journey to Excellence Goal 5

On December 16, 2010, the Roadmap for the Office of Environmental Management's (EM) Journey to Excellence was issued and adopted. Several questions have been raised concerning the interpretation of some of the goals, key strategies, and key success indicators. With respect to Goal 5, "Improve safety, security and quality assurance towards a goal of zero accidents, incidents, and defects," the following key success indicator was incorporated in the Roadmap.

"Achieve and maintain zero cases where poor quality assurance practices by vendors, subcontractors, and prime contractors result in the installation of defective equipment or software within EM nuclear facilities."

As part of the implementation of this goal across EM, a performance element has been developed for inclusion in the site manager's performance plans.

Ensure that at least 95 percent of the defective equipment and/or software procured from vendors, subcontractors, and prime contractors is detected before installation in nuclear facilities.

Through discussions with field Quality Assurance (QA) managers and personnel, a concern was raised regarding the ability to effectively measure this performance element.

The Office of Standards and Quality Assurance has worked with each of your site QA managers to establish a consistent approach to measuring this performance element. The Office of Standards and Quality Assurance has considered all feedback, incorporated results, and established a recommended path forward (Attachment).

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This recommendation has been reviewed by all field QA managers with the conclusion that it adds necessary clarification and does not impose any additional requirements on field personnel.

The recommendation calls for the above performance element to be changed to:

Ensure that at least 95 percent of the safety class and safety significant equipment/software installed during the fiscal year is not defective, suspect, or counterfeit.

In addition, the recommendation provides two methods to measure this key success indicator as described in the attachment.

In conclusion, the above revised performance element should be incorporated into each of your fiscal year 2011 performance plans with the intent that this metric will be used for your end-of-year performance evaluation.

If you have any questions or need additional information, please contact me at (202) 586-5216 or Mr. Kenneth G. Picha, Jr., Acting Deputy Assistant Secretary, Office of Safety and Security Program, at (202) 586-5151.

Attachment

cc: I. Triay, EM-1
R. Moorer, EM-1
C. Anderson, EM-3
F. Marcinowski, EM-4 (Acting)
R. Rimando, Jr., EM-10 (Acting)
K. Picha, Jr., EM-20 (Acting)
R. Murray, EM-23

DISTRIBUTION

Matthew S. McCormick, Manager, Richland Operations Office (RL)
Scott L. Samuelson, Manager, Office of River Protection (ORP)
David C. Moody, Manager, Savannah River Operations Office (SR)
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William E. Murphie, Manager, Portsmouth/Paducah Project Office (PPPO)
John R. Eschenberg, Assistant Manager, Oak Ridge Operations Office (ORO)
Mark L. Searle, Acting Deputy Manager for Idaho Cleanup Project (ID)
Jack R. Craig, Manager, Consolidated Business Center Ohio (CBC)

Performance Element Discussion for Goal #5 with Respect to Quality Assurance

The Roadmap for the Office of Environmental Management's (EM) Journey to Excellence includes Goal #5:

> *Improve safety, security and quality assurance towards a goal of zero accidents, incidents, and defects*.

A key success indicator for this goal has been developed as:

> *"Achieve and maintain zero cases where poor quality assurance practices by vendors, subcontractors, and prime contractors results in the installation of defective equipment or software within EM nuclear facilities."*

As part of the implementation of this goal across EM, a performance element has been developed for inclusion in the site manager's performance plans.

> *Ensure that at least 95 percent of the defective equipment and/or software procured from vendors, subcontractors, and prime contractors is detected before installation in nuclear facilities.*

Potential Issues/Concerns:

The Office of Standards and Quality Assurance have held multiple discussions with the field Quality Assurance (QA) managers and personnel to discuss this performance element and develop a method to measure the 95 percent achievement. Based on a group discussion via conference call, the following questions and concerns have been raised by the field quality assurance managers and personnel:

1) Some type of graded approach is needed. Information on Safety Significant and Safety Class items is already available. However, the vendors, subcontractors, and prime contractors are not currently required to look at more than those items per their contract. As such, the contractors resist modifying performance indicators. In addition, sites and Headquarters measure annual quality performance through Performance Objectives, Measures, and Commitments as part of the annual Integrated Safety Management Quality Assurance Declaration process. Collecting additional data for performance indicators beyond the Safety Significant and Safety Class categories will likely result in additional cost;

2) Defective components that were installed 5-10 years ago and found today are not an indication of a problem with the current site quality program. Therefore, a graded approach should be utilized with respect to the metric;

3) Care needs to be taken with respect to the definition of an "item." For example, if you count a Safety Significant vessel as one item and a box of 1000 bolts as 1000 items, the performance measure can be easily manipulated and may not be a useful measurement for the intended purpose. Some direction or guidance on how to count an item is needed to generate a consistent approach for the sites;

4) There is no current concern on limiting the facilities analyzed by this metric. However, this statement is predicated on the graded approach discussed previously.

The Office of Standards and Quality Assurance and Field QA Manager Recommendations:

1) An "item" should be defined for this measurement consistent with the definition in DOE O 414.1C, *Quality Assurance*; however, the measurement will only apply to Safety Class or Safety Significant systems (including software);

2) EM should re-evaluate the performance indicator at the end of the performance period to determine if any modifications are needed;

3) The performance element should be modified to the following:

   Ensure that at least 95 percent of the safety class and safety significant equipment/software installed during the fiscal year is not defective, suspect, or counterfeit.

4) The performance measurement for this goal should be measured as (with a goal of less than 0.05):

$$\frac{Number\ of\ "items"\ installed\ during\ the\ FY\ and\ found\ to\ be\ defective\ or\ S/CI\ after\ installation}{Total\ Number\ of\ "items"\ installed\ during\ the\ FY}$$

5) If the site desires to have a more restrictive measurement, the following performance measurement can be used (with a goal of less than 0.05):

$$\frac{Number\ of\ "items"\ installed\ during\ the\ FY\ and\ found\ to\ be\ defective\ or\ S/CI\ after\ installation}{Total\ Number\ of\ "items"\ found\ to\ be\ defective\ or\ S/CI\ during\ the\ FY\ (including\ receipt\ inspection)}$$

Example of Performance Metric Calculations for

Goal #5 of the EM Journey to Excellence

Example Calculation Guidance for Implementing the Environmental Management Journey to Excellence Goal #5 Performance Metric

The suggested calculation method is:

$$\frac{Number\ of\ "items"\ installed\ during\ the\ FY\ and\ found\ to\ be\ defective\ or\ S/CI\ after\ installation}{Total\ Number\ of\ "items"\ installed\ during\ the\ FY}$$

Assumptions:

- A total of 100 Safety Class or Safety Significant "items" are procured and received during a given fiscal year.
- A total of 12 of these items are determined to be nonconforming during receipt inspection (5 defective and 7 S/CI.)
- Of the remaining 88 Safety Class or Safety Significant items, 80 are installed in the nuclear facility.
- 50 of the 80 items are installed in the nuclear facility pending postinstallation testing because pre-installation testing was not adequate to detect all possible deficiencies.
- During the planned postinstallation testing, 4 of the 50 items installed in the nuclear facility are found to be defective, as specified by the post installation test criteria.
- The 4 deficient items identified by postinstallation testing were replaced with new items, all 4 of which passed the required postinstallation testing.
- During facility operations, 2 of the items installed in the nuclear facility are subsequently found to be defective and 1 of the installed items is found to be S/CI.
- An extent of conditions evaluation identified that one of the 8 items being held as spares was also S/CI.
- One installed item subsequently failed during facility operation and had to be replaced.

This results in 80 items being installed in the nuclear facility, with 50 items being installed pending postinstallation testing. The 4 items found to be defective during postinstallation testing and subsequently replaced are not counted for the purpose of this metric, and the total number of items installed in the nuclear facility (after completion of all quality inspection and testing) remains at 80. Of these 80 items thus installed, 3 items were later found to be defective or S/CI (i.e. the nonconforming conditions were not detected by the quality assurance practices.) The 1 item held as a spare which was subsequently found to be S/CI is not counted in the metric because it was never installed in the nuclear facility, and the 1 item that failed during operation, is likewise not counted because it was a failure rather than a defective item.

The metric would be calculated as:

$$\frac{\text{(2 items found to be defective + 1 item found to be S/CI) after installation}}{\text{80 items installed in the nuclear facility}}$$

= 3 / 80 = 3.75%, which is within the desired range of less than 5%.

10TH EM QUALITY ASSURANCE CORPORATE BOARD MEETING

List of EM QA Corporate Board Priorities

Current Corporate Board Focus Areas

- Adequate NQA-1 Suppliers
- Commercial Grade Item and Services Dedication
- Design Quality Assurance
- Evaluation of QA/QC Resources
- Strategy for EM QA/QC Training

Priorities Led by EM-23

- Resources (Federal)
- Identifying HQ requirements from memos and other correspondence beyond DOE orders
- Balancing inspection/field work control with HQ program audits and oversight reviews
- QAP/QIP Implementation/Clear Roles and Responsibilities
- ORPS reporting of S/CI Program

Priorities Led EFCOG/Site Offices

- Procedural compliance/execution/conduct of operations
- Effectiveness of corrective actions regarding human performance
- Vendor issues
- Supplier Quality Assurance
- Consistent application/interpretations of regulations/requirements
- Inspector training/mentoring and understanding expectations
- Improve understanding of expectations for safety software/software Quality Assurance
- Path forward for small contractors without rigourous NQA-1 programs
- Overseas suppliers

Letter to the DNFSB Providing a Status on

Suspect/Counterfeit Items and Quality Requirements Flow-Down Issues

Department of Energy
Washington, DC 20585

May 2, 2011

The Honorable Peter S. Winokur
Chairman
Defense Nuclear Facilities Safety Board
625 Indiana Avenue, NW, Suite 700
Washington, DC 20004-2901

Dear Chairman Winokur:

This letter is to provide an update to the Defense Nuclear Facilities Safety Board (Board) on two quality assurance related activities within the Office of Environmental Management (EM): 1) prevention and detection of Suspect/Counterfeit Items (S/CI) involving electronic components in EM nuclear facilities; and 2) flow-down of quality requirements to contractors and subcontractors. Both topics have been the source of recent discussions between the Board and EM.

The EM Office of Standards and Quality Assurance has been reviewing the practices for control of S/CI in the EM complex, with particular emphasis on electronic components used in safety class (SC) and safety significant (SS) applications. The initial round of evaluations has focused on EM's major construction projects. On-site evaluations have been performed at the Salt Waste Processing Facility (SWPF) at the Savannah River Site (SRS) and the Waste Treatment and Immobilization Plant (WTP) at Hanford as detailed below.

An initial evaluation at the SWPF was performed on October 26-28, 2010. At the time of the evaluation, the SWPF was finalizing the planning for procurement of the SS portion of the Digital Control Systems (DCS) for the facility. The evaluation team focused on the controls that the SWPF construction contractor planned to apply to this procurement. Based on the initial evaluation of the system of proposed controls in place at SWPF and review of industry best practices, EM issued a memorandum dated January 11, 2011, to all EM Field Elements regarding control of S/CI electronics components. This memorandum included a series of recommendations to enhance the prevention, identification, and control of S/CI electronics. To foster communication on the subject of S/CI electronics, the results of the initial SWPF S/CI electronics evaluation and the content of the S/CI best practices memorandum were a topic of discussion with the EM Field Elements and major EM contractors during the EM Quality Assurance Corporate Board meeting in Oak Ridge on February 16, 2011.

On February 23-24, 2011, followup evaluations of S/CI electronics controls were performed at SWPF. The evaluation team noted that the construction contractor intended to implement the recommendations of the January 11, 2011, memorandum in the upcoming procurement of the SS DCS. The construction contractor, with observers

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from the Department of Energy (DOE) Office of Health, Safety and Security (HSS) and DOE SRS, performed an initial qualification audit of the DCS supplier. The results of this audit indicate that the supplier has an excellent quality assurance (QA) program, including processes for prevention, identification, and control of S/CI electronics.

On March 8-10, 2011, the prime contractor and EM conducted a joint assessment of the system of controls applied to S/CI electronics at WTP. Similar to the SWPF, the WTP is in the planning stages for the procurement of the SS DCS. The assessment team concluded that WTP also plans to use the best practices identified in the January 11, 2011, memorandum for the procurement of this system.

As the procurements of the SS digital control systems proceed, EM plans to monitor the procurement and acceptance process to ensure that both SWPF and WTP implement their plans related to the prevention, identification, and control of S/CI electronics. Control of S/CI electronics will also be assessed during upcoming Construction Project Reviews (CPR) for both facilities. For example, a CPR was recently held at the SWPF from March 21-24, 2011, where S/CI electronics was again addressed. Given the current rigor that both the SWPF and WTP plan to implement prior to procurement of SS DCS, there is now reasonable assurance that S/CI electronics will be detected and removed from service prior to installation.

In addition to monitoring the major SS electronic procurements at the SWPF and the WTP, EM plans to conduct assessments of processes for prevention, identification, and control of S/CI electronics at a sample of operating nuclear facilities. These assessments should occur within the next few months. EM will also continue to include reviews of S/CI controls, including S/CI electronics, in its ongoing assessments and oversight of other construction and operating projects. EM also intends to work with the Office of Nuclear Safety within HSS on the effort to enhance the QA function throughout the DOE, and specifically provide a central lead with respect to suspect/counterfeit parts.

In regards to the second issue, EM provided a response on September 2, 2010, to your May 5, 2010, letter regarding flow-down of quality requirements. In the EM response, we committed to review the results of flow-down evaluations in: 1) phase II QA program implementation reviews; 2) annual QA Declarations; and 3) recent site office quality assessments. This commitment was recently discussed and follow-on actions agreed upon at the February 2011 EM QA Corporate Board meeting. For the remainder of this fiscal year, EM plans to use the results of this review to further evaluate specific sites where potential issues may exist. We will continue to work closely with your staff to provide any necessary information and relay any findings or issues of interest that may result from the continued oversight.

If you have any further questions, or would like copies of the assessment reports and Lines of Inquiry used for the assessments described above, please contact me or Mr. Kenneth G. Picha, Jr., Acting Deputy Assistant Secretary for the Office of Safety and Security Program, at (202) 586-5151.

Sincerely,

Inés R. Triay

Inés R. Triay
Assistant Secretary for
Environmental Management

cc: S. Horton, DNFSB
C. Lagdon, S-3
M. Campagnone, HS-1.1

EM QA Corporate Board Contact List

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Corporate Board Executive Members (Senior Contractor Executives, Non-Voting)				
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Corporate Board Full Members (Federal, Non-Voting)				
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Other EM Headquarters/DOE/National Laboratory QA Representatives				
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Please provide any updates to Larry Perkins at larry.perkins@hq.doe.gov				

EM QA Corporate Board By-Laws

May 2011

By-Laws
Office of Environmental Management
Quality Assurance Corporate Board

Article 1 Name

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

Article 2 Mission

The Board will serve a leadership role within EM for facilitating, championing, and overseeing the effectiveness of a consistent and graded approach to implementing the corporate QA program, policies and 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 QA Programs. The Board will serve as a consensus-building body to facilitate institutionalization of a streamlined and efficient QA Management System across the EM-Complex.

Article 3 Goals and Objectives

The Board will ensure that QA programmatic decisions and recommendations promote effective execution and performance of EM projects through the use of the best practices and commonly accepted standards in nuclear industry, as applicable, including:

- Standardization and consistency in the graded establishment and implementation of nuclear QA programs in the EM complex;
- Institutionalization of a QA implementation verification process and proper integration of QA and Integrated Safety Management Systems;
- Validation of site and contractor QA programs consistent with the EM Corporate QA Program, EM-QA-001;
- Validation of High Level Waste/Spent Nuclear Fuel QA programs consistent with DOE/RW-0333P;
- Validation that adequate levels of competent and qualified QA personnel and resources are available to support effective implementation of EM projects;

- Implementation of effective collection, communication, dissemination, and application of project QA lessons learned throughout the EM complex; and

- Support continuous improvement of the overall EM mission performance (e.g., capital and major construction projects, accelerated cleanup, and execution of American Recovery and Reinvestment Act (ARRA) funded projects).

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 the Office of Safety and Security Program, EM-20 (voting member).

Voting Members:

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

Advisors (Non Voting Members):

- Site QA Managers/Enviornmental Safety & Health Managers (unless serving as a designated voting member for the Site Manager).
- Senior Site Contractor Representatives.
- Board Secretary, appointed by the Board and approved by the Chair.
- CNS Staff Representatives (unless serving as a designated voting member for CNS).

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.

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 QA Program vision, mission, goals, and objectives.
   b. Has the final approval authority 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 priorities established by senior EM leadership.
   d. Serves as Board spokesperson.
   e. Notifies participants of Board meetings.

2. Deputy Chair (Director of the Office of Standards and QA)
   a. Monitors performance of Board actions in order to make appropriate recommendations to the Board.
   b. Serves as the 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. Tracks issues and work commitments of Board and Board Committees.
   c. Provides facilitation and logistic support for the Board.
   d. Serves as liaison to all standing committees of the Board.
   e. Manages and facilitates the Board's meetings.
   f. Prepares and issues Board Meeting agendas and minutes.
   g. 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 mission, as well as the management expectations and performance goals of the EM Corporate QA Program, EM-QA-001.

2. Actively participates in Board activities and facilitates proactive identification of emerging site-specific or crosscutting QA related issues that impact effective execution of EM mission and projects.

3. Regularly attends Board meetings and participate in committee deliberation of issues.

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

8. Ensures adequate levels of DOE QA staff and contractors trained in QA principles and procedures exist to promote effective execution of EM mission and projects. Ensures that responsible 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 specific 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/her designee(s) will be the liaison with the interface groups. Interface groups will include:

- Energy Facilities Contractors Group (EFCOG)
- EM/Nuclear Energy/Science SQA Support Group
- DOE/Health, Safety, and Security (HSS) QA Council
- Other Departmental or external entities, as appropriate.

Article 10 Committees

The Board Chair will approve or disapprove committees when recommended by the Board. Committees will be established by the Board for a well defined duration (temporary basis) to address specific issues of interest by the Board. Committees will:

1. Collect information from all sources within DOE-Complex, or outside of DOE as needed, related to QA issues of concern and corporate priority.
2. Assign individual investigative teams and actively intervene across all EM sites for orderly and informed disposition of issues.
3. Assess and determine status and effectiveness of performance relative to Board recommendations.
4. Assist sites with implementation and monitoring of recommendations.
5. Draw resources from their sites of record to support implementation of Board actions.
6. Interact with the Director of the Office of Standards and QA to discuss issues and formulate recommendations.
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 shall meet at least two times per year. At least one meeting per year shall be in person. The meetings to review general status of EM QA issues and committee activities may be conducted in a variety of forums deemed appropriate by the Board Chair including use of Video Conferencing, teleconference, and other electronic/web-based capabilities. Supplemental meetings may be scheduled as needed to fulfill the Board's responsibilities as determined by the Board Chair.

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.

3. The Board Members may designate a senior member of their organization (e.g., assistant manager, deputy manager, ESH&Q manager, QA manager) to represent them at Board meetings. The Board Members assigning a designee shall provide a written notification to the Board Chair or Deputy Chair for approval. By providing a designee, the Board Member acknowledges the designee is authorized to represent and vote on behalf of the designated site and Board Member. Any commitments made by the designee will be considered equivalent to a commitment by the Board Member.

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 evaluation and study,
   b. Ask for more information,
   c. To form a 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.

10TH EM

QUALITY ASSURANCE

CORPORATE BOARD MEETING

Minutes from the February 2011 Board Meeting

9th Environmental Management Quality Assurance Corporate Board Meeting Minutes
February 16, 2011 – Oak Ridge, TN

Voting Board Members in Attendance (general attendance sheet for the meeting is attached):

*Greg Hayward – Idaho	Ken Picha (chair) – Headquarters Acting EM-20
Robert Brown – Oak Ridge	Russell McCallister – Portsmouth/Paducah
Ray Corey – Richland	Bob Murray (vice-chair) – Headquarters EM-23
*Bill Rowland – Savannah River	No Voting Member Present - Carlsbad
Bud Danielson –Chief of Nuclear Safety	Jonathan (JD) Dowell - River Protection
T.J. Jackson – EMCBC	

**Note: The by-laws require the voting member to be the Site Manager or assistant/deputy manager. The noted individuals were representing the designated sites at the EM QA Corporate Board meeting but did not meet the requirements in the by-laws as a voting member of the board.*

Introduction by John Eschenberg (Assistant Manager for Environmental Management in Oak Ridge)

John Eschenberg welcomed everyone to the meeting and provided a summary of the current work activities taking place in Oak Ridge.

Presentation by Larry Perkins (EM-23) - Summary of Corporate Board Action Items

Larry Perkins presented the action items from the previous meeting with a status for each action. The actions that have not been completed to date are summarized in the following table with a current status.

SUMMARY OF ACTION ITEMS

Action for Follow-Up	Individual Responsible	Current Status
Provide a revised lesson learned document based on previous events surrounding Commercial Grade Dedication.	Linda Weir (BNI)	The revised lessons learned document is still in draft by BNI and is scheduled for completion in March 2011. The completed document will then be provided to the board.
Update the project plan to include new information.	Larry Perkins (EM-23)	Due to multiple changes, the project plan has not been approved. The plan will be updated based on the results of this meeting and provided to the executive committee for review.
Notify the EFCOG chair when the JSEP is ready to populate and the EFCOG chair will send a letter to member encouraging its use.	Christian Palay (EM-23) Joe Yanek (EFCOG)	This action will follow the completion of the JSEP milestones in March 2011.
Survey of the EM complex to evaluate the needs with respect to resources	Bob Murray (EM-23)	This action will be added to a new focus area as discussed later.

Presentation by Ken Picha (Acting EM-20) and Bob Murray (EM-23) - Summary of EM QA Program and Crosscutting QA Issues

Ken Picha and Bob Murray provided a presentation on the status of the EM QA Program and provided a status of current crosscutting issues of concern to senior management.

Bob Murray noted that the 95% confidence level that was put in the SES performance plans as part of Goal #5 in the Journey to Excellence has been changed. The new language in the performance plans now indicates that 95% of the Suspect/Counterfeit items must be caught prior to installation in lieu of the 95% confidence level.

The EM-20 office has also received an email from the EM front office that requires a monthly status of how EM is meeting the goals of the EM Journey to Excellence. As a group, the EM Corporate Board needs to work together to determine how to provide this type of status (the next report will be due in approximately 30 days.)

Brenda Hawks asked if this discussion was intended to focus on safety significant and safety class items.

Bob Murray and JD Dowell responded that this is correct.

Bud Danielson asked how EM would count this type of effort in start-up etc.

Ken Picha noted that this question is what we are looking at in how to track the status of the requirement.

Bob Murray indicated that the metric was left as 95% of parts going into the facility must meet the requirement to meet the metric. We can discuss this in more detail later.

Bob Murray discussed the concern with S/CI in electronics. EM-23 has completed a review of the Salt Waste Processing Facility and is currently scheduled to perform a review at the Waste Treatment and Immobilization Project.

Bob Murray noted that the standard QA contract language update is being worked with a draft included in the meeting materials. We can discuss the details of the changes later.

Ken Picha discussed that Michael Weis was brought in by S-1 to try and help cut out some of the bureaucracy within the Department. OMB is also challenging the agencies to come back with lower budgets. Mr. Weis is working to interface with the offices and S-1 at addressing ways to reduce duplication etc.

Bob Murray discussed that the DNFSB has been looking at how DOE O 414.1C and the CRD are flowed down from prime contractors to subcontractors. It appears that DOE and the DNFSB have some disagreement on how these requirements are flowed down. After working with the General Counsel, DOE has taken the position that the CRD is flowed down to prime contractors only and the prime contractors determine what attributes should be flowed down to subcontractors, but not the Order and CRD in their entirety.

San Horton noted that the DNFSB has reviewed DOE's position and is currently having the DNFSB General Counsel review the position and will respond as necessary after that discussion is complete.

Bob Murray also noted that EM has provided a shorter version of the flow-down response to the DNFSB staff. The short version is more of an engineering approach to further clarify the formal response that was provided.

Bill Rowland asked what reviews would be conducted to include in the summary report to the DNFSB in March.

Larry Perkins summarized the pieces that will be used to provide report to the DNFSB. The report will include:

- Summary of QA Declarations with respect to flow-down
- Summary of Phase II QAP/QIP implementation reviews with respect to flow-down
- Summary of site reports for some period of time (e.g., 6 months) to address flow-down

Bob Murray continued that he feels we have a good handle on the S/CI with respect to hardware and based on his interactions with the DNFSB and DNFSB staff, they appear to agree. The primary area of concern is with respect to electronics. Bob discussed the issue with the DNFSB and indicated the focus should be on safety components in the facility and not necessarily all components such as laptops without interaction with safety components. EM offered to perform a review of S/CI for electronics at both the Salt Waste Processing Facility and the Waste Treatment and Immobilization Project if that would help with the DNFSB concerns. The DNFSB members indicated that would be beneficial.

Bob Murray discussed that development of a memorandum that was provided to the sites with recommendations on electronics and S/CI was based on the results of the SWPF review. Some feedback from the sites has asked if these recommendations are requirements and if they will be used in future audits and assessments of QA implementation. The answer is that they are only recommendations to consider and are not requirements or mandates.

Jim Tisarunni commented that how to manage a long supply chain is a bigger issue than actually shortening the supply chains.

Bob Murray responded that there is certainly a limited supplier base so that is a potential concern. However, if the supply chain is four levels for example (A-B-C-D), the prime contractor has to somehow ensure they look at all of the suppliers in the chain and establish the pedigree for the components.

Rich Salizzoni asked if the memorandum would be updated and revised as new information became available from subsequent reviews.

Bob Murray answered yes that revisions to the memorandum would be made as needed, but there are no issues or specifics to date that warrant a revision.

Rick Warriner noted that the memorandum appeared to be focusing on more than just the safety function of the item.

Bob Murray indicated that was accurate. Embedded software on electronics is also a concern.

Rick Warriner continued that in order to address that issue, you would have to go to the templates to get chain of custody, serial numbers, etc. and that pedigree may not be available. They test a batch for functionality, but this is pretty extensive to address embedded software.

Bob Murray agreed and stated we need to focus on a risk based approach.

JD Dowell asked if we have benchmarked other organizations such as NNSA or Naval Reactors.

Ray Wood indicated we have looked at some and the commercial world is going so far as to manage returns and trace the documented pedigree. They are even x-raying dyes because chips are failing after months and not only after weeks. The bottom line is that the supply chain is doing a lot of work and we need to ensure our suppliers are looking at that information.

Wayne Ledford noted we really want to try to avoid secondary distributors.

San Horton noted that NNSA and DOD are using “Trusted Foundry” that may be a good source of information. He also noted that Rick Warriner’s comment was valid in that cost will increase quickly. As such, we can’t do this type of pedigree for every piece of equipment but safety significant and safety class equipment and electronics are the primary concern.

JD Dowell noted that we may leverage the existing government contracts to help with the concern.

San Horton stated that risk analysis is the key for cost and addressing the true threat.

Bob Murray noted that this discussion demonstrated the concern which is also present with the DNFSB. Perhaps the Corporate Board should consider forming a focus area to study the issue.

Ken Picha noted that Naval Reactors will be represented at the QA Summit tomorrow and can be engaged on their current approach.

Bud Danielson made two points that the discussion should keep in mind:

- There was a meeting last month and the SAE are developing electronics S/CI standards and guides now. NQA has input on this development. This comment is just intended to point out that this is ongoing and we can get someone tied in with it.
- There was a White House level meeting and NASA and DOD are working the issue for the government. This effort is deciding what guidance is needed and CNS has participated. CNS will share future meeting invitations to keep EM informed of the progress.

Bob Murray mentioned the Phase II reviews at HQ and noted that an independent audit team will be asked to look at the HQ implementation soon. If anyone would like to volunteer for that team, please contact Bob via email.

Bob Murray noted that to date, the EM-23 role has been to support the field, and provided several examples of how that support has been provided. Bob asked that if the field does not have QA resources to complete a

task, please call him and EM-23 will work to help support the effort. Bob emphasized that EM-23 is not only responsible for auditing the field organizations, we can also provide support.

Bob Murray discussed that EM needs real time QA metrics that are not just reactive. However, given the number of efforts on this issue, including a previous Corporate Board Focus Area, it may not be possible. He suggested the Corporate Board may want to consider a new Focus Area to address this issue.

Brenda Hawks noted that for the QA Declaration type of metrics, the sooner we can get the updated metrics to the field and contractors, the better equipped they will be to respond.

Jerry Lipsky asked if there is a problem that needs to be solved that is driving the metrics discussion.

Bob Murray indicated that the Journey to Excellence and subsequent metrics are always discussed, but there is more information and a lot of QA resources here today.

Jerry Lipsky noted that he felt his concern/suggestion related to project readiness reviews (so to speak) for QA would address part of this issue.

Butch Huxford stated that Focus Area #3 was covering this type of issue on forethought in their paper much like Jerry Lispky's suggestion.

Chris Marden noted that EFCOG has a team that is looking at metrics that are more predictive for QA. Bob Toro from EM-23 is currently on that team. Maybe EFCOG is working this issue already without the need for a new Focus Area.

JD Dowell asked to be kept in the loop on the status of the issue.

Presentation by Bud Danielson (CNS) - NQA-1 Accreditation

Bud Danielson indicated that prior to the presentation, he would like to cover a few general topics of discussion:

- CNS has worked to develop a risk ranking for the facilities to ensure they are looking at the hazards and using risk to appropriately assign resources. This risk ranking will be provided to the sites to see if the field offices can also use it to assist in their oversight.
- For those who know Tim Arcano, Tim has been selected for a loan position to teach at the Naval Academy for one year with the option of a second year.
- If you make inquiries to the NQA-1 committee, please ensure you use the correct format or they won't be answered. You may call the chair person or a committee member to ask for help in phrasing inquiries for proper submission.
- The NQA-1 committee is looking to build S/CI in and CGD has been included in the requirements. Section 2.14 is also being reviewed to see if there are any updates needed to address software. A new Part 2 on NQA-1 versus 10 CFR 830 has also been drafted and is working through the comment process.

Debbie Sparkman commented that a software CGD guidance is being developed now.

Bud Danielson presented the NQA-1 Accreditation information and noted that the program is currently scheduled to roll out in June/July 2011 but there are no cost figures to present. Purely as a guess, the cost will likely be similar to an N Stamp or ISO-9001 certification.

Bud Danielson also noted that with an N Stamp, you get the certificate but not the audit report. The NQA-1 certification will also provide the report.

TJ Jackson asked if anyone has looked at ISO-9001 certifications and how similar the NQA-1 certification will be.

Bud Danielson stated that they have looked at them but don't plan to get public comments. The program will all be in-house and will issue a requirements document, but no public comment on procedures. ASME is not applying to be a certifying body with any other organization. The requirements document is drafted and ASME is working in-house to have the program available by the June/July 2011 date. Bud also noted that the service will only be offered to suppliers and not utilities.

Rick Warriner asked if this certification will be similar to the ISO for advertising abilities for a vendor.

Bud Danielson said yes, but ASME says they are looking at the specifics of implementation.

Brenda Hawks asked if we can give credit like in the IMS Order to reduce oversight.

Bud Danielson stated that his personal opinion is yes but HS will need to answer that question formally.

Michelle Dudley asked if similar to the NIAC and NUPIC, will they use services or suppliers.

Bud Danielson stated that this effort is not the same as NIAC or NUPIC.

Mike Mason noted that this is a first attempt so there is more to come. We are still working through the process.

Bud Danielson noted that ANAB could get certification programs for 10 CFR 830 and DOE O 414.1C if we want to pursue that type of effort and get people accredited to do the certification.

Presentation by Mike Mason (BNI) – Focus Area 1: Joint Supplier Evaluation Program

Mike Mason presented the status of the Joint Supplier Evaluation Program. Mike noted that NNSA has BMAC, which is working an issue very similar to JSEP with the same ultimate goal as JSEP. The Focus Area team has been in contact with BMAC and identified that major differences in the two efforts.

Rich Warriner asked that since NNSA has mandated the use of the approved suppliers list, how they handle liability issues. If the list is mandated, isn't it a government supplied item?

Mike Mason said no, they did not treat it as a government supplied item and asked Christina Palay to elaborate.

Christina Palay stated that NNSA has a subgroup of contractors that came up with the MOA and the list was not mandated by NNSA. There is still a sharing of liability since the MOA agreement is among the contractors only. Christian also noted that the information is both ways (i.e., problems with suppliers is also reported into the system).

Bob Murray asked if we have a signed copy of the MOA on BMAC.

Christian Palay said we have a draft but not a signed copy.

Mike Mason noted that the Program Plan for JSEP is out for review now.

Bob Murray stated that we need the Corporate Board to vote on changing the Focus Area to allow further investigation of working with BMAC.

Mike Mason noted that the vote is not to change the existing path but will simply add an additional deliverable to report on the interaction with BMAC.

Ken Picha asked who decides on the representation from the focus area group for JSEP.

Bob Murray responded that he and Christian helped find federal support and Mike Mason found EFCOG support. Bob also noted that interaction with BMAC was ongoing but needed the Corporate Board endorsement.

Ray Corey asked if NNSA was willing to adjust their program to help meet our needs in EM.

Mike Mason indicated that the answer is yes, NNSA has expressed a willingness to work together and adjust as needed.

Norm Barker noted that there have been senior management discussions on the issue as well.

TJ Jackson noted that the tasks for JSEP will be completed with results soon based on the current schedule.

Dave Tuttel noted this could be an added task to the Focus Area or a new Focus Area.

Paul Bills stated that they are finalizing the actions for the Focus Area and will be complete in the next few weeks.

Randy Smyth noted that this was a very good idea to have a common approach and should yield success.

Bob Murray noted that the pilot will be complete in approximately 6 weeks.

Larry Perkins clarified that the vote should add a new deliverable with a date for a status back to the Board within a given time frame and should be included in the project plan for approval.

Norm Barker suggested the status should be provided by the next meeting of the Corporate Board and should address any difficulties discovered.

Vote to realign Focus Area #1 to investigate the integration of EM and NNSA efforts to reduce redundant efforts and improve supplier quality: **(PASSED)**

*Greg Hayward – Idaho **- YES**	Ken Picha (chair) – Headquarters Acting EM-20 **- YES**
Robert Brown – Oak Ridge **- YES**	Russell McCallister – Portsmouth/Paducah **- YES**
Ray Corey – Richland **- YES**	Bob Murray (vice-chair) – Headquarters EM-23 **- YES**
*Bill Rowland – Savannah River **- YES**	No Voting Member Present - Carlsbad **– N/A**
Bud Danielson –Chief of Nuclear Safety **- YES**	Jonathan (JD) Dowell - River Protection **- YES**
T.J. Jackson – EMCBC **- YES**	

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Presentation by Dennis Weaver (BNI) – Focus Area 2: Commercial Grade Dedication

Dennis Weaver presented the current status of Focus Area #2.

Debbie Sparkman noted that May 16-17, 2011 will have a software CGD training course available. More information should be available soon.

TJ Jackson asked why we are calling the deliverable a guide versus a standard since it is more formal to use a standard.

Dennis Weaver responded that the information provided is more in line with a guide and not a requirements document like a standard.

Brenda Hawks asked if we used a standard would it have to be DOE wide.

Bud Danielson indicated that would only be the case if it was to be used DOE wide.

Bob Murray noted that if we go the route of a DOE Standard, it will take an extremely large amount of time to get approved and distributed.

Debbie Sparkman agreed with Bob and noted that this is needed within EM now. Debbie also noted that NNSA has indicated they are not ready for this type of document as a standards and EM should keep the document/guidance local to EM at this time.

JD Dowell clarified that the document was not directive enough to be a standard.

TJ Jackson asked if there was an intention for the document to be contractual.

Dennis Weaver answered that is not the expectation or intent.

Debbie Sparkman noted that earlier versions of NQA-1 did not have Section 2.14 so that was something to consider when contractual discussions were held.

Rick Warriner commented that his impression was NQA-1-2004 with addenda through 2007 address CGD, just not all in one location.

Bob Thompson asked if we have additional software requirements, will the training for CGD instructors have to be updated.

Dennis Weaver indicated his opinion was yes it would need to be updated to specifically address software.

Brenda Hawks asked if we could have the class with software included at the EFCOG meeting at Richland.

Dennis Weaver indicated he thought that was possible.

Rick Salizonni asked if the comments with resolutions will be sent back out to the reviewers of the CGD guide.

Dennis Weaver indicated he would have to check with Pat Carier but thought the answer was yes.

Bud Danielson asked how to find out about the training and do any suppliers attend?

Dennis Weaver indicated that subcontractors have attended the sessions but he was not familiar with how it was marketed/advertised, but he thinks it is primarily on an as requested basis.

Brenda Hawks added that when HQ pays for the classes, they are primarily federal and prime contractors that attend. When the sites pay for the classes, more subcontractors attend.

JD Dowell recommended EM-23 could put a memo out to the sites as information on the classes.

Bob Murray noted that this type of discussion as scheduled for the EMCBC presentation later in the day, but it seems we are at the point of moving the training over to the commercial sector and EM focusing on any new material that is needed.

Debbie Sparkman stated the only problem was that the commercial sector doesn't understand SQA and utilities have different approaches.

Bob Murray clarified that this is similar to CGD. EM didn't turn those courses over to the commercial sector immediately. We can discuss further during the session this afternoon.

Debbie Sparkman noted that Bud Danielson had mentioned NQA with respect to SQA issues earlier and wanted to clarify that DOE is also represented in those meetings to help maintain consistency.

TJ Jackson noted that we require contractors to comply with NQA-1-2004 with addenda to 2007. If this guidance is written based on NQA-1-2009, we need to ensure it is just guidance and not a requirement for future audits.

Mike Mason noted any changes to the version of NQA-1 would have to go through the CO and contract modifications.

Bob Murray agreed and noted that we have multiple versions of NQA-1 in use across the complex, including NQA-1-2000 programs that have added CGD from NQA-1-2008. We audit to the requirements of the contract and not a guide.

Brenda Hawks noted EM could use the guide to say this is an acceptable method to use.

Dennis Weaver clarified that this document is a guide and the version of NQA-1 used is not crucial.

Russell McCallister suggested the note that this guide does not change any contract requirements be placed in the front of the document and clearly marked.

Vote to change the Task deliverable to a "Guide" and not a "Standard".: **(PASSED)**

*Greg Hayward – Idaho **- YES**	Ken Picha (chair) – Headquarters Acting EM-20 **- YES**
Robert Brown – Oak Ridge **- YES**	Russell McCallister – Portsmouth/Paducah **- YES**
Ray Corey – Richland **- YES**	Bob Murray (vice-chair) – Headquarters EM-23 **- YES**
*Bill Rowland – Savannah River **- YES**	No Voting Member Present - Carlsbad **– N/A**
Bud Danielson –Chief of Nuclear Safety **- YES**	Jonathan (JD) Dowell - River Protection **- YES**
T.J. Jackson – EMCBC **- YES**	

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Vote to base guidance on NQA-1a-2009 with appropriate notations made where that version differs from NQA-1-2004 with addenda through 2007; including a note that the basis for the guidance is not intended to alter any contractual requirements that are based on earlier versions of NQA-1.: **(PASSED)**

*Greg Hayward – Idaho **- YES**	Ken Picha (chair) – Headquarters Acting EM-20 **- YES**
Robert Brown – Oak Ridge **- YES**	Russell McCallister – Portsmouth/Paducah **- YES**
Ray Corey – Richland **- YES**	Bob Murray (vice-chair) – Headquarters EM-23 **- YES**
*Bill Rowland – Savannah River **- YES**	No Voting Member Present - Carlsbad **– N/A**
Bud Danielson –Chief of Nuclear Safety **- YES**	Jonathan (JD) Dowell - River Protection **- YES**
T.J. Jackson – EMCBC **- YES**	

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Presentation by JD Dowell (ORP): Improving Mission Execution

Corporate Board Chair Ken Picha added a brief presentation by JD Dowell, Acting Manager for ORP to the agenda.

JD Dowell explained a recent meeting in Washington DC that focused on the Secretary of Energy's initiative on improving Mission Executions. There are 6 goals to improve the decision making process. The effort is focusing on more responsibility in the field offices and clarifying the functional versus line management positions. Another focus is reducing redundancy and reducing resources needed at Headquarters and focusing those resources on efforts in the field. This effort is being led by Michael Weis and is discussed in a recent memorandum from S-1.

Ken Picha asked if they identified points to get back and brief progress to the Secretary and are field managers asked to help work the issues in lieu of other program offices.

JD Dowell indicated that they are going to brief the DASs next on the approach and it is really both. The teams are championed by personnel at the undersecretary level. In addition, an emphasis was made that now is the time to bring up issues that need to be addressed.

Bud Danielson noted from the discussion that ISO was primarily the non-nuclear work and IAEA was the nuclear piece. There is a reason we use NQA-1, and other organizations supplement the ISO 9001 requirements to meet expectations for nuclear work. In discussions on reducing redundancy, this needs to be considered.

Presentation by Butch Huxford (EM-23) – Focus Area #3: QA in Design

Butch Huxford provided a presentation on the status of the QA in Design Focus Area and indicated the effort is nearly complete (85%). The white paper is ready for review outside of the Focus Area team. The group is asking the Corporate Board to upgrade the white paper to a guidance document due to the information that should be used by the projects. A format like the COr CGD guidance that is currently in process, is the best path forward. The next step would be to present the document to the FPDs, EFCOG, and QA groups for comment with final submittal to the Board in June.

Ken Picha asked for clarification since the discussion seemed to originally indicate contractor assurance beyond QA was covered but the focus in the discussion now seems to be focused just on QA.

Bud Danielson explained that they were distinguishing between QA/QE versus quality by the work force. Butch Huxford agreed.

Brenda Hawks noted the paper should consider increasing CGD for example on new contracts.

TJ Jackson asked about the difference in the guide and what is being requested.

Ken Picha asked if we were referring to 'guide' in the same context as the CGD guide.

Butch Huxford responded that this context is correct.

Jerry Lipsky asked if this already existed. It is really how versus what the requirements are.

Butch Huxford indicated the answer was no, this type of paper doesn't exist, but agreed with the explanation. An example was provided on qualifying QC inspectors where the prime contractors have latitude to mandate to subcontractors.

Bob Toro asked if this was something we are trying to standardize.

Butch Huxford answered that the paper provides the steps and a roadmap.

Al Hawkins indicated it should be considered how this relates to 413.

Butch Huxford indicated the guidance would only be for EM.

Jerry Lipsky asked if verification before you do design is a consideration.

Butch Huxford indicated yes to an extent.

Rich Warriner asked is this should be a lessons learned document.

Butch Huxford indicated that the lessons learned document was a consideration.

Ken Picha noted there appears to be some confusion on the reasoning for the Focus Area formation. Should we discuss why this Focus Area was initiated?

Norm Barker explained how things weren't working and discussed procurement versus design.

Brenda Hawks noted that HEUMF had trouble with a recent ORR because design wasn't looking at the end and the documents weren't correct.

Bud Danielson recommended the Board be provided the white paper first and then allowed to discuss what method should be used to distribute the information.

TJ Jackson agreed and thought we may even want to use the lessons learned process.

Bob Murray agreed and indicated the paper needs to be sent out for review by the Board.

Brenda Hawks asked if Butch Huxford could get on the OECM team on 413 that is addressing this type of issue.

Bud Danielson thinks yes and will check on it and provide the team lead/point of contact.

Bob Murray indicated the next step is to distribute the paper to the Corporate Board with the names of potential reviewers and begin participation on 413 team.

Greg Hayward asked if the deliverable schedule would stay the same as presented.

Butch Huxford answered yes.

Ken Picha asked if a crosswalk to 413 guides were included along with other documents that may have pieces of information that should be referenced.

Butch Huxford indicated no crosswalk has been developed but these documents have influenced the white paper and the references were included.

Presentation by Brenda Hawks (ORO) – Focus Area #4: Grading QA for D&D

Brenda Hawks presented the final deliverable for the Focus Area, indicating there is adequate guidance on the subject but the work is on how to use it.

Bob Murray indicated the deliverable was provided with the packages and recommended the Focus Area be closed out.

TJ Jackson asked how we promote the deliverable.

Brenda Hawks recommended the EM QA website or QA Hub for the information.

Bob Murray suggested we may consider the lessons learned process with HSS or have the HSS website link to our QA website. Bob Murray and Larry Perkins will work on how to distribute the information.

Vote to accept the final deliverable and close Focus Area #4: **(PASSED)**

*Greg Hayward – Idaho **- YES**	Ken Picha (chair) – Headquarters Acting EM-20 **- YES**
Robert Brown – Oak Ridge **- YES**	Russell McCallister – Portsmouth/Paducah **- YES**
Ray Corey – Richland **- YES**	Bob Murray (vice-chair) – Headquarters EM-23 **- YES**
*Bill Rowland – Savannah River **- YES**	No Voting Member Present - Carlsbad **– N/A**
Bud Danielson –Chief of Nuclear Safety **- Abstain**	Jonathan (JD) Dowell - River Protection **- YES**
T.J. Jackson – EMCBC **- YES**	

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Presentation by Bob Murray (EM-23) and TJ Jackson (EMCBC) – QA Training Initiative

Bob Murray presented the information and noted there is no real follow up to the previous training efforts.

TJ Jackson discussed that the issue stemmed from losing QA resources to retirement and working to draw younger workers into the profession. The next question is whether this type of training is EM's responsibility. Overall, the vision of the effort got fuzzy and raised the question of whether we needed DOE corporate resources.

Ray Corey noted we have a great imbalance, for example on the federal side we are losing our young people to other disciplines because we can't get higher grades within QA.

Bob Murray noted we went through various options at the CBC and concluded we own a piece of the problem, but not the whole.

Ken Picha asked if this was just a DOE issue.

TJ Jackson answered that it is also a contractor issue on getting and keeping QA resources.

Brenda Hawks noted that this was a concern with the contractors and Oak Ridge has done cost sharing with contractors to help train resources.

Bob Murray noted we have a program on the books that isn't working and going forward we don't have the resources to continue it.

JD Dowell agreed with the approach.

Ray Corey suggested we may want to ask this in the future as well and see how ARRA affected the concept. The landscape may be different in 9 months.

Greg Hayward commented that as EM works our way out of business, there has been a precedent to role these training sessions out, but courses can be expensive without a lot of contractor resources to participate. However, as EM shrinks, we still need QA resources.

Bob Murray noted that projects like Sodium Bearing Waste need veterans in QA not resources with just a few training courses.

Ken Picha asked if we should have two pieces to the recommendation, one on resources now and another in 9 months.

JD Dowell noted this issue is long term and will just get worse, so we need to develop a strategy.

Ray Corey noted our guidance from previous discussions could be distributed via this training initiative.

Brenda Hawks suggested two tasks:

- Is there a need for infrastructure
- Training for current workforce

JD Dowell agreed with the suggestion.

Bob Toro noted that Sandra Waisley had developed a QA resource table on federal and contractors resulting in data that showed we were below industry average in QA resources.

Bob Murray noted that a lot of this discussion was brought up at the last Corporate Board meeting.

Bud Danielson agreed that the two issues are related and need a long term strategy, but noted that we need some things now such as qualifications for federal personnel supporting nuclear facilities.

San Horton commented there are 3 TQP standards, but only 2 apply to EM.

Bob Murray commented that we can ask about resources in light of how many people are qualified to 1150 and get a standardized answer. Bob also noted that EM-23 requires all of our staff to be qualified to 1150 but noted that EM-23 could not train the entire QA staff for EM.

Bud Danielson agreed and noted we need to set priorities. Bud suggested the first step is to see if the sites have TQP qualified personnel.

Russell McCallister noted the information is available for required areas, but also suggested breaking it down by skills to help clarify the resources available.

Brenda Hawks and TJ Jackson noted this appears to be two groups and need EFCOG engagement.

Benda Hawks discussed training for Facility Representatives and what is needed for them. There is a need today for training beyond the standard such as design in QA.

TJ Jackson indicated he sees this effort as using what we did before, determine if it is adequate, and evaluate what else is needed.

Brenda Hawks thinks the lack of resources is a known issue. Training has been on QA experts versus quality training for each person on a team.

Jim Tisarunni felt DOE must develop the need for training by finding problems in audits and forcing training to be used to fix the issue. Without this, Jim felt nothing will improve.

Jerry Lipsky suggested before you go to the next step, you need proper staffing. Projects don't focus on QA until something goes wrong, and should not be allowed to proceed without fixing the problems first. Jerry also noted that the use of the facility representative and contractor equivalent programs could help.

Bob Murray noted that this is the point. The current process is not working and we need the Corporate Board to develop a new Focus Area to evaluate a path forward.

Randy Smyth commented that a Focus Area is timely and we need to define the need and skill mix, resources, etc. There appears to be a need to revamp the current approach.

Jim Tisarunni felt we want to improve performance versus just using training.

Bob Murray noted we are looking at training and not all of performance with this recommendation.

JD Dowell asked for a short recess to reword the recommendations and then take a vote. Ken Picha as the chair agreed.

Vote to Assign two focus groups to: (1) Address the September 13, 2010, commitment to the Board to develop a task team to determine if there is a shortage of QA/QC resources within EM; (2) Evaluate and assess the current strategy for EM QA/QC training and provide a recommended path forward.: **(PASSED)**

*Greg Hayward – Idaho **- YES**	Ken Picha (chair) – Headquarters Acting EM-20 **- YES**
Robert Brown – Oak Ridge **- YES**	Russell McCallister – Portsmouth/Paducah **- YES**
Ray Corey – Richland **- YES**	Bob Murray (vice-chair) – Headquarters EM-23 **- YES**
*Bill Rowland – Savannah River **- YES**	No Voting Member Present - Carlsbad **– N/A**
Bud Danielson –Chief of Nuclear Safety **- Abstain**	Jonathan (JD) Dowell - River Protection **- YES**
T.J. Jackson – EMCBC **- YES**	

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Presentation by Kathy Reid (EMCBC) – NQA-1 Records Management

The presentation was presented to discuss the concerns with the differences in records terminology between NARA and NQA-1.

Bud Danielson asked for clarification in the example scope which used the term QA Records. Is it really QA Records?

Kathy Reid indicated this was accurate because QA Records are a subset of the federal records.

Bud Danielson noted that QA Records are discussed in NQA-1 but not DOE O 414.1C.

Kathy Reid noted that this is one of the issues – what is a QA record?

Bud Danielson noted that there are a lot of requirements for records outside of NQA-1.

Brenda Hawks asked about rewording the issues in the recommendations.

TJ Jackson commented that this issue needs a group to further investigate the concerns. For example, lifetime can be for the component, plant, glass product, etc.

Rick Warriner asked if it would be worth adding an end product to the mission statement.

Ken Armstrong suggested we need to give latitude to decide the deliverable and propose that deliverable back to the Board.

Mike Hassell asked if we are focusing on QA records or all requirements for federal records.

Kathy Reid responded that we are focusing on QA records for this proposed group.

Ray Corey asked if we are reconciling requirements and terminology.

Kathy Reid responded yes and indicated both may have to give some to make the process work.

Robert Thompson noted we need to include QAP, NQA-1, QARD, and NARA requirements in the evaluation.

Rick Warriner commented that it would seem everyone with a compliant QAP would have already done this type of evaluation.

Bob Toro asked if there was a cost impact consideration.

Kathy Reid responded that this has not been done since everyone is supposed to be following the requirements anyway.

TJ Jackson noted that some projects have said it's too hard to distinguish and everything is a lifetime record so the overall cost may decrease for the projects.

Chris Marden asked if the guidance in NQA-1 is inadequate and should a clarification be requested from the NQA-1 committee.

Kathy Reid responded that the guidance is not inadequate but doesn't merge well with NARA.

Dave Tuttel noted that the Corporate Board had a list of original issues to consider that did not include records. Should this be in EFCOG and not a consideration for the Corporate Board?

JD Dowell asked if the list is still valid given the amount of time that has passed.

Norm Barker noted that the list has been revised once and is not 3 years old.

Brenda Hawks asked if they already have the group at the EMCBC and are just needing a couple QA people to support the group.

Kathy Reid responded that this is correct.

Chris Marden asked what the protocol for presenting issues to the Corporate Board was and if it was followed to present this information.

(Note the by-laws are available online at http://www.em.doe.gov/Pages/QACorporateBoard.aspx)

Bob Murray stated that given the comments, the request for a focus area will be withdrawn and EM-23 will provide the EMCBC with the requested support outside of the Corporate Board.

Bud Danielson indicated that CNS will also provide support for the effort outside of the Corporate Board.

Presentation by Bob Toro (EM-23) – EM Corporate QA Program: Oversight and Implementation

Bob Toro presented the EM Corporate QA Program: Oversight and Implementation strategy.

Jimmy Winkler requested a copy of the EM-23 assessment schedule.

Jim Tisarunni asked how many sites were included in the Phase II reviews.

Bob Toro responded it was 10-14 sites, he would have to get the exact number but an average of ~10 issues per site were identified.

San Horton asked if there was any double counting between the issues for the chart provided, such as an issue noted as Requirement 2 and also a testing issue.

Bob Toro indicated that there was not any double counting.

Rich Salizzoni asked if the issues were federal or contractor issues.

Bob Toro and Larry Perkins both responded that the issues are primarily federal but do include a few contractor issues.

Ken Picha asked if there was any action requested for this presentation.

Bob Toro indicated no vote or action was requested.

General Discussion by the Corporate Board Members

JD Dowell would like to look at the list of issues that were originally prioritized for the Corporate Board, and recommended a discussion at the next meeting.

A recommendation was made to have HSS provide a status of the DOE O 414.1D revision.

JD Dowell mentioned the QA Summit for the next day.

Ken Picha noted that the Corporate Board is EM and EFCOG but EFCOG is doing their own investigation of some of the issues such as metrics and training. How do we ensure no duplication of effort?

Chris Marden noted that EFCOG was working with EM on the Focus Areas and the EFCOG efforts such as metrics were initiated prior to the Corporate Board Focus Areas. There may be a benefit in combining efforts for these Focus Areas.

Norm Barker suggested a discussion of current EFCOG issues be included in the next Corporate Board meeting.

TJ Jackson asked how the teams for the Focus Areas are selected.

Bob Murray answered that EM-23 will work with the appropriate representatives from EFCOG to assign team members.

The next meeting was decided to be a video conference call in the June timeframe.

The next face-to-face meeting was decided to be in Hanford in conjunction with the ISM conference which is scheduled for September 12, 2011.

Meeting Adjourned

SUMMARY OF ACTION ITEMS

#	Action for Follow-Up	Individual Responsible	Current Status
1.	Provide a revised lesson learned document based on previous events surrounding Commercial Grade Dedication.	Linda Weir (BNI)	The revised lessons learned document is still in draft by BNI and is scheduled for completion in March 2011. The completed document will then be provided to the board.
2.	Update the project plan to include new information.	Larry Perkins (EM-23)	Due to multiple changes, the project plan has not been approved. The plan will be updated based on the results of this meeting and provided to the executive committee for review.
3.	Notify the EFCOG chair when the JSEP is ready to populate and the EFCOG chair will send a letter to member encouraging its use.	Christian Palay (EM-23) Joe Yanek (EFCOG)	This action will follow the completion of the JSEP milestones in March 2011.
4.	EM Corporate Board members should provide recommendations on how to report the status of the Goal #5 metrics in the Journey to Excellence.	EM Corporate Board Members	N/A – New Action Item
5.	Provide the updated QA contract language for review/vote.	Bob Murray (EM-23)	N/A – New Action Item
6.	Work with the sites to develop a summary report of recent assessments (e.g., last 6 months) to address flow-down	EM Corporate Board Members Bob Murray (EM-23)	N/A – New Action Item
7.	Evaluate whether the EFCOG efforts on QA metrics can be combined with the needs of EM.	Larry Perkins (EM-23)	N/A – New Action Item
8.	Realign Focus Area #1 to investigate the integration of EM and NNSA efforts.	Mike Mason (BNI) Christian Palay (EM-23)	N/A – New Action Item
9.	Provide a resolution to the comments on the CGD guidance.	Dennis Weaver (BNI) Pat Carier (ORP)	N/A – New Action Item
10.	Change the CGD Guidance Task deliverable to a “Guide” and not a “Standard”.	Dennis Weaver (BNI) Pat Carier (ORP)	N/A – New Action Item

SUMMARY OF ACTION ITEMS

#	Action for Follow-Up	Individual Responsible	Current Status
11.	Base CGD guidance on NQA-1a-2009 with appropriate notations made where that version differs from NQA-1-2004 with addenda through 2007. Include a note that the basis for the guidance is not intended to alter any contractual requirements.	Dennis Weaver (BNI) Pat Carier (ORP)	N/A – New Action Item
12.	Distribute the draft Design QA paper to the Corporate Board for review.	Butch Huxford (EM-23)	N/A – New Action Item
13.	Investigate EM participation on 413 development team.	Butch Huxford (EM-23)	N/A – New Action Item
14.	Investigate the use of the lessons learned process with HSS or have the HSS website link to our QA website for distributing the corporate board deliverables.	Bob Murray (EM-23) Larry Perkins (EM-23)	N/A – New Action Item
15.	Develop a Focus Area Team to address the September 13, 2010, commitment to the Board to develop a task team to determine if there is a shortage of QA/QC resources within EM (consider a follow up in 9 months).	TJ Jackson (EMCBC) Bob Murray (EM-23)	N/A – New Action Item
16.	Develop a Focus Area Team to evaluate and assess the current strategy for EM QA/QC training and provide a recommended path forward.	TJ Jackson (EMCBC) Bob Murray (EM-23)	N/A – New Action Item
17.	Distribute a copy of the most recent EM-23 assessment schedule.	Bob Toro (EM-23)	N/A – New Action Item
18.	Provide a discussion at the next meeting of the latest list of issues that were prioritized for the Corporate Board.	Larry Perkins (EM-23)	N/A – New Action Item
19.	Ask HSS to provide a status of the DOE O 414.1D revision at the next meeting.	Bob Murray (EM-23)	N/A – New Action Item
20.	Ask EFCOG to provide a status and list of issues they are currently working at the next meeting.	Larry Perkins (EM-23)	N/A – New Action Item

ATTENDANCE			
#	First Name	Last Name	Organization
1.	Larry	Adkinson	DOE SRO
2.	John	Almon	CH2M Hill
3.	Ken	Armstrong	DOE
4.	Norm	Barker	Energy Solutions
5.	Paul	Bills	INL
6.	Robert	Brown	DOE-ORO
7.	Steve	Calvert	Navarro
8.	Ray	Corey	DOE RL
9.	Gustave	Danielson	DOE CNS
10.	Jonathan	Dowell	ORP
11.	Michelle	Dudley	LATA
12.	Jerome	Ebner	AREVA Fed. Svcs.
13.	John	Eschenberg	DOE-ORO
14.	Stacey	Evans	Navarro
15.	Thomas	Fallon	Bechtel-BWXT
16.	James	Gambrell	DOE/EMCBC
17.	Ana	Gonzalez	DOE-EM
18.	Daryl	Green	DOE-ORO
19.	Mike	Hassell	WCH
20.	Al	Hawkins	DOE-RL
21.	Brenda	Hawks	DORO
22.	Rich	Higgins	WRPS
23.	Joyce	Hopperton	WSI-SRS
24.	Walter	Horton	DNFSB
25.	William	Huxford	EM-23
26.	TJ	Jackson	DOE
27.	Dave	Kimbro	Navarro
28.	Susan	Kimmerly	Bechtel Jacobs
29.	Prakash	Kunjeer	EM-45
30.	Wayne	Ledford	Navarro
31.	Larry	Lewis	PPPO/RSI
32.	Jerry	Lipsky	DOE
33.	Chris	Marden	ES
34.	Mike	Mason	Bechtel

ATTENDANCE			
#	First Name	Last Name	Organization
35.	Patrice	McEahern	Shaw
36.	Tim	McEvoy	Bechtel
37.	Robert	Milazzo	TetraTech
38.	Bob	Murray	DOE
39.	Mike	Nicol	ES
40.	Christian	Palay	DOE-EM-23
41.	Larry	Perkins	EM-23
42.	Ken	Picha	DOE-EM
43.	Kathy	Reid	DOE-EMCBC
44.	Bill	Rowland	DOE-SR
45.	Richard	Salizzoni	SRR
46.	Lawrence	Smith	UDS, LLC
47.	Randy	Smyth	EM-ORO
48.	James	Sowers	Bechtel
49.	Debra	Sparkman	CNS
50.	Billy	Sullivan	Newport News Industrial
51.	Ali	Tabatabai	Link
52.	Robert	Thompson	CWI
53.	Jim	Tisarunni	URS
54.	Robert	Toro	EM-23
55.	Dave	Tuttel	DOE-EM
56.	Rick	Warriner	RL/CH2M Hill
57.	Dennis	Weaver	BNI
58.	Linda	Weir	BNI-WTP
59.	Aaron	White	DOE-EM
60.	Cynthia	Williams	SRS
61.	Peggy	Wilson	DOE-EM-ORO
62.	Jimmy	Winkler	SRNS
63.	Ray	Wood	Trinity Energy