18th Quality Assurance Corporate Board U.S. Dept. of Energy - Office of Environmental Management May 8, 2017 – 8:00 am – 12:00 pm (MST)		
Time	**Subject**	**Facilitator**
8:00-8:20	Quorum/Announcements/Focus Area Status	Perkins
8:20-8:40	Opening Comments from the EM Deputy Chief for Field Operations	Lachman
8:40-9:00	Comments from the Board Chair	Hutton
9:00-9:30	Integrated Assessment Program/CNS	Sosson
9:30-10:00	EM-QA-001 Revision 2 Development	Murray/Perkins
10:00-10:20	Break	--
10:20-10:50	QA Requirement Applicability and Standard QA Contract Language	Murray/Perkins
10:50-11:20	Staffing and Resource Issues	Murray/Perkins
11:20-11:50	Commercial Grade Dedication	Lipsky
11:50-12:00	General Discussion/Summary	Murray/Perkins

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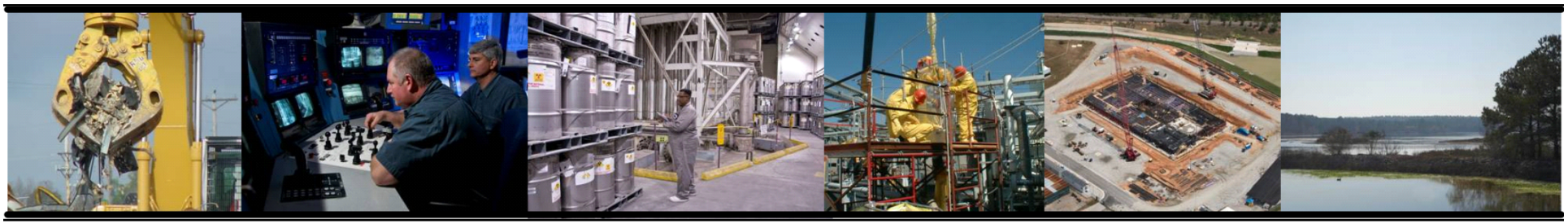

18th EM QA Corporate Board Meeting

Los Alamos National Laboratory

May 8, 2017

EM Environmental Management

safety ❖ performance ❖ cleanup ❖ closure

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Outline

- Quorum
- Announcements
  - VTC
  - Slides and meeting minutes
  - Sign-in Sheets (email for VTC participants)
- Focus Area Status

Focus Area #1: HLW Integration with NQA-1

- The purpose of Focus Area 1 was to support the NQA-1 subcommittee efforts on integration of HLW/SNF into NQA-1 as a subpart via a gap analysis provided by the HLW/SNF community in EFCOG.
- Draft Subpart 2.25 has been completed
- Draft Subpart 2.25 presented to the Waste Management Subcommittee in April 2017.
  - After Subcommittee review and approval, Draft Subpart 2.25 will be balloted for the Standards Committee
  - Expectation is to have Subpart 2.25 approved and included in NQA-1-2019.
- It is recommended that Focus Area 1 be closed as completion of the Subpart will now be up to the NQA-1 committees

Focus Area #2: QA Resources

- The purpose of Focus Area 2 is to provide a review function of the process used by EM-3.113 in evaluating QA resources at an EM site office.
- The documents were reviewed and input received.
- The documents were distributed at the last meeting and can be posted on the EM QA website for reference.
- It is recommended that Focus Area 2 be closed

Focus Area #3: Enhance Annual QA Metrics

- The purpose of Focus Area 3 is to identify a set of easily measurable, readily available ***objective*** metrics to use with the ISM/QA Declarations.
- There is no clear path forward:
  - Committee discussions were inconclusive
  - Response to a test set in the 2016 ISM/QA Declaration was minimal
- It is recommended that Focus Area 3 be closed without issue

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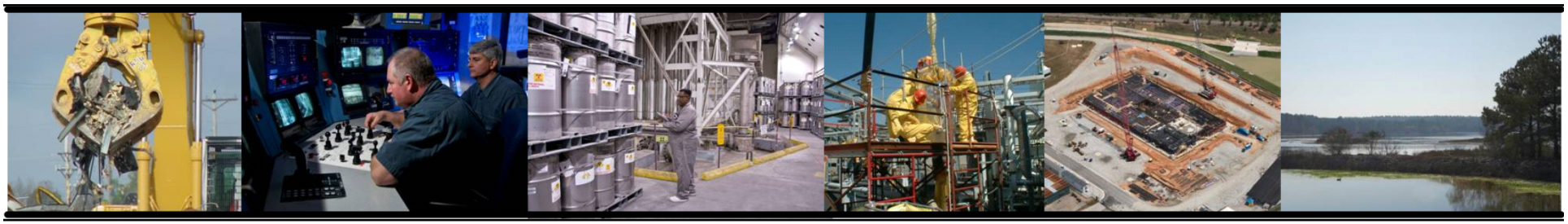

18th EM QA Corporate Board Meeting

Kirk Lachman
Deputy Chief for Field Operations, EM-3

May 8, 2017

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01/20/2017

Safety, Security, & Quality

Savannah River National Laboratory Policy Office

EM-1 Assistant Secretary
Sue Cange, Acting
EM-2 Principal Deputy Assistant Secretary
Sue Cange

EM-2.1
Chief of Staff
Betsy Connell

- International Program
- Correspondence Center

Site Managers

EM-4
Regulatory and Policy Affairs
Frank Marcinowski, APDAS
Vacant, Deputy Chief

EM-4.1 Infrastructure Management and Disposition Policy
Barton Barnhart, Director
- 4.11 Infrastructure and D&D (Andy Szilagyi)
- 4.12 Subsurface Closure (Kurt Gerdes)

EM-4.2 Waste and Materials Management
Mark Senderling, DAS
- 4.21 National TRU Program (Elizabeth Forinash)
- 4.22 Waste Disposal (Doug Tonkay)
- 4.23 Nuclear Materials (Steve Schneider)
- 4.24 Packaging & Transportation (Joanne Lorence)

EM-4.3 Regulatory Intergovernmental and Stakeholder Engagement
Rob Seifert, Acting
- 4.31 Regulatory Compliance (Rob Seifert)
- 4.32 Intergovernmental and Stakeholder Programs (Rob Seifert, Acting)

EM-3
Field Operations
Stacy Charboneau, APDAS
Kirk Lachman, Deputy Chief

EM-3.1 Safety, Security, and Quality Assurance
Jim Hutton, DAS
Greg Sosson, ADAS
- 3.11 Field Operations Oversight/CNS (Greg Sosson)
  - 3.111 Safety Management (Ted Wyka)*
  - 3.112 Operational Safety (Terrance Tracy)
  - 3.113 Standards and Quality Assurance (Robert Murray)
  - 3.114 Safeguards, Security, and Emergency Preparedness (Jimmy McMillian)

EM-3.2 Technology Development
Rod Rimando, Director

EM-3.3 Chief Engineer
John Marra, Chief Engineer
- 3.31 Major Constructions and Modifications (John Moon, Acting)
- 3.32 Operations and Processes (Michael Norato)

Field Operations
- Carlsbad
- EM CBC Field Operations
  - *Energy Technology Engineering Center*
  - *Lawrence Berkeley National Laboratory*
  - *Nevada & NV National Security Site*
  - *Separation Process Research Unit*
  - *Uranium Mill Tailing Remedial Action*
  - *West Valley Demonstration Project*
- Idaho
- Los Alamos
- Oak Ridge
- Office of River Protection
- Portsmouth & Paducah
- Richland
- Savannah River Site
- HQ Field Liaisons

EM-5
Corporate Services
Candice Trummell, APDAS
Jason Donaldson, Deputy Chief

EM-5.1 Resource Management
Connie Flohr, DAS
Melody Bell, ADAS**
- 5.11 Budget and Planning (Steve Trischman)
  - 5.111 Budget (Michele Torrusio)
  - 5.112 Program Planning (Lois Jessup)
- 5.12 Information Systems (Jeanne Beard)
- 5.13 Workforce Management (Mary Ann Maloney)

EM-5.2 Acquisition & Project Management
Ralph Holland, DAS
Norbert Doyle, ADAS
- 5.21 Acquisition and Contract Management (Norbert Doyle, Acting)
- 5.22 Project Management (Briant Charboneau)

EM-5.3 Communications
Vacant
- 5.31 External Affairs (Kristen Ellis)
- 5.32 Communications Services (Melanie Holt)

* On detail assignment (Jomaries Rivera, Acting)
** On detail assignment

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EM Believes in the Importance of QA

- Safety and Quality are integrated into all work
- Quality serves as the Framework for performing work safely and correctly
  - Right People
  - Right Equipment
  - Right Procedures
- Independent assessments
- Allows management to drive priorities by focusing quality resources on problem areas
- Identify small problems and correct before becoming big problems

Recent QA Successes

- Waste Isolation Pilot Plant (WIPP) successful Operational Readiness Review and restart after two events
- Salt Waste Processing Facility (SWPF) vessel supplier qualification
- SWPF Work Package Closure and Testing
- Quality Assurance Requirements Document (QARD) incorporated into NQA-1
- RADCALC Contractor qualification

Current Focus and Expectations for QA

- Assess and Assist
  - Enable the field to successfully complete the mission
- QA Site Representatives
- Consistency in implementation
- Consistent contractual implementation

Opportunities for the EM QA Corporate Board

- How to share resources to overcome limited budgets
- How to be consistent in our implementation
- Areas where we can improve

EFCOG Cost Saving Opportunities

- EFCOG had a number of recommendations from their January 2017 workshop

- Consider expanding and rejuvenating EFCOG's Joint Supplier Evaluation Program to provide a national database of qualified suppliers so that each contractor does not have to spend money on repetitive, individual audits

EFCOG Cost Saving Opportunities (cont.)

- Re-examine regulatory “creep”
- One item of regulator “creep” EFCOG suggested be looked at
  - EM Agreement on Graded Approach in QA
    - Corp. Board has issued guidance on Graded Approach
    - Concerns with implementing consistent terms and levels
    - Guidance document is not consistently implemented
    - Does the effort need revisited and how can the Corp. Board help re-energize this effort?

Look ahead

- Things are changing everywhere and QA is not immune
- Look ahead on how QA can enable the field to complete the mission
- You can do this without compromising your oversight independence

Questions

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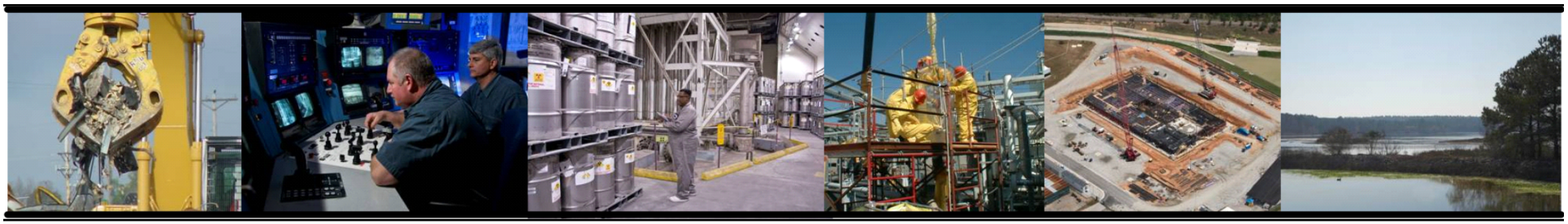

18th EM QA Corporate Board Meeting

Jim Hutton
Deputy Assistant Secretary
Safety, Security and Quality Programs (EM-3.1)

May 8, 2017

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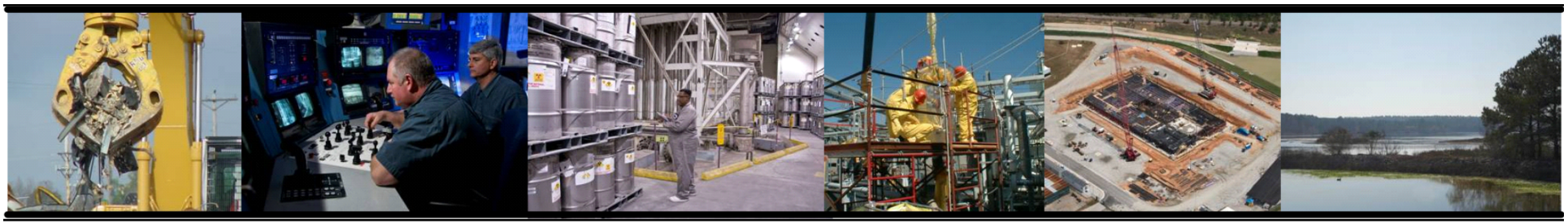

18th EM QA Corporate Board Meeting

Greg Sosson

ADAS for Field Operations Oversight/Chief of Nuclear Safety

Gustave (Bud) Danielson, CNS Staff

May 8, 2017

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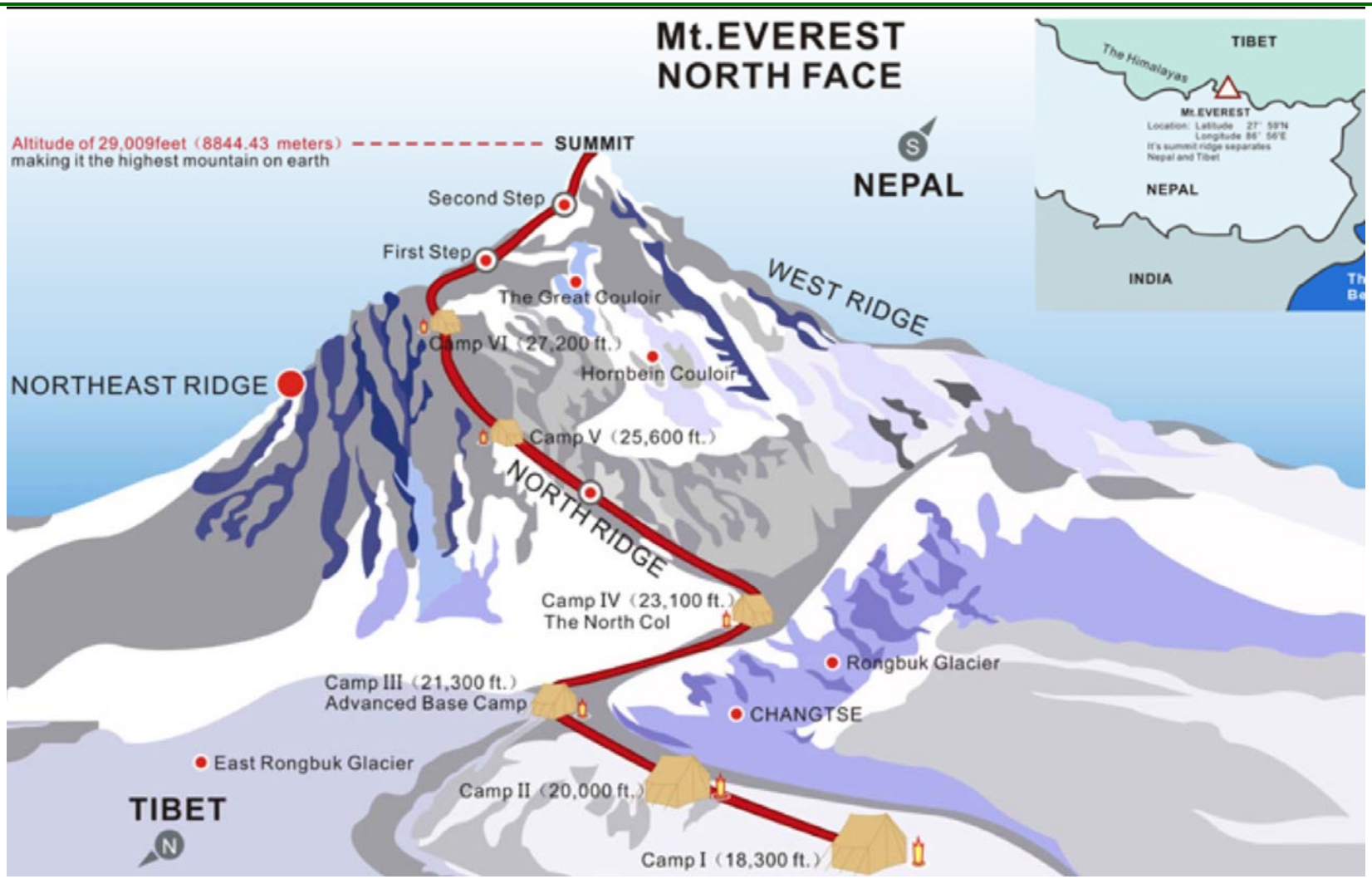
EM – 3.1 Updates

- Integrated Oversight Process
- CNS QA Updates

Journey To Excellence is a Process



www.tibettravel.org/tibet-travel-advice/everest-nepal-tibet.html

EM HQ Integrated Oversight Process

- Why do we do oversight?
  - Compliance? Excellence?
- Many different oversight organizations:
  - DNFSB, EA, EMHQ, Field Offices, CAS, CNS
- Effective oversight needs to offer insight
  - To line organizations to promote continuous improvement.
    - Journey To Excellence!!!
  - To DOE Management to understand performance
- This can be tricky with DOE as Owner/Regulator.
- Role of EM HQ Field Operations Oversight
  - Assess - Assist - Advocate
- EM SOPP- 49 is our vehicle

Integrated Oversight Process

Appendix One
List of Organizational Owner and Required Functional and Cross Functional Areas

Functional Area	Org Owner
Emergency Preparedness	EM-44
Fire Protection	EM-41
Industrial Safety/Occupational Safety and Health	EM-41
Nuclear Safety	
• Criticality Safety	EM-41
• Facility Startup/Restart	EM-42
• Safety Basis	EM-41
• Safety System Operability	EM-42
• Technical Safety Requirements Implementation	EM-42
• Environmental Management	
Process Safety	
Conduct of Operations	EM-42
Maintenance	EM-42
Work Planning and Control	EM-42
Quality Assurance	EM-43
Defense HLW/UNF Oversight (ID, ORP, Richland, SRS, West Valley, RP)	
QAP/QIP Qualification	
Supplier Qualification	
Software Quality	
Independent Assessments (Audits, Surveillances, Assist Visits)	
QA Analysis (operational awareness)	
Radiological Protection	EM-42
Safeguards & Security and Classification	EM-44
Information Security	
MCAA	
Personnel Security	
Physical Security	
Protective Force	
Security Classification Program	

Cross Functional Area	Org Owner
Administration of Federal Field Oversight	
Assessment Program	
Issues Management	
Performance Metrics	EM-41
Training and Qualifications	
Contractor Assurance System	EM-43
Safety Culture	EM-40
• Employee Concerns Program	
• Safety Conscious Work Environment Sustainability Plans	
Safety Performance Measures and Monitoring	EM-41

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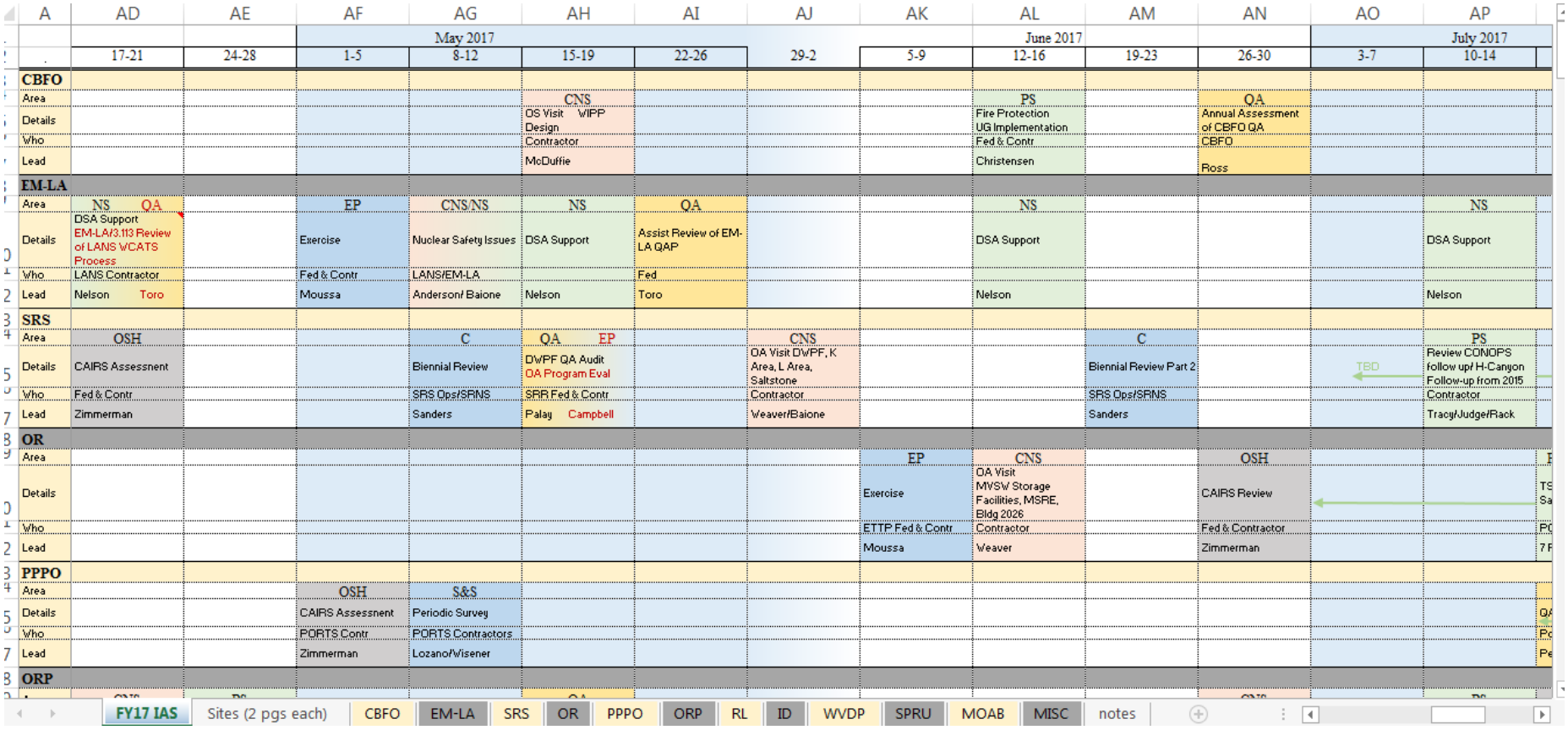
Integrated Oversight Process -Schedule

- Pulled together all EM-3.1 field oversight activities
  - Included CNS Operational Awareness
- Iterative Collaboration with Field Sites
- Oversight and Assistance Are Included

Integrated Oversight Process - Schedule



A	AD	AE	AF	AG	AH	AI	AJ	AK	AL	AM	AN	AO	AP
			May 2017						June 2017				July 2017
	17-21	24-28	1-5	8-12	15-19	22-26	29-2	5-9	12-16	19-23	26-30	3-7	10-14
CBFO													
Area					CNS				PS		QA		
Details					OS Visit WIPP Design				Fire Protection UG Implementation		Annual Assessment of CBFO QA		
Who					Contractor				Fed & Contr		CBFO		
Lead					McDuffie				Christensen		Ross		
EM-LA													
Area	NS QA		EP	CNS/NS	NS	QA			NS				NS
Details	DSA Support EM-LA/3.113 Review of LANS WCATS Process		Exercise	Nuclear Safety Issues	DSA Support	Assist Review of EM-LA QAP			DSA Support				DSA Support
Who	LANS Contractor		Fed & Contr	LANS/EM-LA		Fed							
Lead	Nelson Toro		Moussa	Anderson/ Baione	Nelson	Toro			Nelson				Nelson
SRS													
Area	OSH			C	QA EP		CNS			C			PS
Details	CAIRS Assessment			Biennial Review	DWPF QA Audit OA Program Eval		OA Visit DWPF, K Area, L Area, Saltstone			Biennial Review Part 2		TBD	Review CONOPS follow up/ H-Canyon Follow-up from 2015
Who	Fed & Contr			SRS Ops/SRNS	SRR Fed & Contr		Contractor			SRS Ops/SRNS			Contractor
Lead	Zimmerman			Sanders	Palay Campbell		Weaver/Baione			Sanders			Tracy/Judge/Rack
OR													
Area								EP	CNS		OSH		
Details								Exercise	OA Visit MWSW Storage Facilities, MSRE, Bldg 2026		CAIRS Review		
Who								ETTP Fed & Contr	Contractor		Fed & Contractor		
Lead								Moussa	Weaver		Zimmerman		
PPPO													
Area			OSH	S&S									
Details			CAIRS Assessment	Periodic Survey									
Who			PORTS Contr	PORTS Contractors									
Lead			Zimmerman	Lozano/Wisener									
ORP													

FY17 IAS | Sites (2 pgs each) | CBFO | EM-LA | SRS | OR | PPPO | ORP | RL | ID | WVDP | SPRU | MOAB | MISC | notes

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Integrated Oversight Process - Schedule

Functional Areas
OSH: Ocupational Safety & Health (EM-3.111)
PS: Process Safety (EM-3.111)
NS: Nuclear Safety (EM-3.112)
PS: Process Safety (EM-3.112)
RP: Radiological Protection (EM-3.112)
QA: Quality Assurance (EM-3.113)
S&S: Safeguards & Security (EM-3.114)
EP: Emergency Preparedness (EM-3.114)
C: Classification (EM-3.114)
Cross Functional Areas
SC: Safety Culture (EM-3.1)
AFFO: Administration of Federal Field Oversight (EM-3.111)
SPMM: Safety Performance Measures and Monitoring (EM-3.111)
CAS: Contractor Assurance System (EM-3.112/3.113)
CNS
CNS Activity (EM-3.11) is for Reference Only; not a part of SOPP #49.
** Maintains operational awareness of the implementation of nuclear safety requirements and guidance consistent with the Integrated Safety Management (ISM) guiding principles and core functions across the EM complex as defined in DOE O 450.2. Awareness is accomplished by working with Headquarters, Field Office, and Facility Representative (FR) staff to implement DOE O 226.1B, Implementation of DOE Oversight Policy. To fulfill this responsibility, CNS staff participate in project reviews, , ensure operational readiness, and review documented safety analyses to evaluate the adequacy of safety controls and their implementation.
Ensures that DOE Orders, Guides, and Standards, and industry standards are correctly applied in the conduct of DOE's mission.
Periodically reviews and assesses whether DOE EM organizations are maintaining adequate numbers of technically competent personnel necessary to fulfill their nuclear safety responsibilities.
DOE O 450.2, Integrated Safety Management. Provides concurrence on delegation of approval of documented safety analyses, technical safety requirements, and unreviewed safety question procedures below the most senior-level program officer or deputy at a Field Element. Provides concurrence on compensatory measures related to the delegation-of-authority process. Conducts an annual review of the delegation process to evaluate whether it is adequate and functioning properly and to identify any concerns to the CTA, who will notify the Under Secretary and the Secretarial Office (SO) and recommend action, as appropriate. Independently reviews the EM self-assessments of delegations; notifies the Under Secretary if issues are unresolved.
Concurs with the determination of the applicability of DOE directives involving nuclear safety included in Environmental Management (hereafter specifically referring to EM activities) contracts pursuant to Department of Energy Acquisition Regulation (DEAR), Title 48 of the Code of Federal Regulations (CFR), Section 970.5204-2, Laws, regulations, and DOE directives, item (b).
Concurs with nuclear safety requirements included in EM contracts pursuant to DEAR 970.5204-2(c).
Concurs with all exemptions from nuclear safety requirements in EM contracts that were added to the contract pursuant to DEAR 970.5204-2.

Integrated Oversight Process - Next Steps

- Reviewing Quarterly Safety Reports Roll Ups For Actionable Improvements/Follow ups
- Looking farther forward in assessment Planning
- Integrated Projected Budget with Oversight Requirements and Assessed Risks to Allocate Oversight Resources.
- Collaborate with other Oversight Entities to:
  - Minimize Site Impact/Duplication

Integrated Oversight Process – Next Steps

- Rollup multiple data streams
  - EM-3.1 Oversight Reports (including QA, CNS, Safety and Security)
  - ORPS Data
  - CAIRS Data
  - EA Reports
  - DNFSB Reports
  - Field Office Assessments and Self Assessments
- Produce Integrated Picture of Field Site/Contractor/EM Complex Performance

EM CNS QA Updates

- CNS's independent advisory role and subject matter expertise to support the EM Central Technical Authority and Under Secretary for Management and Performance

Where Can We Improve Quality Assurance Implementation?

- Future project planning must include realistic staff and budget resources paid for out of the project funds.
  - DOE site & contractor staff adequate for QA Program development, QE & Oversight
  - Subcontractor/supplier oversight travel resources, shop inspectors
  - What level of resources triggers work impacts?
  - Apply and grade NQA-1 application based on nuclear safety significance
- Allow contractors flexibility to chose NQA-1 editions beyond 2008/9 w/o permission from HQ
- Routine process for updating NQA-1 editions that does not involve massive costs
  - HQ and site office acceptance
  - Contractor method built-in the QAP approval process
  - Selective adoption of improvements w/o need for QAP approvals or wholesale update

What's Next in Quality and Management Systems Requirements and Implementation?

- Coming changes to NQA-1 for 2017/18 Edition and plans for 2019 (especially changes that support 10 CFR 830 implementation)
  - Part I Req. 7 and Part II Subpart 3.1-4.1, -7.1, -18.1, on acceptance of 3rd Party Certified QAPs
  - SP 2.17 New Subpart on electronic records management
  - Subpart 2.18, Maintenance
  - SP 3.1-7.x Calibration & Testing Facilities
  - SP 4.1.1 ISO 9001:2015 comparison with NQA-1
  - SP 4.2.1 R&D graded application
- NQA-1 2019 Edition - work started on: Graded Procurement, Reverse Engineering, Counterfeit Items, CGD update with EPRI, High Level Waste Requirements to meet 10CFR 63.142 (replaces DOE QARD)...
- ISO 19443 progressing and eventually impact US nuclear industry

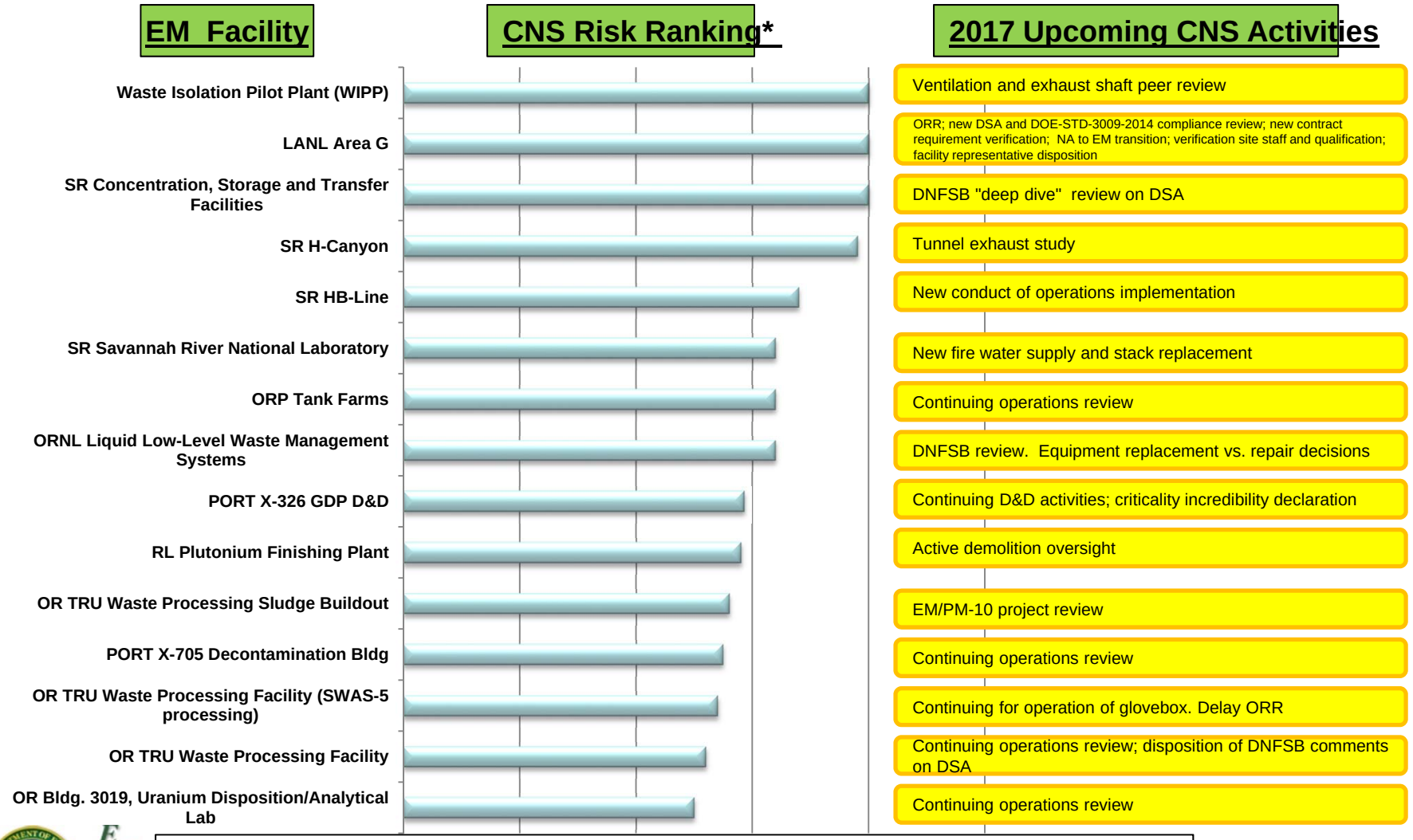
Ongoing CNS Activities in Support of the US for M&P and EM

Assure:

- Safety, engineering, and design issues impacting project cost, schedule, and quality are identified and addressed.
- Early integration of safety and design to allow the development of timely and cost-effective solutions. Minimizes potential for costly back-fit during facility operations on one-of-the-kind and first-of-the-kind projects, (ie., Hanford WTP).
- Safety and engineering reviews are part of the project startup/commissioning processes prior to facility operations (ie., Idaho IWTU and Savannah River SWPF projects.)
- Nuclear facilities being transferred to EM have the proper nuclear safety documentation as part of turnover (ie., Los Alamos Area G facilities from NNSA).
- Safety in design is performed correctly during facility major modifications at the Carlsbad WIPP project.
- Nuclear safety requirements are properly addressed in RFPs and contracts, and properly implemented during design, commissioning, operations, and decommissioning.
- Nuclear safety requirements and guidance are properly developed.

The relevancy and corporate value-added of CNS activities are examined based on a transparent and data-driven strategic planning process https://energy.gov/em/chief-nuclear-safety

CNS Perspectives on Top 15 EM Facilities*



* Developed based on application of risk-informed methodology and operational awareness data

Near-Term CNS Focus Areas associated with Major Design, Construction, and Startup Nuclear Projects

Projects

1. SR Salt Waste Processing Facility
2. ID Integrated Waste Treatment Unit
3. ORP WTP Direct-Feed Low Activity Waste Facilities (LAW, Effluent Management Facility , and Analytical Lab)
4. ORP Tank Farm Low-Activity Waste Pretreatment System
5. ORP Tank Farm Waste Characterization and Staging
6. ORP WTP High Level Waste Facility
7. ORP WTP Pretreatment Facility

2017 Upcoming CNS Activities

- EM/PM-10 project review; equipment labeling issues; ventilation problems
- Ongoing facility modifications at commissioning.
- Preliminary Documented Safety Analysis (DSA) change package for Effluent Management Facility
- 60% design review. EM/PM-10 project review.
- Critical Decision deliverables review
- Technical issues resolutions
- Technical issues resolutions

Major Awareness

- Startup/ Commissioning
- Safety In Design

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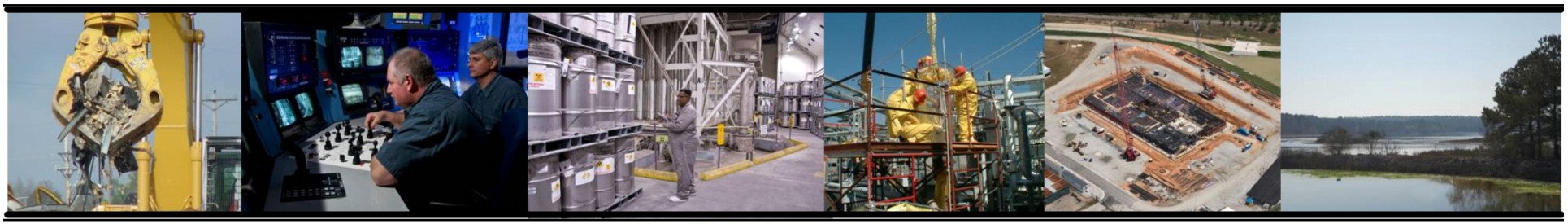

18th EM QA Corporate Board Meeting

EM-QA-001 Revision 2 Development

May 8, 2017

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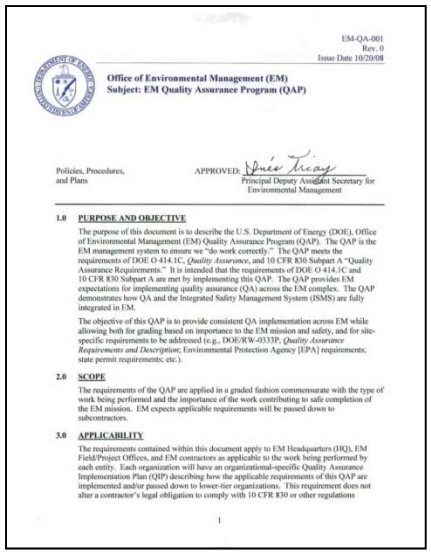
Background of EM-QA-001

- EM-QA-001 was issued in 2008 to provide the basis to achieve quality across the EM complex addressing:
  - 10 CFR 830, Subpart A
  - NQA-1
  - DOE O 414.1
  - EM Policy Statements



EM-QA-001
Rev. 0
Issue Date 10/20/08

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

Policies, Procedures, and Plans

APPROVED: Principal Deputy Assistant Secretary for Environmental Management

1.0 PURPOSE AND OBJECTIVE

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

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

2.0 SCOPE

The requirements of the QAP are applied in a graded fashion commensurate with the type of work being performed and the importance of the work contributing to safe completion of the EM mission. EM expects applicable requirements will be passed down to subcontractors.

3.0 APPLICABILITY

The requirements contained within this document apply to EM Headquarters (HQ), EM Field/Project Offices, and EM contractors as applicable to the work being performed by each entity. Each organization will have an organizational-specific Quality Assurance Implementation Plan (QIP) describing how the applicable requirements of this QAP are implemented and/or passed down to lower-tier organizations. This requirement does not alter a contractor's legal obligation to comply with 10 CFR 830 or other regulations

1

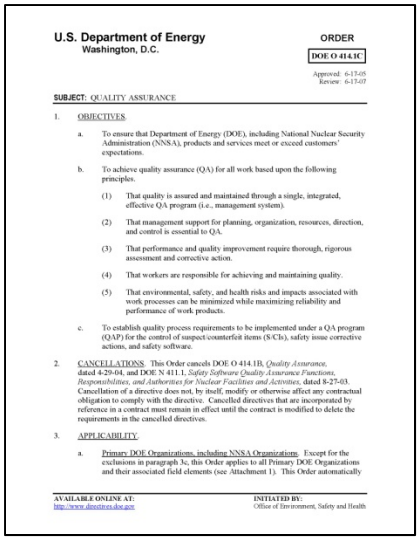
- EM-QA-001 provides a consistent set of QA requirements and expectations for the entire EM organization, including HQ, Field Offices, and Contractors.

Background of EM-QA-001 (continued)

10CFR 830, Subpart A (QA Rule)

code of federal regulations

QA Order



U.S. Department of Energy
Washington, D.C.

ORDER
DOE O 414.1C

Approved: 6-17-05
Review: 6-17-07

SUBJECT: QUALITY ASSURANCE

1. OBJECTIVES

a. To ensure that Department of Energy (DOE), including National Nuclear Security Administration (NNSA), products and services meet or exceed customers' expectations.

b. To achieve quality assurance (QA) for all work based upon the following principles.

(1) That quality is assured and maintained through a single, integrated, effective QA program (i.e., management system).

(2) That management support for planning, organization, resources, direction, and control is essential to QA.

(3) That performance and quality improvement require thorough, rigorous assessment and corrective action.

(4) That workers are responsible for achieving and maintaining quality.

(5) That environmental, safety, and health risks and impacts associated with work processes can be minimized while maximizing reliability and performance of work products.

c. To establish quality process requirements to be implemented under a QA program (QAP) for the control of suspect/counterfeit items (S/CIs), safety issue corrective actions, and safety software.

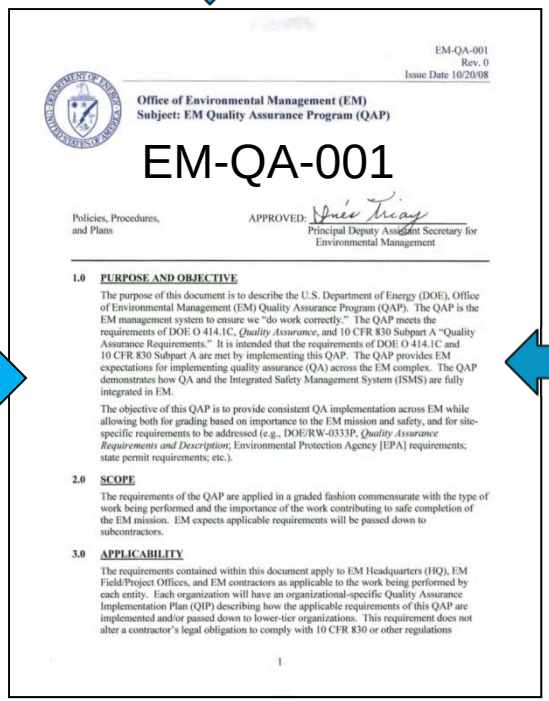
2. CANCELLATIONS. This Order cancels DOE O 414.1B, *Quality Assurance*, dated 4-29-04, and DOE N 411.1, *Safety Software Quality Assurance Functions, Responsibilities, and Authorities for Nuclear Facilities and Activities*, dated 8-27-03. Cancellation of a directive does not, by itself, modify or otherwise affect any contractual obligation to comply with the directive. Cancelled directives that are incorporated by reference in a contract must remain in effect until the contract is modified to delete the requirements in the cancelled directives.

3. APPLICABILITY

a. Primary DOE Organizations, including NNSA Organizations. Except for the exclusions in paragraph 3c, this Order applies to all Primary DOE Organizations and their associated field elements (see Attachment 1). This Order automatically

AVAILABLE ONLINE AT:
http://www.directives.doe.gov

INITIATED BY:
Office of Environment, Safety and Health



EM-QA-001
Rev. 0
Issue Date 10/20/08

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

EM-QA-001

Policies, Procedures, and Plans

APPROVED:
Principal Deputy Assistant Secretary for Environmental Management

1.0 PURPOSE AND OBJECTIVE

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

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

2.0 SCOPE

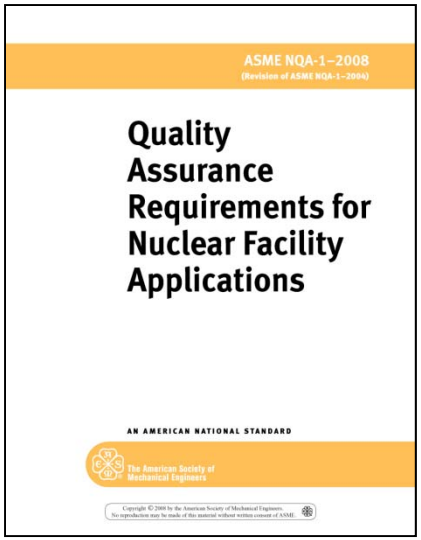
The requirements of the QAP are applied in a graded fashion commensurate with the type of work being performed and the importance of the work contributing to safe completion of the EM mission. EM expects applicable requirements will be passed down to subcontractors.

3.0 APPLICABILITY

The requirements contained within this document apply to EM Headquarters (HQ), EM Field/Project Offices, and EM contractors as applicable to the work being performed by each entity. Each organization will have an organizational-specific Quality Assurance Implementation Plan (QIP) describing how the applicable requirements of this QAP are implemented and/or passed down to lower-tier organizations. This requirement does not alter a contractor's legal obligation to comply with 10 CFR 830 or other regulations

1

Consensus Std (NQA-1)



ASME NQA-1–2008
(Revision of ASME NQA-1–2004)

Quality Assurance Requirements for Nuclear Facility Applications

AN AMERICAN NATIONAL STANDARD

The American Society of Mechanical Engineers

Background of EM-QA-001 (continued)

- EM-QA-001 Rev. 0:
- Was intended as a EM-specific QA Plan but also included requirements as management expectations
- Adopted NQA-1-2004 with addenda through 2007 as Consensus Standard
- Issuance of the EM QAP required a gap analysis prior to implementation
- Specifically allowed for use of a graded approach
- Allowed for adoption of the EM QAP in whole or development of a site specific QAP that met the requirements of EM-QA-001

Background of EM-QA-001 (continued)

- EM-QA-001 Rev. 1:
- Was also intended as a EM-specific QA Plan but emphasized that management expectations are not requirements
- Included updates to accommodate Order 414.1D and adopted NQA-1-2008 with addenda through 2009 as Consensus Standard
- Enhanced discussion with regards to federal records and qualification for federal QA and SQA personnel
- Updated software QA to include safety and non-safety software; added requirements for V&V of computer models
- Added Transportation Quality Assurance based upon Order 460.1C

EM-QA-001 Rev. 2 Suggested Changes

- Add an Attachment to include the Standard QA Contract Language
- Add an Attachment to address HLW via NQA-1 Subpart 2.25
- Update existing document references and attachments
- Identify Management Expectations that are derived from EM policy or lessons learned and should be retained as requirements
- Modify the current hybrid QAP/Requirements Document
  - Establish EM-QA-001 Rev. 2 as a requirements document
  - Remove non-requirements
  - Additional clarification added to mandatory management expectations where necessary
  - All sites, contractors, and HQ develop a QAP to meet the requirements

Recommendation to the Corp. Board

- Request the sites provide recommended changes and input for consideration in EM-QA-001 Revision 2
- Input should emphasize what is working and what is not working and needs revision
- Designate a committee/focus area to collect and consolidate input and provide to EM-3.113.
- EM-3.113 will develop a draft EM-QA-001 Revision 2 and provide it to the EM QA Corporate Board for review

Questions/Discussion

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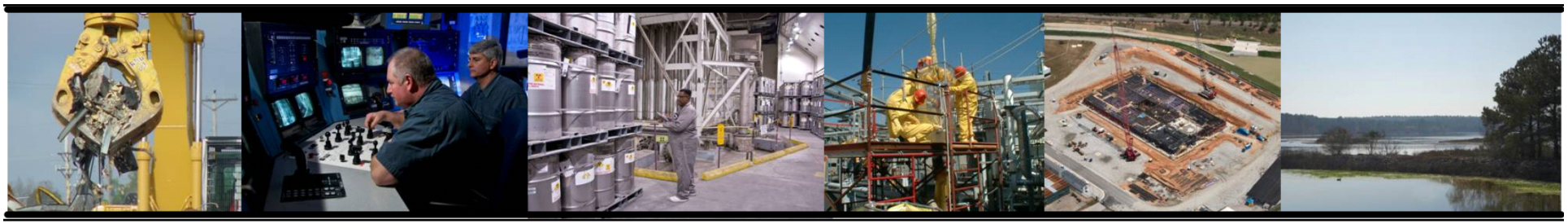

18th EM QA Corporate Board Meeting

BREAK

May 8, 2017

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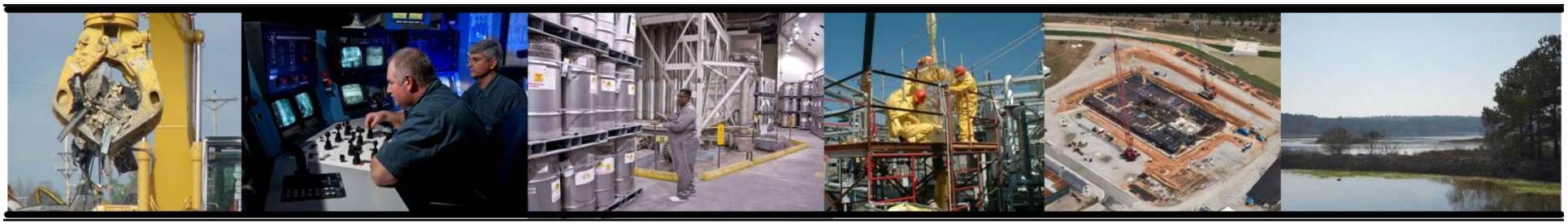

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EM-QA-001 Applicability and Standard QA Contract Language

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Confusion on EM-QA-001 Applicability

- EM-QA-001 Revision 1
  - "The scope of the EM QAP is applied in a graded approach and encompasses: All work performed by EM within both federal offices [Headquarters (HQ) and Site Offices] and prime contractors, as well as their respective subcontractors, vendors, and suppliers."
- EM QA Policy
  - "The EM Quality Assurance Program (QAP) provides the basis for achieving quality across the EM complex for all EM mission-related work….

Confusion on EM-QA-001 Applicability

- EM-QA-001 Revision 1
  - "The scope of the EM QAP is applied in a graded approach..."
  - "EM implements … the NQA-1 standard in a graded approach, as applicable to the activity"
- EM has adopted NQA-1-2008/2009a as the consensus standard for EM work

Confusion on EM-QA-001 Applicability

- Default is NQA-1-2008/2009a but there is a process to use other consensus standards for work.
- Current process per EM-QA-001 Revision 1
  - Nuclear Facilities or Activities require approval of EM-3.1
  - Nonnuclear Facilities or Activities require approval of local approval authority (if delegated from EM-3.1)

Clarifications

- New standard contract language
  - Requires NQA-1 for nuclear facilities or activities
  - Allows NQA-1 or other standard for nonnuclear facilities or activities
  - Level of approval will remain the same
  - Provides clarification to what is expected
  - Will apply to all EM contracts

Clarifications

- Will be reflected in EM-QA-001 Revision 2 which we will ask for evaluation of effort and cost to implement
- Standard contract language will be used for all new contracts
- Current contractors will continue to operate under the existing contracts unless a decision is made to update the contract clause
- DOE will discuss whether there is any benefit to updating the existing contracts based on requested evaluations

Question/Discussion

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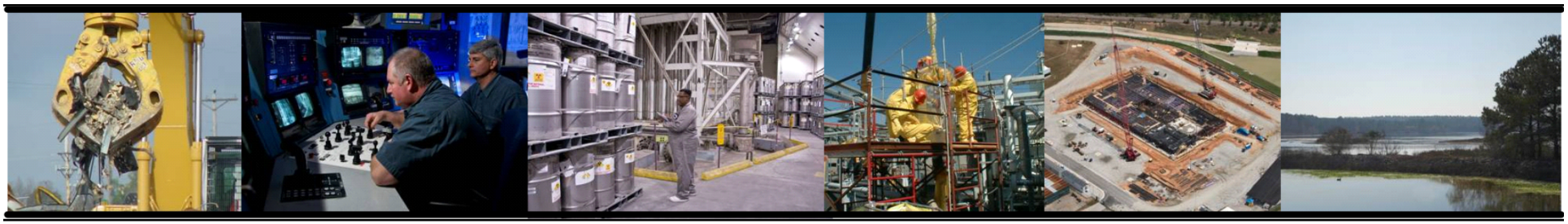

18th EM QA Corporate Board Meeting

Discussion of Staffing and Resource Issues in QA

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Adequate QA Staffing and Resources

- Note: QA = QA, QC, QE, and SQA
- Do we have adequate QA staffing? Feds? Contractors? How do we know?
- What is the best way to capture and maintain existing QA staffing levels complex-wide?
- How do we determine how many QA staff are needed? Per site? EM-wide?
- Should we have the sites each perform a resource analysis like the one discussed in the recent focus area?
- What impact is insufficient QA resources having on mission work scope?
- How are we tracking and documenting potential QA resources shortages that impact the ability to complete mission work scope?
- How can we share QA resources across EM projects and sites? Feds? Contractors?
- Should we have a group develop recommendations for the QA Corporate Board?

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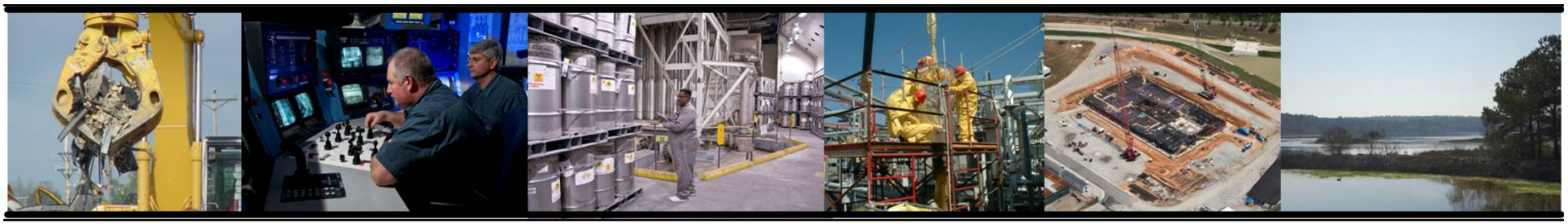

18th EM QA Corporate Board Meeting

Clarifying Procurement and CGD Expectations

Jerry Lipsky
DOE-SR, Chief Engineer

May 8, 2017

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Background

- Currently, most EM site contractors have implemented the Commercial Grade Dedication (CGD) process discussed in American Society of Mechanical Engineers (ASME) NQA-1 Quality Assurance (NQA-1-2008) as modified in the 2009 addenda (NQA-1a-2009).
- DOE and EPRI have both issued guidance documents to further explain the CGD process.
- DOE-AU is currently working on updated guidance to implement a CGD program.

General Problem Statement

- At SRS, and at many other sites, there have been a lot of growing pains as both DOE (at the field and HQ levels) and the DOE contractors struggle in their efforts to “force fit” the NQA-1 CGD requirements into their engineering and procurement practices.

Specific Problem Statements

1) At SRS, and at many other sites, there is an excessive amount of effort and resources being applied to dedicate items that may not need to be built or dedicated to NQA-1 standards.
2) At SRS, and at many other sites, once the decision is made to dedicate an item, both the contractor and DOE are struggling to align their expectations on how much effort and detail is enough to obtain “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.

Proposed Solution (s)

Since the grading of QA requirements for the order and NQA-1 must be done in a DOE approved QAP, QAPs should be modified to include and implement the philosophy below. The EM QA Corporate Board should concur with adopting the following approaches via appropriate interim and long term measures.

Proposed Solution (s)

EM-3.113 should:

- expeditiously promulgate this philosophy via an interim change to the EM-QAP,
- update the existing CGD guide to address all procurement options,
- provide this updated guidance to AU to incorporate into the guidance they are currently working on.

Alternate approaches resulting in a similar outcome may also be appropriate.

Proposed Philosophy

This discussion is geared toward replacement of items in existing SSCs, but it can be readily applied to purchasing new items for new SSCs. “

SSC” includes Software for the purposes of this discussion.

Items includes parts of *items*.

Design

- The NQA-1 and the EPRI Guide relate the decision on whether a commercial grade item needs to be dedicated (or not) to who owns (or controls) the design.
- Since many DOE SS/SC SSC were upgraded to SS/SC via a **backfit analysis**, the determination of who owns or controls the design may not support a clean fit into this philosophy.
- The system engineer will often find it easier to arrive at a defensible answer if he considers the overall design of the safety system prior to focusing on the major components.
- This should become clearer as we go forward.

Example - Back Up Power System

Scenario: You have a diesel generator that supplies back up power and it was determined to be SC by backfit analysis.

- Many of the backfit analyses were not performed with regard to future NQA-1 related procurement strategies, and therefore do not fit well into the current DOE-EM and EPRI guides.
- You want to buy replacement parts for that generator.
- You do not own or control the design of the diesel, so you may think the EPRI guide 3.4.2 leads you down the path of having to perform a CGD.

Path Forward - Back Up Power System

- Consider the Backup Power System to be the SC System.
- The diesel generator would then be a component of the SC system.
- If the original design of the diesel generator did not call out for a diesel generator to be procured from an NQA-1 supplier (or be CGD'd) then it probably specified some other set of consensus codes or standards to meet. (e.g. NFPA-110, NEC Article 445)

Path Forward - Back Up Power System continued

- When working through the technical evaluation prior to selecting a procurement path, a reasonable outcome might be that the diesel generator (or parts of it) can be procured to applicable codes and standards outside NQA-1.

- This may be relevant in question #3 of the process outlined next.

Philosophy for Selecting a Procurement Path

- When there is a need to procure replacement parts or items, many contractor and DOE staff are under the impression that if the item supports a safety SSC, then
  - it must either be procured from an NQA-1 vendor or
  - it must be dedicated using CGD.
- The resulting CGD effort is frequently very costly and may not necessarily provide much return on investment for additional assurance.
- NQA-1 and the EM CGD Guide section 2.1.1 both discuss an "***alternative***" for procuring items.

Philosophy for Selecting a Procurement Path continued

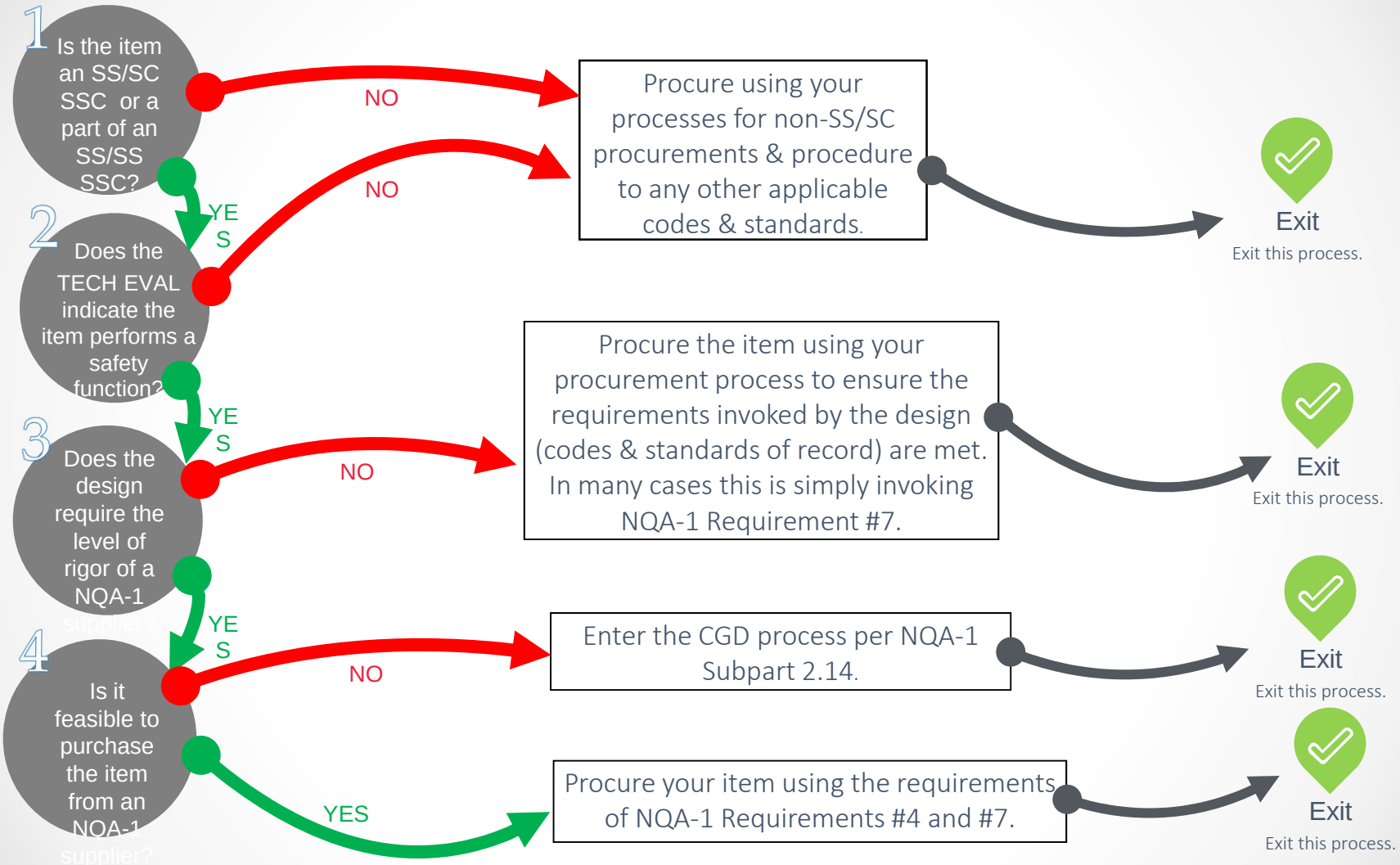
- A proper **technical evaluation** must be done PRIOR to making a decision to enter a particular procurement process.
- Based on this **technical evaluation**, the engineer should be able to determine which items/services of the procurement must be procured
  - to ASME NQA-1 requirements (or be dedicated) and
  - from a commercial vendor/supplier (and **not** be dedicated).

Philosophy for Selecting a Procurement Path continued

- A general thumb rule that may help is that replacement items/parts should normally be procured to
  - the codes and standards that were either called out in the design or
  - the codes and standards that they were originally built to
- This should not be construed as discouraging an engineer to upgrade to a more conservative code or standard based on the technical evaluation conducted.

Technical Evaluation

- The technical evaluation should identify
  - the codes and standards or other attributes that should be satisfied by the procurement,
  - the level of rigor (or assurance) to be applied, and
  - the attributes to be verified by the designer before, during, or after installation of the item/part.
- With respect to procurement path, the technical evaluation should provide one of the following results for a procurement path:


1
Is the item an SS/SC SSC or a part of an SS/SS SSC?
NO
YES
Procure using your processes for non-SS/SC procurements & procedure to any other applicable codes & standards.
Exit
Exit this process.
2
Does the TECH EVAL indicate the item performs a safety function?
NO
YES
Procure the item using your procurement process to ensure the requirements invoked by the design (codes & standards of record) are met. In many cases this is simply invoking NQA-1 Requirement #7.
Exit
Exit this process.
3
Does the design require the level of rigor of a NQA-1 supplier?
NO
YES
Enter the CGD process per NQA-1 Subpart 2.14.
Exit
Exit this process.
4
Is it feasible to purchase the item from an NQA-1 supplier?
YES
Procure your item using the requirements of NQA-1 Requirements #4 and #7.
Exit
Exit this process.

Rationale for Determining the Safety Function or Required Characteristics

- Need not be lengthy or time consuming if a **reasonable** person can follow the rationale for the decision.
- Documented such that another knowledgeable engineer could understand the basis.
- There must be an understanding between the contractor and the customer/regulator on an engineering decision being **reasonable**, even if it is different from that of the customer/regulator.

Additional Philosophy for CGD

- For procurements where a CGD is chosen, many contractors are going to extreme lengths to determine the critical characteristics of the item.
- Components that perform a safety function can contain items that do not perform a safety function.
- For relatively simple items or relatively simple replacement parts for items, the dedicating entity may elect to significantly grade (or simplify) the CGD process.

Tech Eval Considerations for CGD

- If the **Tech Eval** determines an item or replacement part for an item does not have a safety function, then the CGD process does not apply.
- The EM CGD guide section 2.1.1 states:
  - *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.*

Tech Eval Considerations for CGD - continued

- The dedicating entity should not confuse the concept of a replacement part having a safety function with the replacement part having an operational function.
- This distinction will not always be the same for a specific part of the same equipment at all facilities in all applications.

Examples

- Does anyone have an example they would like to discuss?

References

- DOE O 414.1D, *Quality Assurance*
- ASME NQA-1a-2009 Sub-Part 2.14, *Quality Assurance Requirements for Nuclear Facility Application*
- *U.S. Department Of Energy Office of Environmental Safety and Quality Guidance For Commercial Grade Dedication*, September 2011
- EPRI NP-5652 and TR-102260, *Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications,* 2014 Technical Report

Acknowledgements

- Gary Gilmartin
- Dennis Weaver
- David Little

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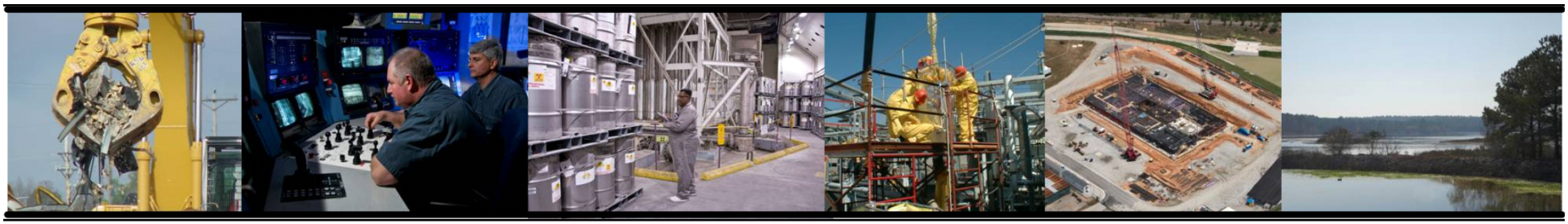

18th EM QA Corporate Board Meeting

General Discussion

May 8, 2017

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