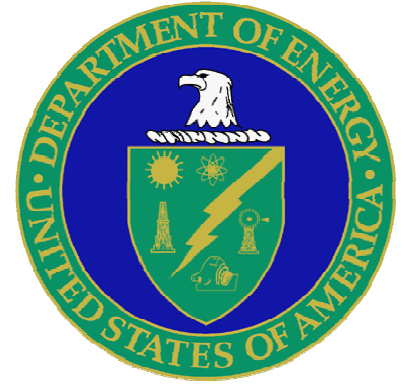


ASME NUCLEAR QA COMMITTEE



Quality Assurance Policy Meeting
with
Los Alamos National Laboratory
June 8, 2004

OBJECTIVES

Governmental organizations, including facilities and laboratories have become a significant user of the NQA Standard.

- Review recent & future direction of the Standard
- Obtain user feedback on implementation
- Identify emerging issues or new technology
- Encourage Committee involvement

NQA PUBLICATION HISTORY

- 1979 - Initial publication (N45.2 Standards)
- 1997 - Major revision performance/clarity
- 2000 - Current edition with 2002 Addenda
- 2004 - Next edition (to be published 12/04)

NQA-1 UNIQUE & PREFERRED

The national consensus standard for quality & safety.

Unique focus on nuclear facilities & activities.

Contractors must use standards to implement 10 CFR 830 Subpart A

NQA-1 is the first choice for DOE nuclear facility applications (O 414.1B)

NQA-1 UNIQUE & PREFERRED

Significant progress on endorsement

- NRC endorsed 1994 edition Exelon's QA Topical
- DOE O 414.1B prefers 2000 edition
- ASME Section III evaluating 2000 edition
- DOE Next Generation Reactor
- NRC evaluating 2000 edition for endorsement

2000 REQUIREMENT ENHANCEMENTS

- Historical performance, lessons learned and technology advancements
 - Commercial Grade Items
 - Software Controls
 - Configuration Management
 - Stronger Design Organization Controls
 - Corrective Action
 - Electronic Records

2000 GUIDANCE ADDITIONS

SUBPART 4.2 – Guidance on the Graded Application of Quality Assurance (QA) for Nuclear Related Research and Development

- NQA can be applied to R&D
- Technology life cycle
- Peer reviews
- Graded approach
- Applications

2004 REQUIREMENTS ENHANCEMENTS

- Introduction and Forward revision
- Clarification of “stop work” authority
- Commercial Grade Items update
- Clarification of calibration requirements
- Audit frequency
- Performance based audits
- Risk informed graded QA

2004 GUIDANCE ENHANCEMENTS

- Use of NQA-1 for Compliance with DOE QA Requirements (10 CFR 830, O 414.1B, NNSA QC-1)
- Modification of ISO 9001 QA Program to meet NQA-1 Requirements
- Qualification of Existing Data
- Control of Scientific Investigations
- Use of NQA for NRC 10 CFR 71/72 QA Requirements

2004 SUBPART 4.3

NQA-1 for Compliance with DOE QA Requirements 10 CFR 830
Subpart A and DOE O 414.1

100 PURPOSE

This guide may be used by organizations intending to adopt NQA-1 as a national consensus Standard for development and implementation of a Quality Assurance Program (QAP) that meets the Department of Energy (DOE) Quality Assurance (QA) requirements. This guide describes how NQA-1-2000 addresses the DOE QA requirements and identifies DOE QA requirements that are not addressed by NQA-1.

NQA FOR COMPLIANCE EXAMPLE FROM NEW PART IV

DOE Quality Assurance Criteria	NQA-1 Requirements	Comments
<p><u>Criterion 1 - Management/Program</u></p>	<p><u>NQA Requirements 1 and 2</u> The NQA-1 requirements meet the DOE Criterion, as noted.</p>	
<p>(1) Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing work.</p>	<p>The NQA-1 requirements satisfy this element of the DOE Criterion.</p>	<p>None</p>
<p>(2) Establish management processes including, planning, scheduling, and providing resources for the work.</p>	<p>NQA Requirement 1, 201 General and Requirement 2, 100 Basic meet the DOE Criterion. NQA-1 requires senior management to establish overall expectations for effective implementation of the quality assurance program and is responsible for obtaining the desired end result. This implies that adequate resources are provided to obtain desired results.</p>	<p>A DOE QAP will need to describe the management process for providing resources.</p>

<p><u>Criterion 3 - Management/Quality Improvement</u></p>	<p><u>NQA Requirements 2, 15, and 16</u></p> <p>The NQA-1 requirements partially meet the DOE Criterion.</p>	
<p>(1) Establish and implement processes to detect and prevent quality problems.</p>	<p>The NQA-1 requirements partially meet the DOE Criterion.</p> <p>NQA-1 provides a system of establishing quality requirements and monitoring compliance to prevent nonconforming conditions from causing quality problems. This is accomplished through various controls, inspections and test. Requirement 16 includes criteria to prevent recurrence of identified problems.</p>	<p>A DOE QA Program will need to extend the requirements of NQA-1 to ALL conditions adverse to quality not just significant conditions adverse to Quality.</p>

FUTURE ISSUES FOR NQA

- Correct perception that ISO 9001 is a quality standard that will assure safety
- NRC endorsement of a recent edition of NQA-1
- Establishment of risk-informed graded levels of quality
- QA for construction of new nuclear power generating facilities
- Integration of NQA with facility requirements

DISCUSSION QUESTIONS

1. How is NQA utilized at your facility/QAP?
2. What rationale provided for non-use of NQA-1?
3. Are the proposed/new changes planned for NQA beneficial to your QAP?
4. Do you have activities in need of NQA-1 guidance?