

# Quality Assurance Standards

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# Learning Objectives

Upon completion of this lesson, the student will be able to:

- Understand the difference between quality control (QC) and quality assurance (QA)
- Understand the applicability of quality standards to Department of Energy (DOE) QA
- Understand early misconceptions regarding quality programs
- Understand basic evolution of DOE's nuclear quality program



# Basic Definitions

- **Consensus Standard** – A set of quality attributes which, through consensus of its developers, provides a consistent method for satisfying requirements. It is available for adoption and use by its reference in contracts, or required by regulation
- **Quality Control (QC)** – Physical actions taken (such as examinations, inspections, measurements) of items or activities to verify that they conform to specified requirements



## Basic Definitions<sub>continued</sub>

- **Quality Assurance (QA)** – Planned actions (programmatic) necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service (quality control is generally included as a segment of quality assurance)



# Early QA Misconceptions

- Early Atomic Energy Commission (AEC), DOE, and contractor project management:
  - Believed that quality was achievable without a formal, documented, and integrated QA program
  - Believed that quality assurance was primary responsibility and role of the QA organization. QA organizations also fostered, in part, the belief that the program was written by and for them
- This was a failure to recognize that quality and its achievement is a primary management responsibility; QA verifies quality is achieved
- QA organizations support management's execution of their QA programs and by conducting independent audits



# DOE Quality Standards

- The DOE QA Rule cites, in 10 CFR 830.121, that QA programs must use voluntary consensus standards in their development, where practicable
- The DOE QA Order (DOE O 414.1C) directs that QA programs must use national or international consensus standards where practicable. The following standards were listed as examples:
  - American Society Mechanical Engineers (ASME) Nuclear Quality Assurance 1 (NQA-1) 2000 Edition
  - American National Standards Institute (ANSI)/International Organization for Standardization (ISO)/American Society of Quality (ASQ) Q 9001:2000
  - ANSI/ASQ Z 1.13



# What is a Quality Standard?

- A documented process to control work resulting in a certain level of excellence (quality)
- Two basic types:
  - Consensus standards (NQA-1, ANSI/ISO/ASQ Q 9001:2000, etc.) are those that, via consensus of their developers, identify quality criteria to be addressed, and often provide a method for satisfying the criteria (voluntarily adopted or imposed by regulation)
  - Regulatory “standards” are documented criteria used to control specific activities such as nuclear activities (imposed by regulation)



# Quality Standards

- Standards may have similarities or may differ widely. The purpose of each is to control work, resulting in an expected level of quality
- Each may have multiple editions incorporating minor or major changes (specific NQA-1 editions may be adopted and used; ISO requires user's program to adjust to each new edition)
- Each standard's strengths or approaches may or may not allow it to be suitable for DOE nuclear activities
- The adequacy of a standard used to assure nuclear quality must be determined prior to its being invoked
- Two of the common national/international quality consensus standards are NQA-1 and ANSI/ISO/ASQ Q 9001:2000



# Consensus Standards

ASME NQA-1 (the edition is shown as a suffix, e.g., NQA-1-2004)

- Nuclear industry's response to the Nuclear Regulatory Commission's (NRC) 10 CFR 50 Appendix B
- Uses the same 18 basic NRC quality criteria
- Includes consensus on methods for satisfying the quality criteria
- Developed using procedures meeting criteria for American National Standards; NQA-1 was first published in 1979
- Supported by committee of industry volunteers that reports to ASME Board of Nuclear Codes
- Early (1979 – 1994) editions were requirements-based; 1997 - 2000 editions shifted towards performance-based; 2004 and 2008 editions are returning towards requirements



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# Consensus Standards (continued)

### ANSI/ISO/ASQ Q 9001:2000 (referred to as ISO 9001:2000)

- Developed by International Organization for Standardization (ISO), patterned from a British quality program; first published in 1987
- Based on need to meet customer's requirements, regulations, and satisfaction
- Organizations elect to adopt it, and then must become accredited
- Used worldwide, new edition is ISO 9001:2008
- Applies broadly to all products; doesn't differentiate between picture frames and nuclear components
- NRC evaluated ISO 9001:2000; concluded additional quality requirements needed to meet current regulations. Some regulated industries still use now (aerospace, telecommunications, automotive)



# Evolution of Nuclear Quality Standards

- Nuclear quality assurance standards evolved along four paths:
  - **AEC → Energy Research and Development Administration (ERDA) → DOE Standards and Directives** [1950s quality control and inspection practices for nuclear weapons, and 1960s QA requirements for government-owned reactor and technology development programs] Owner changed due to Congressional actions
  - **AEC → NRC Regulations and Regulatory Guides** [1970s licensing regulations for designing, constructing, and operating commercial nuclear power plants and fuel reprocessing plants]
  - **ANSI N45.2 → ASME NQA-1** [1970s ASME assigned by ANSI to develop national consensus standards for nuclear facilities]
  - **ASME Section III Boiler & Pressure Vessel Code** [1960s Appendix IX established quality assurance criteria]



# Evolution of DOE Quality Program

- **AEC → ERDA → DOE Standards and Directives**
  - 1954 origins in AEC Santa Fe Weapons Quality Policy QC-1 – general principles for acceptance inspection of nuclear weapons from prime contractors
  - QC-1 (1954 – 2004) placed maximum responsibility/accountability:
    - On prime contractors for quality control systems
    - On AEC/DOE for surveillance and acceptance inspections that focused on quality evidence presented by the prime contractor
    - On AEC/DOE for verification of the quality evidence



# Evolution of DOE Quality Program

(continued)

## – AEC → ERDA → DOE Standards and Directives

- In the 1980s, the DOE Military Applications policy for nuclear quality assurance required procedures that:
  - Controlled work to an extent consistent with defined objectives
  - Had objective, measurable means to assure effectiveness
  - Emphasized continuous improvement in all activities
  - Applied appropriate elements of recognized standards
- In 1981, DOE issued DOE Order 5700.6, a Department-wide quality assurance policy and requirements document



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# Evolution of DOE Quality Program

(continued)

- DOE Order 5700.6A and B were issued for specific objectives, but 5700.6C (1991) was a major restructuring that established the 10 QA criteria, grouped in three categories
- **AEC → ERDA → DOE Standards and Directives**
  - In 1992, DOE Albuquerque Operations Office (AL) issued standard QC-2 to complement QC-1 for research, development, and testing; QC-2 was later incorporated into QC-1
  - In 1992, DOE Defense Program (DP) declared they would comply with DOE Order 5700.6C with certain exemptions for classified work [they recognized that it would be an advantage to be able to demonstrate to oversight organizations (Congress, NRC, Environmental Protection Agency, etc.) that it had a disciplined assurance program]



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# Evolution of DOE Quality Program

(continued)

– **AEC → ERDA → DOE Standards and Directives**

- QC-1 Revision 10 was restructured similar to NQA-1-2000 to ensure it could be implemented using the NQA-1 standard
- DOE Order 414.1A was issued to replace DOE O 5700.6C in 1999
- QC-1 clarified that it is the DOE/NNSA method of complying with DOE Order 414.1A and the DOE Rule 10 CFR 830 Subpart A



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# Evolution of DOE Quality Program

(concluded)

– **AEC → ERDA → DOE Standards and Directives**

- QC-1 adopted some NQA-1 requirements, but there were differences:
  - QC-1 established a two-party Government-Owned Contractor-Operated (GOCO) contractual relationship
  - QC-1 added QA requirements, e.g., metrics, quality cost management, Government Furnished Material, NNSA-Accepted Material, etc.
- DOE Order 414.1C is current today



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