

Introduction to Quality Assurance

Basics of Quality Assurance

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Learning Objectives

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

- Understand the basic concept of quality assurance (QA)
- Understand the basic history of QA
- Understand the basic structure of the Department of Energy (DOE) QA Program



What is Quality?

- Simply put, quality is a degree of excellence
 - Good or bad
 - Workmanship
 - Accuracy
 - Value
- A system to ensure we “Do Work Correctly”



What is Quality Assurance?

- It is an action or actions that provide confidence of a planned or expected level of excellence
- Previously, a craftsman's pride and reputation assured excellence
- In complex or high-risk activities, an individual's pride alone cannot always be depended upon to assure the needed level of excellence



Why Have QA?

- Provide confidence of adequate planning
- Provide confidence of safety
- Provide confidence of meeting planned results
- Provide capability to later prove work results to:
 - The affected workers
 - Other workers in the area
 - General public
 - Regulators
 - Lawmakers/budget approvers



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What is a QA Program?

- Literally, it is all those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service
- Simply, it is a documented recipe for planning and controlling work



Various QA Programs

- Some driven by regulation or requirements
 - 10 CFR 830.120 (federal law requiring DOE to implement quality assurance programs for nuclear-related work; commonly called the QA rule) (also called 10 CFR 830, Subpart A)
 - DOE Order 414.1C (DOE invokes by contract)
 - 40 CFR 194.22 (federal law imposing quality assurance programs on civilian power plants under NRC regulation)
 - 10 CFR 50 Appendix B (cites the NRC QA Program)
- Some adopt available consensus standards
 - International Organization for Standardization (ISO) 9001:2000 (requires certification by independent agency)
 - American Society of Mechanical Engineers Nuclear Quality Assurance 1 (NQA-1) (either a certain edition or latest edition)



Various QA Programs (continued)

- Some (not driven by others, but wanting controlled processes) self-impose and develop their own requirements
- Programs are intended to achieve satisfactory results, but may differ in format and emphasis (ISO strives for finished results and customer satisfaction; DOE and Nuclear Regulatory Commission regulate safety and finished results)



How Did Nuclear QA Evolve?

- 1954 AEC QC-1 QC for AEC weapons programs
- 1958 DoD Mil-Q-9858A Quality specifications
- 1962 NASA NPC 250-1 Quality standard
- 1964 AEC QRC-82 QC for AEC naval reactors
- 1965 ASME Section III QA for Nuclear Pressure Vessels
- 1970 AEC 10CFR50 Appendix B – QA Criteria
- 1971 ASME N45.2 Began QA Program development
- 1979 ASME NQA-1 Consolidated N45.2 program
- 1981 DOE 5700.6 DOE QA Policy
- 1983 ASME NQA-2 Consolidated NQA-2 QA methods
- 1987 ISO ISO 9000 Quality Management System
- 1990 ASME NQA-3 QA data standard
- 1994 DOE 10CFR830.120 Quality Assurance Requirements
- 1999 DOE Order 414.1A Replaced DOE Order 5700.6C



The DOE QA Program

- The Rule [10 CFR 830.120]
- The Order [DOE O 414.1C]
- The Guides [DOE G 414.1 series]



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The DOE QA Program (continued)

The Rule (10 CFR 830.120 – also known as 10 CFR 830 Subpart A):

- Establishes quality assurance requirements for contractors conducting activities, including providing items or services, affecting nuclear safety of DOE facilities
- Requires contractors to conduct work in accordance with the QA criteria in 10 CFR 830.122
- Requires contractors to integrate the QA criteria with the Safety Management System
- Requires contractors to describe how they ensure subcontractors and suppliers satisfy the QA criteria of 830.122
- Requires contractors, responsible for a DOE nuclear facility, to submit their QA program to DOE for approval
- Enforcement is established via the Price-Anderson Amendments Act



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The DOE QA Program (continued)

The Order (DOE O 414.1C)

- Establishes Quality Assurance Program requirements in 10 criteria
- Applies to Primary DOE Organizations and their associated field elements (except the Bonneville Power Administration)
- Applies to National Nuclear Security Administration (NNSA) Organizations (except Naval Reactors Program)
- Attachment 2, the Contractor Requirements Document (CRD), lists the requirements of this Order that will apply to contractors whose contracts include the CRD. The Order also requires the CRD to be included in contracts for work at or for DOE facilities.



The DOE QA Program (continued)

The Rule and Order require development of a QA program addressing 10 criteria summarized below:

1. **Program** (organization structure, interfaces, planning, scheduling)
2. **Personnel training and qualification**
3. **Quality improvement** (identify problems, causes, improvements)
4. **Documents and Records** (use documents; maintain records)
5. **Work Processes** (perform work correctly; control items/material)
6. **Design** (incorporate requirements; verify/validate adequacy)
7. **Procurement** (buy proper material; check adequacy of suppliers)
8. **Inspection and Acceptance Testing** (and calibrate equipment)
9. **Management Assessment** (check for problems that hinder work)
10. **Independent Assessment** (perform unbiased check of quality)



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The DOE QA Program (continued)

The Guides provide additional implementing methods and instruction

- DOE G 414.1-1B Management and Independent Assessments
- DOE G 414.1-2A QA Management System Guide
- DOE G 414.1-3 Suspect/Counterfeit Items
- DOE G 414.1-4 Safety Software Guide
- DOE G 414.1-5 Corrective Action Program Guide



Exercise – Building a Garage

1. Firmly decide who is to do what, and how long it should take
2. Learn and understand construction methods
3. Make detailed drawings of the garage to be built; get permits
4. Buy the right materials, doors, and windows; order concrete
5. Check delivered materials, store them securely, hired qualified workers
6. Build the garage according to the drawings; check workmanship
7. Keep eyes open to detect problems that occur and fix them
8. Maintain the permits and save the receipts
9. Step back periodically and evaluate the overall progress
10. Have the city building inspector visit the job



Exercise – Building a Garage

(concluded)

- You've just exercised the 10 elements of DOE Order 414.1C. The QA Program is actually a business plan to assure your everyday work is planned and completed as designed.



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