

Introduction to Quality Assurance

Quality Standards and Applicability to DOE

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Student Text

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Learning Objectives

Upon completion of this module, 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 the DOE nuclear quality program



Quality Standards and Applicability to DOE

Basic Definitions

Consensus Standard – A term used to indicate that the quality standard was developed by a group or committee of experienced people. Where everyone on the committee may not agree with every point made, the resulting decisions are based on a consensus of the participants. By itself, it is not a regulation, but is available for voluntary adoption and use by its being specified in contracts or procedures. In certain instances, consensus standards have been invoked by a regulation for a specific purpose.

Quality Control (QC) – Consists of all those physical actions taken, such as observations, examinations, inspections, measurements, etc., of components, systems, structures, or activities to objectively verify that they conform to requirements. The object is to verify that an item is correct, not just to look for errors.

Quality Assurance (QA) – All those planned actions (programmatic) necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service. QA relies on evaluating the processes that control the work in order to assure that the end result will meet specified requirements. Quality Control is generally included as one of the planned actions of quality assurance.

Early QA Misconceptions

There was an early belief by American management and government entities that quality was not dependent on formal quality programs. However, early quality-related problems brought the need for formal quality to the attention of those entities.

A second belief was that a quality assurance program existed only for the quality assurance group. At that time, there were also quality assurance organizations that, based on their newfound authority, presented the QA Program as being theirs alone. Instances of this attitude can still be found today. These attitudes prevent the program from achieving its objective of involving everyone in the achievement of quality.

This was a failure to recognize that quality and its achievement is a primary management responsibility; QA verifies the achievement of quality.



Quality Standards Apply to DOE

Both the QA Rule and Order very specifically require QA Programs to use consensus standards where practicable. This doesn't mean that any consensus standard can be used for any application. Incorporation of a standard requires an evaluation to determine that it is suitable and adequate for its intended use.

There are many more standards available than are shown here, but the bulleted list shows three that are in common use currently for specific purposes.

- 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?

Simply put, a quality standard is a documented process intended to control work resulting in a certain level of excellence (quality). The standard's degree of control is a basis for its selection for achieving that level of quality.

For the purposes of this training, there are two basic types of standards: voluntary consensus standards and regulatory standards.

As we discussed in the Definitions, consensus standards are standardized methods of controlling work. They are not regulations, but are available to be adopted for use. If electing to use a consensus standard, an organization declares its intention by incorporating the standard into contracts, specifications, or procedures. Once the standard is incorporated, it must be followed.

There are those who don't think of regulations as "Standards," but the development and regulated use of work controls certainly standardizes the cited methods.

Quality Standards

This discussion of Quality Standards is intended to make you aware that some quality standards differ in their approach or rigor, and others have strong similarities.

Certain editions of standards, such as NQA-1-2000, may be adopted forever, while others, such as ISO 9001:2000, require the organization using them to adjust to each new edition within a specified time after it is issued.



Each standard being considered for, or used by an organization for which you are providing oversight, must be evaluated for its adequacy to control the work.

Two common consensus standards currently in use are NQA-1 and ISO 9001:2000.

Consensus Standards

ASME NQA-1

The acronym “ASME” indicates that NQA-1 is sponsored by the American Society of Mechanical Engineers. Back in the mid 1970s, the American National Standards Institute assigned responsibility to ASME to develop a comprehensive nuclear quality standard. NQA-1 was issued in 1979.

NQA-1 is based on the same 18 quality criteria that the Nuclear Regulatory Commission (NRC) uses in its regulation of commercial nuclear power plants. The language is focused more on compliance. Earlier editions had more rigor, later ones eased somewhat, and current editions are recapturing the level of rigor. Generally, an organization will adopt a specific edition of NQA-1 for its standard.

The Committee on Nuclear Quality Assurance is the “consensus” group maintained by ASME to continually monitor the needs of the nuclear industry against the provisions of NQA-1. New editions are issued approximately every three or four years, with addenda being issued during the interim years.

ISO 9001:2000

This is an international quality standard that was originally based on a British standard. Since its original issue, businesses and organizations in approximately 140 countries have adopted it for use.

When an organization plans on adopting the ISO standard, they must develop a quality program around the ISO criteria, put it into practice, then have an independent ISO registrar certify them as adequately implementing the program. Organizations using the ISO standard must update their quality programs, and renew their certifications, each time the ISO standard is revised. A period of time is granted for this to be done. The current ISO standard is ISO9001:2008.

ISO 9001:2000 applies to any product, and does not differentiate between high-risk or no-risk items. When this standard is used by suppliers to regulated industries, such as nuclear, telecommunications, and aerospace, additional quality requirements are necessary.



Evolution of Nuclear Quality Standards

Nuclear quality programs have been growing along independent, and sometimes interdependent, pathways for many years. There are four main paths within the nuclear industry.

The first is the path that DOE's program has evolved along. It originally came from the nuclear weapons program. We'll look at this path in detail in the next slides.

The other three paths are the nuclear power generation industry, the industry standards path for commercial entities engaged in nuclear business, and the ASME Boiler and Pressure Vessel Code.

Evolution of DOE's Quality Program

DOE's quality program had its beginnings in the Atomic Energy Commission Santa Fe Weapons Quality Policy QC-1 issued in 1954. It contained the general principles for acceptance of weapons from contractors and identified who had what responsibility for what activities.

The contractors were responsible for quality control and inspections. The AEC and later the DOE performed surveillance and acceptance inspections. Much of the acceptance was based on records provided by the contractor, which the AEC/DOE then had to verify.

In the early 1980s, the DOE Military Applications policy required that procedures address controlling work with rigor consistent with established objectives. It required that procedures include objective and measurable means as a method of evaluating effectiveness.

Continuous improvement was also required. This is indicative of DOE's interest in the Total Quality Management (TQM) concept that was gaining widespread acceptance in America at the time. In addition, use of recognized quality standards was introduced by this policy.

DOE Order 5700.6 was issued in 1981 for a Department-wide quality assurance program. Revisions A and B followed soon after to adjust minor items, but 5700 6.C contained major changes. It was restructured to establish the 10 quality assurance criteria that are still in use today.

In 1992, DOE Albuquerque Operations Office issued a second standard (QC-2) to complement QC-1 with additional quality criteria for activities not previously covered. QC-2 was later made a part of QC-1.

Also during this time, the Defense Program aligned with DOE Order 5700.6C, with exemptions for classified work.

QC-1 was restructured along the lines of NQA-1 so that it could use the standard for implementation. It also established a Government-owned – contractor-operated (GOCO)



contractual relationship for its facilities, and added requirements for subjects not covered by NQA-1, such as metrics, quality cost management, and government furnished material.

DOE Order 414.1 was issued in 1999 to supersede Order 5700.6C, and 414.1C is current today.

