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

Basic Concepts of Quality Assurance

What is Quality?

The word "Quality" is often used, but not often defined. You will find a variety of usages in any dictionary but, for our purposes, a "degree of excellence" is the closest.

Quality can be good or bad, or somewhere in between. Where a product or service is being provided, the end result is largely based on workmanship. A craftsperson takes great pride in producing something with flawless features.

The accuracy of an effort, whether it is for data collection or training material presentation, results in a perceived level of quality for the effort – good or bad.

There is little value in poor quality.

What Is Quality Assurance?

Literally, it is the assurance of quality, and in the case of nuclear quality, it means assurance of HIGH quality. In nuclear work, it is the actions planned and taken to achieve an expected result.

Where a craftsperson previously built a reputation on flawless workmanship, that workmanship alone can't be depended upon in higher-risk nuclear work.

Why Have Quality Assurance?

Quality assurance controls work. When you control your activities, you build in safety and efficiencies, and when the work is completed, you can show evidence of satisfactory completion. All of this provides confidence in your ability to manage your work.

Who needs confidence that you can control work?

- The workers
- The general public
- Regulators
- Law makers and budget approvers

What Is A Quality Assurance Program?

In this case, it is all of the actions that you have planned in order to work safely and reliably, and to provide confidence that your facility will perform as planned.

Some apply the simple adage, “Plan your work, and work your plan.”

Various Quality Assurance Programs

The aim of a quality assurance program is to control work and assure an expected quality level. Programs are developed in various industries.

In the nuclear industry, some quality programs were developed and imposed as regulations. Some were developed by committees of experienced volunteers, and are referred to as “consensus standards.” These standards are made available for adoption and use. They are not a requirement until you adopt them. Once you do, they become your requirement.

Rarely, an organization will self-commit to controlling their work, and develop their own quality assurance program. It may or may not bear any resemblance to an established program.

Quality assurance programs seem to all have one thing in common – they control the work in order to achieve an expected quality result.

Because various quality programs come from different sources, there may be similarities as well as differences in their format, emphasis, and ultimately in their degree of control. For example, the DOE and Nuclear Regulatory Commission (NRC) quality programs are focused more on direction and compliance for safety reasons, and a commonly used QA program (International Organization for Standardization (ISO) 9001:2000) focuses moderately on direction, but highly advocates customer satisfaction as the goal.

How Did Nuclear QA Evolve?

In a nutshell (in fact, a very small nutshell) nuclear quality assurance for DOE had its beginnings in Atomic Energy Commission (AEC) weapons programs.

Nuclear quality was also under similar development in commercial nuclear as well as the civilian sector and the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code.

Original programs were tried, and then revised.

Title 10 Code of Federal Regulations Part 830 Subpart A provides regulation and enforcement capabilities. DOE Order 414.1 is currently in revision C, and establishes the quality assurance program for the DOE.

The DOE QA Program

DOE's QA Program is made up of "the Rule" and "the Order."

The Rule is 10CFR830 and its Subpart A (830.120). It provides the DOE with the ability to levy civil and criminal penalties for noncompliance of nuclear safety and quality requirements.

The Order is DOE Order 414.1C. This Order and its predecessor, DOE Order 5700.6C, established the QA program format of 10 quality criteria that we use today.

There are several DOE Guides that provide methods of meeting the quality criteria.

The Rule
The Rule addresses Nuclear Safety and Quality. It lays out a set of requirements for contractors working on DOE nuclear facilities. It requires them to work to this Rule, and to describe how they will assure that their subcontractors will also meet these requirements.

DOE reviews contractors' quality programs for adequacy in controlling work through a requirement that contractor quality programs be submitted to DOE for approval.

The Rule is enforceable under the provisions of the Price-Anderson Amendments Act, a process that will be explained in more detail in a later module.

The Order
The Order (currently DOE Order 414.1C) established the DOE QA Program. The QA program established the 10 criteria that are now also reflected in the Rule.

The Order contains direction to DOE and includes, as an attachment, a Contractor Requirements Document. DOE must include the attachment in contracts, and contractors must work to the DOE QA Program – and require its subcontractors to do the same.

Both the Rule and the Order are based on the same 10 quality criteria. They both require the development of a QA program addressing the 10 criteria. These 10 criteria very closely reflect the 18 criteria used by commercial nuclear organizations, but DOE has reorganized them and combined a few.

The Guides
DOE has issued five Guides to date to provide acceptable methods for complying with various portions of the Rule and Order. These guides are not mandatory unless invoked by contract.

The methods described are workable under many circumstances, but are not intended to be used as requirements under all circumstances.

Exercise – Discuss Building A Garage

This exercise was previously used with DOE at the earlier Hanford Vitrification Project. Set aside, for the moment, the academic side of learning about quality. Visualize your project as building a garage at your home.

The decisions and actions that you might go through to build this garage would probably consist of the following steps.

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, and hire 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

By using these steps to control your work, the finished garage will be what you had imagined and planned. Each of the 10 actions you went through is very much the same as each of the 10 quality criteria found in the DOE QA Program.

Another name that would be suitable for a QA program could be Controlled Business Program, or something similar, but the point is, the QA program belongs to everyone, makes everyone responsible for quality, and intends to involve everyone in its implementation.

Useful Links

DOE Directives	http://www.directives.doe.gov/
ASME Code Stamps	http://www.asme.org/Codes/CertifAccred/Certification/
American Society for Quality	www.asq.org
History of Quality	www.asq.org/learn-about-quality/history-of-quality/overview/overview.html
Basic Concepts of Quality Costs	http://www.asq.org/learn-about-quality/basic-concepts.html
American National Standards Institute	www.ansi.org

Good Additional Reference Materials

Figure 1 provides a timeline of quality. "Quality" as a concept has a very long history. Beginning prior to the age of writing, people would make items to satisfy their needs. In some cases, they would make something to trade or barter with their neighbors. If the neighbor didn't like what you made, no trade was made.

Quality really came into its own when someone had to make a product to someone else's specification. The "customer" had to be satisfied before the transaction was considered to be done.

In the 1300s, the Craftsman/Apprentice concept was created. Guilds were formed to help develop the craft and to bring in new apprentices. The master craftsman set the standard for the shop. The master craftsman and all apprentices were expected to meet the standards of the master craftsman before the product was presented to the customer.

In the mid-1800s, there was a need for interchangeability of parts in the manufacture of products. Up until then, each product (for example, a rifle) was hand-made and the parts were specific to that rifle. If all parts were the same, more craftsmen could make parts and ship them to one location where the parts could be assembled into the product. This led to the development of measurement standards and dimensional drawings with tolerances.

The 1920s saw the development of the "time and motion" studies which were embraced by management and are still in use today. As a result of breaking the process down into small, discrete steps that could be performed by unskilled people, workers tended to lose their sense of responsibility for quality.

In the 1930s, Dr. W. Edwards Deming was at the Bureau of the Census, where he was an adviser in sampling. In what is probably the first application of statistical quality control principles to a non-manufacturing problem, Deming brought the time and motion principles into use on clerical operations for the 1940 census.

Figure 1 – Quality Time Line

Quality Time Line

5,000 BP		Pyramids
1300s		Crafts & Guilds
1800s		Standard Parts
1920s		**Taylor** (Time & Motion) **Shewhart** (Control Charts)
1930s		**Deming** and **Juran** become influential in U.S.
1940s	Military Specifications	Statistical QC used as part of war effort
1950s	**1954** – QC-1 **1959** - MIL Q 9858	**Deming** and **Juran** teach quality principles to Japanese. **U.S.** drops QA/QC from management programs.
1960s	**1960** – MIL-I-45208 **1967** - ASME B&PV III, Appendix IX **1969** - RDT F 2-2T	
1970s	**1970** - 10CFR50, App. B **1971** - ANSI N 45.2 **1979** - BS 5750 **1979** – NQA-1	**Crisis** in automotive industry. **U.S.** discovers QA/QC. **Europe**: "Say what you do. Do what you say. Write it down."
1980s	**1986** - DOE O 5700.6B **1987** - ISO 9000	
1990s	**1998-1999** - DOE O 414.1 and 1A	
2000s	**2002** - 10 CFR 830.120 **2004** – DOE O 414.1B **2005** – DOE O 414.1C	

During World War II, the military had many problems with parts not working, not being suitable for use, and failing in use. Military safety and the need for true interchangeability led to development of many military specifications (MIL-SPECs). During the war, “liberty ships” and “victory ships” were being built at a rate of about one a week. Unfortunately, they initially had the problem of breaking in half while sailing the oceans. This led to material studies and the adoption of both material and welding specifications. Once these were incorporated into the building process, the ships stopped breaking in half.

Following World War II, Drs. W. Edwards Deming and Joseph M. Juran were working in Japan to help the country recover from the war. The Japanese readily adopted the concept of quality assurance and instituted statistical quality control, while U.S. manufacturers did not. While Japanese quality was quite poor in the 1950s, their quality continued to improve with the result that in the 1960s and 1970s, Japanese quality surpassed U.S. quality, particularly noticeable in the quality of automobiles manufactured at that time. See **Figure 2** for a listing of “quality” standards beginning in the 1950s.

In 1954, the Atomic Energy Commission (AEC) Santa Fe Operations (SFO) office issued their Weapons Quality Policy, QC-1. QC-1 is now in Revision 10, issued in 2004.

For the military, MIL Q 9858A was issued in 1959 (cancelled October 1, 1996). Although only 11 pages long, it had a great effect on manufacturing. MIL Q 9858A was adopted by many manufacturers because it worked. In 1960, MIL-I-45208A was issued to cover inspection, including calibration.

In the 1960s, process controls came about in the U.S. American Society of Mechanical Engineers (ASME) Boiler & Pressure Vessel Code Section III, Appendix IX was published in 1967. It contained 15 quality assurance criteria and required ASME review and approval of the quality program.

Reactor Development and Technology (RDT) F2-2T, and other RDT standards, were issued by the AEC in June 1969 for government-owned and contractor-operated (GOCO) reactors and test facilities.

All the knowledge available at the time was used in building the early commercial nuclear power plants, but contractors at some of these plants had a less than stellar performance record regarding quality, and the need for enforceable quality standards was recognized. Title 10 Code of Federal Regulations (CFR) Part 50, Appendix B, was developed and issued in 1970 by the Nuclear Regulatory Commission (NRC). It contained eighteen quality assurance criteria that applied to utilities and their contractors at the nuclear plants. Recognizing that external companies supporting nuclear plants lacked a quality standard, The American National Standards Institute (ANSI) initially developed a small series of individual quality standards. Soon after, they assigned responsibility to ASME to develop a comprehensive standard. Nuclear Quality Assurance (NQA)-1-1979 was issued to address the problem of process control and quality assurance. The concept that quality could not be inspected into a product was being recognized.

In 1979, the British Standards Institute (BSI) published BS 5750, "Quality Systems." Although the BSI claims it was the "first management systems quality standard," some may disagree. BS 5750 was based on "Say what you do. Do what you say. Write it down." After several revisions, BS 5750 became the first International Standards Organization (ISO) 9000-1987. This is a voluntary standard that must be adopted to be used. Upon adoption, the organization must be independently certified to use the standard. This standard is in use in approximately 140 countries worldwide.

The Department of Energy (DOE) issued DOE Order 5700.6, *Quality Assurance*, for use within the Department. This was superseded by DOE Order 414.1A in1999. In 2002, 10 CFR 830.120 was issued containing 10 criteria. DOE O 414.1C followed in 2005, to address 10 CFR 830.120.

Figure 2 – Quality Assurance Standards Evolution

Quality Assurance Standards Evolution

Year and ID	Title
1954 – QC-1	*AEC Santa Fe Operations (SFO) Weapons Quality Policy*
1959 – MIL Q 9858	*Quality Program Requirements* (22 Criteria in MIL-Q-9858A-1963)
1960 – MIL I 45208	*Inspection System Requirements*
1967 - ASME B&PV III, Appendix IX	*Quality Assurance Criteria* (15 Criteria)
1969 - RDT F 2-2T	*Quality Assurance Program Requirements*
1970 – 10 CFR 50, App. B	*Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants* (18 Criteria)
1971 - ANSI N 45.2	*Quality Assurance Program Requirements*
1971 – ASME NQA-1	*Quality Assurance Requirements for Nuclear Power Plants*
1979 - BS 5750	*Quality Assurance Systems*
1986 - DOE O 5700.6B	*Quality Assurance Systems* (10 Criteria)
1987 - ISO 9000 Series	*Quality Management System* (currently a series of two standards: ISO-9000 and ISO-9001)
1998 – DOE O 414.1	*Quality Assurance*
1999 - DOE O 414.1A	*Quality Assurance*
2002 - 10 CFR 830.120	*Quality Assurance*

2004 – DOE O 414.1B *Quality Assurance*

2005 – DOE O 414.1C *Quality Assurance*

Pioneers of Industrial Quality

Frederick Winslow Taylor (1856 - 1915) – Father of Scientific Management
Taylor's goal was to increase productivity without increasing the number of skilled craftsmen. Quality was ancillary to production for Taylor. He is most remembered for developing the **time and motion study** that is still used today. The television program "How It's Made" often quotes a time that each person has for completing the task assigned, whether assembling TV sets or automobile seats. Taylor would break a job into its component parts and measure each to the hundredth of a minute. Taylor's scientific management consisted of four principles:

1. Replace rule-of-thumb work methods with methods based on a scientific study of the tasks.
2. Scientifically select, train, and develop each employee rather than passively leaving them to train themselves.
3. Provide detailed instruction and supervision of each worker in the performance of that worker's discrete task. Time and motion studies set the standard for performance, not quality.
4. Divide work so that the managers apply scientific management principles to planning the work and the workers actually perform the tasks.

Walter A. Shewhart, 1891 - 1967 – Father of Quality Control
Shewhart used statistical methods. While working at Bell Labs in the 1920, he developed and popularized the **control charts** we use today. These charts told management and workers whether the process was in control. Even if the process was "in control," bad parts could be made because of the variation allowed by the process. Shewhart was the first to develop, but not popularize, the PDCA Cycle: Plan, Do, Check, Act.

W. Edwards Deming, 1900 – 1993 – Father of Continuous Improvement
W. Edwards Deming, named an ASQ Honorary member in 1970 for his role as adviser, consultant, author, and teacher to some of the most influential businessmen, corporations, and scientific pioneers of quality control, is the most widely known proponent of statistical quality control. He has been described variously as a national folk hero in Japan, where he was influential in the spectacular rise of Japanese industry after World War II; as a curmudgeon; as the high prophet of quality control; as an imperious old man; and as founder of the third wave of the Industrial Revolution. Deming popularized the Shewhart PDCA Cycle. Although he didn't specifically define quality, he did state:

> "Costs go down and productivity goes up, as improvement of quality is accomplished by better management of design, engineering, testing and by improvement of processes…Cutting costs without improvement of quality is futile."

Figure 3 gives us a look at the relationship between cost and quality.

Figure 3 – Costs of Quality

http://www.thefreelibrary.com/Where+is+the+Xerox+Corporation+of+the+LIS+sector%3f-a018015825

Herget, J. (1994). Implementing quality management system in information organisations. Unpublished report, University of Kostanz. Herget, J. (1995). The cost of (non-) quality - why it matters for information providers.

"Instead, this article concludes with a report of two studies which take a novel, and perhaps significant, look at the cost of "nonquality" and a quotation from a Baldrige Award assessor…

"The report on the cost of "nonquality" was undertaken by Herget (1994). He opens with some startling observations:

- only 4 to 6 percent of customers complain at all
- one dissatisfied customer tells ten other people
- one satisfied customer tells three other people
- only 9 percent of the dissatisfied customers who did not complain remained customers
- it costs five times more to win a new customer than to retain an existing one
- 100 loyal customers generate 50 to 70 new customers

"In the main part of Herget's paper, he quotes two sets of figures from actual studies:

Cost of quality at Infomat (Crashaw, 1993)	European Currency Units
Loss of clients (40 p.a. @ ECU 5000 p.a. 50 percent (losses due to quality failures)	100,000
Quality inspection	16,000
Cost editing	20,000
Feedback	10,000
"Defensive" clients visits	25,000
Internal fire fighting	25,000
Internal administration	10,000
Total	**206,000**
Ratio: Quality costs to turnover = 20 percent	

The second set of figures is rather more disturbing:

Cost of quality at Company Beta (Herget, 1994)	ECU
Prevention costs	10,000
Appraisal	21,000
Failure costs (internal)	90,000
Failure costs (external)	40,000
Total p.a.	161,000
Ratio: Quality costs to turnover = 41 percent	

p. a. = preventive and appraisal

"Herget (1995) concludes with the statement that "producing quality costs money, but not producing quality costs much more. This is the conclusive refutation of the argument which is continually leveled against the pursuit of quality."
LIS = library and information science

Joseph M. Juran, 1904 – 2008 – Father of Quality
As part of his philosophy of managing for quality, Juran said, **"It is most important that top management be quality-minded. In the absence of sincere manifestation of interest at the top, little will happen below."** One of his observations from this informal study was that statistics was overdone; in his view, it was an important element in quality but shouldn't be treated as the "be-all and end-all." In 1937, Dr. Juran popularized the "Pareto principle," which millions of managers rely on to help separate the "vital few" from the "useful many" in their activities. This is commonly referred to as the 80-20 principle. Juran defined quality as **"Fitness for Use"** as defined by the customer.

Philip B Crosby, 1926 - 2001
"Do it right the first time." Crosby put forth his "Four Absolutes of Quality Management".

1. **Quality is defined as conformance to requirements**, not as "goodness" or "elegance."
2. The system for causing quality is prevention, not appraisal.
3. The performance standard must be Zero Defects, not "that's close enough."
4. The measurement of quality is the Price of Nonconformance, not indices.

Crosby wrote many books for both public and professional consumption. "Quality Without Tears" was possibly his most famous book.

Genichi Taguchi, 1924 – Present
Taguchi developed the concept of a "loss function." As an outcome of this thinking, Taguchi related quality to "The loss a product imposes on society after it is shipped".