

Introduction to Quality Assurance

Anatomy of a Successful Quality Assurance Program

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Learning Objectives

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

- Understand Lessons Learned regarding quality programs
- Understand difference between Total Quality Management (TQM) and regulated quality assurance (QA)
- Understand the elements of a QA program
- Understand the DOE QA Program basic structure
- Understand what NQA-1 provides to DOE
- Understand to whom the QA program applies
- Understand what is expected from managers, performers, and QA organizations



Anatomy of a Successful QA Program

QA Lessons Learned

The nuclear industry has developed steadily in the last half century. During that time and at various locations, it was noted that organizations were not adequately implementing their work controls. Following evaluations of this pattern, similarities across the nuclear programs became evident:

- Quality was seen by many as something that was inspected into an item by the QA group (There are still nuclear industry personnel who do not have a strong understanding of nuclear quality assurance program or the responsibilities of all participants.)
- The QA Program was ‘that book’ in the QA office (possibly naming the program Quality Assurance, and then naming the independent oversight group with the same label led to this misconception, or a lack of effective training)
- The QA Program was written by QA and was used only by them. QA has sometimes furthered this misconception with an over-zealous attitude or a lack of support to management that was intended. (QA often plays a large part in the development of an organization’s QA Program, but the program belongs to and controls the work of every person including senior managers, procurement, laborers, clerical, supervisors, and even quality assurance. The quality assurance personnel are to support others in use and application of the QA program.)
- The QA Program was an “all or nothing” type of program – either you had to pay attention to it, or you didn’t pay attention to it at all. (In fact, DOE’s QA Program requires that it be applied in a graded manner, depending on the importance, risk, or complexity of the task – more rigor is applied for more important or higher risk tasks.)
- Quality programs and work controls cost time and money. (If you see work controls as an impediment, then you’d feel this way also. But, after you have experienced the cost of stopping work because of an error, fixing the error, and planning and executing actions or program changes to effectively preclude the error from happening again, the perceived cost savings not only disappears, but you’ve lost a large chunk of time and money.)
- It’s more efficient to make progress and only fix problems if they occur. (As introduced above, the efficiencies come from doing it right the first time and consistent high quality doesn’t just happen, it is planned and controlled.)

TQM vs Regulated QA

Total Quality Management, or TQM, is a way of achieving quality. Its founder was a statistician for the U.S. Census Bureau, and he believed that work could be controlled statistically to



increase output, cost savings, and customer satisfaction. A customer's satisfaction was used to measure the program's effectiveness.

Although its roots date back to post-World War II and American assistance with the rebuilding of Japan, general acceptance of TQM in the U.S. peaked in the 1980s.

In 1991, DOE Order 5700.6C was restructured to establish the 10 quality criteria that remain in use today. That issue of 5700.6C reflected the concept that all work is a process that can be managed, performed, and improved by adopting a management system approach to quality. The TQM concept applies to all activities, including support activities.

In practice, the concept was subjective and difficult to measure and enforce. Regulation based on TQM was difficult, and led to varying interpretations of its meaning.

Nuclear activities would require better defined requirements that could be measured and enforced.

Regulated Nuclear Quality is, as the term states, a type of quality assurance that provides more control over the eventual quality than TQM. Current programs that fall into this category include NQA-1 and the NRC's 10CFR50 Appendix B, which identifies elements of work that affect the quality of nuclear, and require that the elements be addressed in a quality assurance program.

In simple terms, regulated QA requires that work be planned, performed as planned, and then verified by someone independent of the work. There is little subjectivity in this type of QA. The recorded results are relied upon to objectively prove the quality.

With less subjectivity, the QA program is able to be followed and enforced, and its results measured.

Elements of a QA Program

The elements of different QA programs generally control the same activities, but may be presented in a different sequence or emphasis.

Because the elements of QA are individually shown in 18 parts in NQA-1, and not grouped into 10 as in the DOE program, the NQA-1 elements will be used for discussion.

1. **Organization** – Responsibilities are important to making any program work. In this element, the organizational structure is identified, along with functional responsibilities, levels of authority, and lines of communication.
2. **Quality Assurance Program** - A documented quality assurance program must be planned, implemented, and maintained. It must identify the activities and items to which it applies. It also must be applied to an extent consistent with their importance.



- Personnel must be trained and qualified, proper tools must be used, and management must regularly assess the program's effectiveness.
3. **Design Control** – The control of design is an extensive control. In order to build or develop the item or software as planned, every aspect of design must be purposely performed. Input, interfaces, activities, verifications, and any changes made must be planned and recorded.
 4. **Procurement Document Control** – To ensure adequate quality, contract documents must include all technical and quality requirements, be clearly stated and understood by the supplier, and be legally enforceable. To trust your suppliers, you can require them to also have a quality assurance program consistent with yours.
 5. **Instructions, Procedures, and Drawings** – These documents prescribe what is to be done, how it is to be done, and what the result must be. Failures in achieving quality can be traced to poor communications. Verbal communication can vary by individual; documented communication is firm.
 6. **Document Control** – The documents that are created to control work must themselves be controlled to assure that the latest approved ones are put into use.
 7. **Control of Purchased Items and Services** – To assure that you receive what you purchase, you may evaluate potential suppliers, visit their facility, observe your product or service as it is being developed or built, inspect it upon receipt, and review certifications related to it.
 8. **Identification and Control of Items** – Item identification is necessary to assure that the correct item is installed in the correct location. The identification is also necessary to track the life span of items with a limited shelf life. Any item that is important to quality must be identifiable and traceable in the event of a problem.
 9. **Control of Special Processes** – Certain processes such as welding, heat treating, or nondestructive examination require special training and qualification. Upon completion of the process, it may not be possible to verify that it was performed correctly. These processes are described as special processes and require special training and qualification. Personnel are qualified, and procedures are qualified prior to use.
 10. **Inspection** - Inspections performed to verify acceptance of an item must be planned, performed in accordance to procedures, results analyzed, and documented. Workers cannot inspect their own work; it must be objective. Inspectors generally belong to an organization that is totally independent from the work organizations.
 11. **Test Control** – Just as in “Inspections” above, tests used to gather data or prove acceptability must be planned and documented. Test methods must be defined, and results must be compared to test requirements.
 12. **Control of Measuring and Test Equipment** – Measuring equipment, test equipment, tools or gauges used for activities affecting quality must be accurate within specified tolerances. Calibrations must be performed at regular intervals, and documented. Items should be uniquely identified for tracking purposes.



13. **Handling, Storage, and Shipping** – These work controls might sound minor or inconsequential, but if control is lost for a moment, it’s lost. Handling includes rigging, which if done improperly can result in injury or death. In order to control items and material, and assure safety, the controls must be extended to every activity to which the item or material is subjected.
14. **Inspection, Test, and Operating Status** – Only acceptable items, material, and software may be installed and used. In order to know that products are available for installation or use, their acceptance status must be readily available. Tags or labels must be on the products, or records traceable to the products must be available.
15. **Control of Nonconforming Items** – Items that don’t meet requirements are nonconforming. They must be controlled to prevent their inadvertent installation or use. This is often done by tagging the item or segregating it from acceptable stock.
16. **Corrective Action** – This criterion addresses those cases where programmatic requirements are not followed. These may or may not involve hardware. They may be detected by observation, reviews of records, or self-reported. In any case, the “condition adverse to quality” must be corrected. And, if the error is significant, its cause must be determined and preventive actions taken to prevent recurrence. Lessons learned may be communicated to others for their information and possible use.
17. **Quality Assurance Records** – Records provide the proof of quality. Records must be identified in the QA program, generated, authenticated, maintained for a specified time. In the 1980s a commercial nuclear plant under construction was prevented from getting its operating license when the records were determined by the NRC to be inadequate. It took four years and \$460 M to re-verify that the plant had been built as specified, but the acceptability just had not been adequately documented.
18. **Audits** – This final element involves the verification that performance criteria are being met, and the determination of the effectiveness of the quality program. It is accomplished by people who are independent of the work being audited.

How Do I Expect to See These Criteria Applied?

Quality criteria may be in the form of the 18 we just reviewed, or they may be the 10 of the DOE program, but not all criteria apply to every company or organization.

A “full-service” architect-engineer-constructor would likely use all criteria because they perform activities covered by each criterion. A smaller organization such as a calibration laboratory would likely not require the “design” criterion, so their program wouldn’t contain any controls for “design.”

Each organization must address the criteria for which they perform quality affecting activities.



Points to Ponder

When reviewing another organization's quality program:

- Look for controls for each of their activities that affect quality. The degree of control should be dependent on the importance of the activity. This is subjective, but should be reasonable.
- Format is not specified in requirements.
- The program structure does not align with a recognized structure from the cited quality standard. In this case, a comparison must be made to see if each applicable criterion is addressed. Remember, the quality standard directs what is to be addressed.
- If a quality-affecting activity appears to be silent in the organization's quality program, ask the organization to explain.
- "Indirect" or support activities, such as, Organization, QA Program, etc., are inherent in quality controls, and always apply. They cannot be eliminated.
- "Direct" controls, such as Design, Calibration, Special Processes, and the remaining bullets apply only if they perform the activity.

An Approach to Oversight of a QA Program

The first action is to determine the activities that are controlled by the QA program. List the activities that are performed by the organization or company. This sets the baseline for the program controls that you'll be expecting to see in their program.

Use a checklist. A checklist is a document that shows evidence of your planning and the eventual results.

Develop questions based on the Basic Requirements of NQA-1. NQA-1 is preferred because it expresses the quality criteria individually in eighteen criteria. It's easier to answer each of the criteria individually in lieu of having to clearly identify the portion of a combined criterion. Or just "cut-and-paste" portions of the Basic NQA-1 Basic Requirements into the checklist, and verify compliance (or noncompliance) during the oversight.

Add checklist items from other regulators that apply, such as the Department of Transportation, Nuclear Regulatory Commission, Environmental Protection Agency, state regulators, etc.

The quality program always has two phases to check: adequacy and implementation. Adequacy checks whether or not the QA program has addressed all the functional areas that need control. Implementation is the company's degree of use of the program in their daily activities.

On the checklist, identify the activities that the company or organization performs. If any of the NQA-1 checklist items appears to not apply, verify the item with the organization. If it truly does not apply, mark the checklist with that result, and provide the reason, such as, "This company states that they do not have or use measuring and test equipment, and none was observed."

Complete the checklist, obtaining answers or information for each question. If for some reason a question cannot be answered, say so and provide an explanation.

