

Introduction to Quality Assurance

Anatomy of a Successful QA Program

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Learning Objectives

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

- Understand the difference between Total Quality Management (TQM) and regulated quality assurance (QA)
- Understand the elements of a QA program
- Understand the Department of Energy's (DOE) QA Program basic structure
- Understand what American Society of Mechanical Engineers (ASME) Nuclear Quality Assurance (NQA)-1 provides to DOE
- Understand to whom the QA program applies
- Understand what is expected from managers, performers, and QA organizations



QA Lessons Learned

- DOE and other nuclear entities have learned that:
 - Quality is not “inspected into” an item or service by QA
 - The QA Program is not just a document in the QA office
 - The QA Program is not just written by and for QA
 - The QA program is applied in a graded manner depending on the risk of an item, but it cannot be graded totally out
 - Controlling work with the quality program does provide accuracy, repeatability, provable results; it has also added efficiencies
 - Errors are more costly than work done correctly



TQM vs Regulated QA

- Total Quality Management (TQM)
 - A concept emphasizing continuous improvement based on ‘Plan-Do-Check-Act’ model
 - Based on the belief that work could be controlled statistically to increase productivity, efficiency, and customer satisfaction
 - Customer satisfaction was used as a gauge
 - Highly regarded during 1980s; many work controls were developed or revised to embrace the concept



TQM vs Regulated QA (continued)

- Concept applied to virtually all activities
 - Participative management approach instead of top-down management (extensive use of “quality circles”)
 - Product (design, manufacturing, packaging)
 - Internal activities (strategic plans, budget, safety analysis, procurement)
- Concept was subjective, less able to be measured or enforced; was later determined to not be adequate by itself for nuclear safety



TQM vs Regulated QA (continued)

- Regulated Nuclear Quality
 - Identifies elements of work that affect nuclear activities and components, and requires they be addressed in quality programs
 - Requires work to be planned
 - Requires work to be performed as planned
 - Requires work to be checked by independent persons
 - More objective, and able to be measured and enforced; enforcement is necessary to implement 10CFR830 Subpart A and Price-Anderson Amendments Act



Elements of a QA Program

- Each of the 18 criteria of NQA-1 is a requirement, and all of them together comprise a quality program

1. Organization

- Define the structure of the organization (who does what)
- Establish who is responsible and has authority for what (if responsibility is not defined, no one is responsible)
- Lines of communication (who coordinates with whom)

2. Quality Assurance Program

- Document the entire program so it is usable, verifiable, and it becomes objective evidence of planned quality. Includes:
 - Identification of activities and items subject to the Program
 - Use of controlled conditions when appropriate
 - Personnel indoctrination, training, and qualification
 - Management overview of quality program implementation



Elements of a QA Program

(continued)

3. Design Control – In order to know what you want or have, control:

- design input
- design interfaces
- design activities
- design verification
- design changes
- software design
- configuration management

4. Procurement Document Control – The key to getting needed items and services is complete and accurate procurement documents

- Document all the design and quality requirements the supplier is expected to deliver
- A supplier can't be watched constantly, so define when the supplier has to have a stand-alone compliant quality assurance program
- How requirements must flow down to their sub-suppliers



Elements of a QA Program

(continued)

5. Instructions, Procedures, and Drawings – Use these to control work to achieve

- Consistency
- Repeatability
- Completeness
- Accuracy
- Acceptability

6. Document Control – The documents directing work are

- Correct
- Up-to-date
- Available for use



Elements of a QA Program

(continued)

7. Control of Purchased Items and Services – Make sure that the supplier does exactly what is needed

- Qualify suppliers
- Perform shop inspections
- Review objective evidence of quality supplied by the supplier
- Check the items or services when received or completed
- Prevent substitution of items that may not do the job right
- Ensure supplier errors are fixed

8. Identification and Control of Items

- Items with similar functions may not be identical and may not work in the intended application
- Ensure the correct item is installed
- Traceability of items to its procurement
- Control of limited shelf or operating life of items



Elements of a QA Program

(continued)

9. Control of Special Processes

- Processes that require a high degree of skill, and cannot be verified after completion (heat treating, welding, etc.)
- The controls are built into the process
 - Requirements are specified
 - Workers are qualified
 - Procedures are qualified

10. Inspection

Critical characteristics of item or activity identified

Acceptance criteria established

Performed by persons other than those who performed or directly supervised the work

11. Test Control

1. Testing can be done for
 1. Collecting data
 2. Siting or design input
 3. Verification that items or computer programs meet requirements
2. Must be planned and documented
3. Characteristics to be tested and test methods must be specified
4. Results must be compared to acceptance criteria and evaluated by the responsible design organization



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Elements of a QA Program

(continued)

12. Control of Measuring and Test Equipment

- Tools, gauges, and instruments, etc., used for measuring must be accurate
 - Periodic calibration
 - Traceability to certified equipment or reference standards
 - Correct precision and accuracy capabilities for the job
- Traceability of use

13. Handling, Storage, and Shipping

- Can affect the integrity of an item and its ability to perform satisfactorily in service
 - Storage
 - Cleaning
 - Packaging
 - Shipping
 - Preservation
 - Marking and labeling



Elements of a QA Program

(continued)

14. Inspection, Test, and Operating Status – Is an item OK to be installed?

- Is its acceptance status known (inspected? tested? accepted or rejected?)
- Status indicators
 - Physical location (segregation)
 - Tags
 - Markings
 - Shop travelers
 - Stamps
 - Inspection records
- Who has authority to attach and remove status indicators?



Elements of a QA Program

(continued)

15. Control of Nonconforming Items

- Items that aren't acceptable must be controlled (tagged or segregated, etc.) to prevent inadvertent installation or use. The mindset should be that if an item hasn't been fully approved (e.g., visual inspection OK but waiting for required documents), it must still be held to prevent use.
- Must be documented, evaluated, and dispositioned
 - “Use-as-is”
 - Reject
 - Repair
 - Rework
 - Dispose/destroy
- Physical controls
 - Tags
 - Segregation
- Markings



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Elements of a QA Program

(continued)

16. Corrective Action

- Not to be confused with ‘nonconforming’ items, this criterion addresses errors made in meeting programmatic requirements (more people-oriented).
- When errors are made, they must be documented and corrected.
- If the error is severe (significant), the cause must be determined so corrective action can be assigned to prevent a recurrence.
- Tracking and trending of errors provides opportunity for improving overall process quality

17. Quality Assurance Records

- Without records, there is no proof that work was performed correctly. QA records furnish evidence that quality was achieved. Because records are so important, they must be
 - specified
 - legible
 - traceable
 - authenticated,
 - maintained (against loss or damage), and
 - retained for a designated length of time.



Elements of a QA Program

(concluded)

18. Audits

- Intended to
 - Verify compliance to requirements
 - Verify performance criteria are met
 - Determine effectiveness of the program
- This is independent oversight by persons not responsible for the work being audited (not necessarily QA people)
- Must be documented



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How Do I Expect to See These Criteria Applied?

- All quality criteria may apply to some organizations, but certain criteria may not apply to other organizations.
 - An architect-engineer-constructor would likely require all 18 criteria because they perform activities that are candidates for control by all 18
 - A calibration laboratory would likely not require the “design” criterion
 - A software development company would include “design” but may not require “Item Identification and Control” or “Control of Measuring and Test Equipment”
- Each organization’s quality program must address all the criteria for which they perform related activities.



Points to Ponder

- When reviewing a contractor's or supplier's quality program:
 - An organization must develop controls only for the activities it performs (selective application).
 - The level of rigor of each control is subjective and is based on the activity's importance or complexity (graded approach).
 - Nothing says that the format must be identical to the standard (but it generally is).
 - Some QA programs are not formatted in the same manner as the parent standard. In these cases, a comparison must be made to verify that each criterion applicable to the company's work is adequately addressed within the program.
 - If a criterion appears to be applicable, but the QA Program does not address it, challenge the organization to demonstrate why it is not addressed. Can their answer be proven objectively?



Points to Ponder (continued)

- Any organization performing quality activities should address these criteria:
 - Organization
 - QA Program
 - Instructions, Procedures, and Drawings
 - Document Control
 - Corrective Action
 - QA Records
 - Audits



Points to Ponder (concluded)

- When evaluating the adequacy of a QA program, ask yourself: “Are they...”
 - Involved in Design (anything that is quality related)?
 - Involved in Procurement of Items or Services?
 - Responsible for assuring acceptability of purchased items or services?
 - Responsible for assuring control of items that are in their possession?
 - Performing inspections?
 - Using special processes, or other processes affecting quality?
 - Handling, storing, or shipping items that require special controls?
 - Testing items or systems?
 - Measuring items where accuracy needs to be assured?
 - Other?

