CHAPTER 2

ESSENTIAL ELEMENTS OF A QA/QC SYSTEM

This chapter discusses the fifteen elements that are the basis for FTA's guidance regarding QA/QC involving design, procurement, manufacturing, and/or construction. In addition, this chapter provides some guidance in determining which elements are appropriate for different projects. Note that each project is unique in scope and size and not all elements are applicable to all projects. An analysis of the project is recommend in order to determine what elements are applicable and warrant procedures.

The background section describes the origin of the fifteen elements, other efforts to develop construction oriented QA/QC standards, the justification for FTA adaptation of the fifteen elements, and organizational definitions required to understand the fifteen elements.

The fifteen quality elements are as follows and should be considered in the development of detailed quality procedures:

1. Management Responsibility
2. Documented Quality Management System
3. Design Control
4. Document Control
5. Purchasing
6. Product Identification and Traceability
7. Process Control
8. Inspection and Testing
9. Inspection, Measuring, and Test Equipment
10. Inspection and Test Status
11. Nonconformance
12. Corrective Action
13. Quality Records
14. Quality Audits
15. Training.

Following each of the elements is a comment(s) section that includes information and guidance that can be used when developing the procedures.

2.1 Background

The fifteen elements were originally adapted from the 1987 version of the American National Standards for Quality Systems (ANSI/ASQC Q90 - Q94). The International Standards for Quality Systems (ISO 9000 - ISO 9004) were almost identical to the ANSI standards. Both sets of standards have been subsequently updated, but they still contain the fundamental information upon which these guidelines are based.

The ISO 9000:1994 standard has been revised to ISO 9000:2000. This new revision requires a significantly different format for documenting a Quality Management System. The original twenty elements have been reorganized into six basic elements. ISO 9001:2000 contains two conversion tables to show how the old elements are included in the new standard and visa-versa. This table is an ideal cross-reference for the FTA, grantee, and companies who use the latest ISO standard's documentation format. It can be used as an aid in indicating that all of the required elements of these guidelines have been properly addressed. ASQC (now ASQ) and ISO Standards represent sound management practice. Evidence of the acceptance of these standards to industry is the proliferation of companies that have become ISO certified over the past ten years.

A number of organizations have developed quality program standards for specific types of work. Among these are ASQ, which formed a Construction Technical Committee in 1982 to address construction quality; the American Society of Civil Engineers (ASCE), which addressed the need for a quality standard in engineering and construction; and the Construction Industry Institute (CII), associated with the University of Texas at Austin, which was founded in 1983 to improve the cost effectiveness of the construction industry. In developing the QA/QC Guidelines for FTA, consideration was given to adopting one of these standards. However, it was decided to use the more generic approach of the ANSI/ASQC Q90 - Q94:1994 standards. The reasoning is as follows:

- This standard has been broadly accepted in the United States and in the international community. There has not yet been universal acceptance of the various QA/QC guidelines for the design and construction industry.

- The capital programs of the transit industry include design and construction activities and equipment procurement. The ANSI/ASQC Q90 standard sets forth a generic quality program based upon sound management practices that is adaptable to all transit capital projects.

- The organization and management of transit capital programs can take many different forms. Some transit agencies may do construction activities in-house, they may hire a construction contractor, or they may hire both a CMC and construction contractor. Given the variety of formats, the most useful quality guidance would seem to be to present the essential quality elements, and let the transit agency determine where the elements are appropriate, and which organizations should have responsibility for implementation.

The fifteen quality elements are adapted from some twelve to twenty quality elements included in the ANSI standards. These fifteen are the elements most relevant to an FTA grantee. The elements should be seen as good management practice to ensure quality of design, manufacturing, and construction services. They are applicable not only for quality programs of the FTA grantees, but also for organizations providing goods and services to grantees.

Each of the elements may refer to QA or QC activities. QA activities include planning for quality activities and verifying that those activities were carried out. QC activities include the actual implementation of quality activities and the documentation thereof.

The elements sometimes refer to generic organizational entities that could be the transit agency/grantee or the construction contractor, for example, depending upon the role being played. Following are some of the generic organizational entities referenced in the quality elements:

Management	Management of the grantee or management of any contractor to the grantee.
Designer	The organization responsible for design. This could be the grantee itself, and/or a contractor providing architectural/engineering services.
Purchaser	The grantee or other organization responsible for specifying, contracting, and accepting requirements for capital goods or services.
Supplier	Any organization providing services, products, or materials for grantee capital projects. The supplier could be a product manufacturer, or a provider of raw materials.
Contractor	Any organization providing services or products to a transit agency under direct contractual agreement. The contractor could be part of the grantee organization in the case of force account work.
Subcontractor/ Subconsultant	Any organization supplying services or products under contract to a contractor. The subcontractor would not contract directly with the transit agency, but with a contractor or another sub-contractor.

2.2 The Fifteen Elements of a Quality Program

2.2.1 Element 1: Management Responsibility

The grantee should define and document a quality policy, and should communicate, implement, and maintain that policy at all levels of its organization. Management should designate a representative who shall have defined authority and responsibility for ensuring that the quality policy is implemented and maintained. Management should also identify those persons responsible for the quality assurance function and should define in writing the responsibility, authority, and interrelation of those persons.

The responsibility for and commitment to the quality policy belongs to the highest level of management. Management should, therefore, declare and document its commitment to quality. Management should ensure that the quality policy is understood, implemented, and maintained throughout the organization.

There should be a person designated as the representative of management who has the responsibility and authority to ensure that management's quality policy is implemented and maintained. Maintenance includes documented review of the policy at appropriate intervals to ensure that it remains suitable and effective.

Project personnel who have responsibility for ensuring or controlling quality should be identified and their interrelationships with project management defined. These relationships should be shown on an organization chart. In particular, the personnel should be identified who have responsibility to initiate action to prevent quality problems, to identify and record quality problems, to initiate solutions through appropriate channels, and to verify implementation of solutions to quality problems. Those personnel responsible for assuring quality must be independent of those having direct responsibility for the work being performed. This can be accomplished satisfactorily if those ensuring or controlling quality report on a level higher than those having direct responsibility for the work.

Comment:

A concern for the grantee is the assignment of responsibility for QA and QC. So far as possible, each organization involved in a transit capital project should be responsible for its own QC. Exceptions include the case where a grantee has its own materials testing laboratory and thus provides some QC for its construction contractors.

While consultants or contractors to the grantee can assume some responsibility for QA, this responsibility should not be completely delegated. The grantee should maintain a QA oversight capability to ensure that quality programs are working at the agency itself and within the supplier and contractor organizations.

The Army Corps of Engineers quality program is a successful model for construction projects. With the Corps program, the contractors are responsible for QC and the Corps is responsible for QA. The contractors may also have some QA responsibility as part of their own quality management system.

2.2.2 Element 2: Documented Quality Management System

The grantee should establish and maintain a documented quality management system to ensure project quality objectives are satisfied. The quality management system requirements should extend to the grantee's suppliers and contractors as appropriate.

Written procedures and instructions should be developed for activities affecting quality in design, procurement, manufacturing, and construction as applicable to the work performed. Procedures and instructions should also be developed for control of processes including inspection, testing, nondestructive examination, disposition of nonconforming product, corrective action, maintenance of quality records, quality audits, and training.

The procedures should contain a statement of the purpose and scope, and should contain any references to appropriate codes, standards, or specifications. In developing the quality procedures, consideration should be given to identifying and acquiring any inspection equipment, skills, or special quality processes needed to ensure quality performance. Inspection and testing techniques should be kept up-to-date. Where new techniques are being used for construction or manufacturing, adequate time should be allowed to develop appropriate quality procedures for the new techniques. The procedures and instructions should contain formats for the quality records needed to ensure that the procedures and instructions are followed and documentation requirements are understood.

Comment:

The quality procedures described above are generic to the design, procurement, manufacturing, and construction industry. Each transit agency determines which procedures are applicable to the specific capital project.

2.2.3 Element 3: Design Control

The designer should establish and maintain procedures to control and verify the design of the transit systems in order to ensure that the design criteria, other specified requirements, and requirements of the relevant regulatory agencies are met. Design control includes ensuring that the design requirements are understood, planning the design interfaces and design verification activities, executing the design verification activities, and controlling design changes through project completion.

The designer should prepare a plan for design activities. The plan should identify who has responsibility for the different design parts, and who has the QA responsibility for design. It should also identify the various organizational interfaces required between various groups producing and commenting on the design, and specify the information to be documented, transmitted, and regularly reviewed. Finally, the plan should specify how the operating and maintenance departments of the transit agency would interface with those producing the design.

Design input requirements should be identified, documented, and reviewed by the designer. Any ambiguity in the design input requirements should be resolved between the designer and those responsible for developing the requirements.

Design output should be documented. It should meet the input design requirements, include acceptance criteria, conform to appropriate regulatory requirements whether or not these have been stated in the design input requirements, and identify those aspects of the design which are crucial to the safe and proper functioning of the final product or system.

The designer should assign to competent personnel those activities required to verify the quality of the design. Design verification activities should include the carrying out of alternative calculations, independent checks of design calculations, specifications, drawings, and contract documents, conducting and documenting design reviews, undertaking qualification tests and

demonstrations, and comparing the design with a similar proven design, if available. Design reviews include reviews for constructibility, operability, and maintainability.

Appropriate procedures should be established for the identification, documentation, review, and approval of all changes and modifications to the design. This responsibility should extend to those responsible for construction or manufacturing to ensure compliance to design requirements and for development of "as-built" documents as part of the design documentation at the end of the project.

Comment:

Each group responsible for design should provide its own written QC procedures. These include peer review of drawings and check calculations. QA activities are performed to verify compliance to established QC procedures and to determine the effectiveness of the procedures in meeting quality program objectives.

The *Project and Construction Management Guidelines* uses the term "Control of the Configuration" to refer to control of design changes, and the related document control (see below). The following detail about configuration control was taken from the 1990 version of the *Project and Construction Management Guidelines* [Ref. 38]:

> Configuration control consists of the evaluation, coordination, and approval or disapproval of changes in the configuration of an item after establishment of a configuration baseline. A configuration baseline consists of the approved or conditionally approved technical documentation for an item as set forth in drawings and associated lists, specifications, and referenced documents. In an effective configuration control program, drawings are uniquely numbered and otherwise identified. Specifications follow a standard format and each paragraph is numbered and identified. Complete drawing lists are established and the total number of drawings, the titles of the drawings, the revision status, and the dates the drawings were approved are recorded. Changes to approved drawings or specifications should only be made in accordance with established procedures. Permanent files are maintained of all contract documents which include historical information relating to all project changes. As the project becomes implemented, configuration control evolves to include the documentation of the completed improvement in terms of "as-built drawings."

2.2.4 Element 4: Document Control

Procedures for control of project documents and data should be established and maintained. The document control measures should ensure that all relevant documents are current and available to all users who require them.

Control of project documents includes the review of documents by authorized personnel, the distribution and storage of these documents, the elimination of obsolete documents, and control of changes to the documents.

Copies of the documents should be distributed so that they will be available at all locations that need them for effective functioning of the quality management system. Obsolete documents should be promptly eliminated from each work location. Any superseded documents retained for the record should be clearly identified as such.

The same authorized personnel who reviewed and approved the original documents, unless the control procedures specifically allow otherwise, should review changes to the documents and data. Changes should be promptly distributed to all locations, along with a master list enumerating the current revisions of each document.

Following are examples of the types of documents requiring control:

- Drawings
- Specifications
- Inspection procedures
- Test procedures
- Special work instructions
- Operational procedures
- QA program and procedures.

Comment:

A useful tool for keeping track of project documents is the Design Output Index that lists every document developed for the execution of the project. The Design Output Index contains a listing of the latest revisions of the following:

- Drawings
- Technical specifications
- Special processes
- Test specifications
- Engineering change notices.

2.2.5 Element 5: Purchasing

The purchaser should ensure that the purchased service or product conforms to the purchaser's specified requirements. The purchaser should require supplier quality programs appropriate to the work being performed and in accordance with these guidelines.

The purchaser should establish a documented list of acceptable suppliers and contractors for the desired service or product, consistent with applicable procurement requirements. The purchaser should select suppliers or contractors on the basis of their being able to meet contract requirements, including quality requirements. The quality requirements placed on the supplier or contractor will depend upon the nature of the service or product.

The contract or purchasing requirements should clearly specify the expectations of the purchaser, including relevant standards, drawings, specifications, process requirements, inspection instructions, and approval criteria for materials, processes, and product. The purchasing documents should be reviewed and approved by a designated authority for adequacy of specified requirements prior to release. The purchaser of services or products should ensure that the supplier fully understands the contract, agrees with the contract, and has the capacity to perform as required.

Where construction or equipment procurement is involved, the contract between the purchaser and the supplier should specify the right of the purchaser or other authorized representatives to carry out inspection and testing at the source and upon receipt to verify that the work or product meets specifications. Such provision should not absolve the supplier of the responsibility to provide acceptable work or product, nor should it preclude subsequent rejection.

Where equipment procurement is involved, the purchaser should define, as appropriate, the means and methods for handling, storage, packaging, and delivery of product. The purchaser should establish procedures to receive, inspect, store, and maintain equipment procured. Any equipment that is damaged or is otherwise unsuited for use should be documented and reported to the supplier.

Comment:

Purchasing requirements apply to all contractors and suppliers, including consultants, construction contractors, and manufacturers. The purpose of this element is to ensure that purchasing requirements are clear and complete, that the supplier understands them, and that appropriate quality elements are made part of the contract. Additional requirements, such as on-site inspection and handling and receiving procedures, may be required for construction or equipment procurement contracts.

The level of quality program specified in the contract will depend upon the complexity and importance of the service or product. For some projects, all fifteen elements of this quality guidance might be specified. In other cases, the supplier may only be required to use its existing quality program. In addition, FTA Circular 4220.1D “Third Party Contracting Requirements” delineates contracting requirements that to assist grantees in procuring third party services on capital projects receiving federal funding.

2.2.6 Element 6: Product Identification and Traceability

Measures should be established and maintained for identifying and controlling items of production (batch, materials, parts, and components) to prevent the use of incorrect or defective items and to ensure that only correct and acceptable items are used or installed.

Physical identification and control should be used to the extent possible. Where physical identification is impractical, physical separation, procedural control, or other appropriate means may be employed. Items that fail to possess identification, or items for which record traceability

has been lost, or items that do not conform to requirements should be segregated to prevent use or installation. An item should be able to be identified by how it is marked or where it is located.

Comment:

Product identification and traceability should take place during all the various production phases – from receipt of raw materials, components, or subassemblies through the manufacturing process, to delivery of final products or systems.

Traceability may mean traceable to a particular project, specific warranty, test report, supplier, point in time, purchase order, or through production.

Raw materials should be traceable back to a particular batch number, shipment number, packing slip, or invoice and should be accompanied by applicable test data sheets and material certifications.

Store room or inventory tracking procedures should allow for items to be traceable back to a particular order number, batch number, date received, test lot, or other pertinent source.

Assemblies in production should be traceable to particular projects through the use of some form of routing documentation. Routing documentation should contain sufficient manufacturing information, including work instructions, manufacturing standards, tooling, etc.

Final assemblies should be clearly marked with project numbers, model numbers, serial numbers, bar codes, etc., so that all pertinent information regarding that assembly may be retrieved.

2.2.7 Element 7: Process Control

Suppliers and contractors should identify and plan the production and installation processes that directly affect quality and should ensure these processes are performed under controlled conditions. Special processes, the results of which cannot be verified by subsequent inspection and testing of the product, should be continuously monitored.

To achieve accuracy and consistency in production and installation processes, the quality program should provide for:

- Documented work instructions where such are needed to ensure quality, use of suitable production and installation equipment, a suitable working environment, personnel qualifications, and conformance with referenced standards/codes and Quality Plans

- Monitoring and controlling of processes and product characteristics during production and installation.

Continuous monitoring and/or conformance with documented procedures is required during special processes, such as welding, nondestructive testing, and heat treatment, where the results

will impact quality of the final product, but where inspection after the fact will not reveal the deficiencies.

Comment:

A major issue in process control is to ensure that work is performed in the proper sequence. For example, welds should be inspected before they are painted. Earth should be compacted before concrete is poured. Documented work instructions can help with sequence control where there is complex work or when there are multi-disciplined interfaces.

2.2.8 Element 8: Inspection and Testing

Inspection and testing procedures should be planned and executed as necessary to verify quality. Procedures should be specified, implemented, and the results documented for receiving incoming products, and for final inspection and testing.

When products are delivered to the purchaser, it is the responsibility of the purchaser to verify they are in conformance with requirements. Verification should be in accordance with the Quality Plan or documented procedures. The extent of receiving inspection can vary with the amount of inspection at the source, the safety criticality of the product, and the confidence in the quality procedures of the supplier.

In-process testing and inspection of the work to verify conformance of an item or work activity to specified requirements should be in accordance with the Quality Plan or documented procedures. Both inspection and process monitoring methods should be performed, as necessary, to ensure that the specified requirements for the control of work processes and the quality of the item are being achieved throughout the duration of the work.

Final inspection and testing should ensure that all specified inspections and tests, including those specified for receipt of product or in-process work, have been carried out and the resulting data meet specifications. Final inspection and testing should be carried out and properly documented to ensure conformance of the finished product to the specifications.

Records should be maintained of the various inspections and tests to provide evidence that the product has passed inspection and/or test with defined acceptance criteria.

Comment:

Given that everything cannot be inspected, the following criteria are offered as guidance for what to emphasize in an inspection and testing program:

- Items or work affecting safety
- Items that affect system reliability
- Items that affect service life
- Long lead time items or custom manufactured items
- High visibility areas.
- ADA compliance items.

2.2.9 Element 9: Inspection, Measuring, and Test Equipment

Inspection, measuring, and test equipment required to carry out inspection and testing should be identified, controlled, calibrated, and maintained in order to demonstrate the conformance of work to the specified requirements. Provisions should be made for recalibration of such equipment in a timely manner.

Inspection, measuring, and test equipment used should meet the standards of accuracy for the measurements which are required. The equipment should be calibrated according to national standards where available, and to documented standards where no national standards exist. The equipment should be recalibrated at regular intervals, and the recalibration properly documented. A record of the equipment calibration status should be maintained.

The equipment should be properly maintained to ensure its fitness for use. When in use, the user should ensure that the environmental conditions are suitable for the use of the equipment. When inspection, measuring, or test equipment is found to be out of calibration, the validity of previous inspection and test results should be assessed and documented.

Comment:

All testing equipment must be calibrated prior to its use on the project. Periodic calibrations must be performed in accordance with certifying agency requirements and industry practice. ISO/DIS 10012, " Quality Assurance Requirements for Measuring Equipment - Part 1: Metrological confirmation system for measuring equipment" provides guidelines on the main features of a calibration system to ensure that measurements are made with the intended accuracy. ISO 10012-2:1997, "Quality Assurance for Measuring Equipment - Part 2: Guidelines for control of measurement of processes" provides supplementary guidance on the application of statistical process control when this is appropriate for achieving the objectives of Part 1.

2.2.10 Element 10: Inspection and Test Status

A means should be provided for identifying the inspection and test status of work during production and installation. The purpose of this is to ensure that only work that has passed the required inspections and tests is accepted.

The test and inspection status should be identified by means of markings, stamps, tags, labels, routing cards, inspections records, test software, physical location, or other suitable means. The status identification indicates the conformance or nonconformance with regard to inspections and tests performed.

Comment:

The inspection and test status of planning and design documents should be identified by suitable means that indicate the conformance or nonconformance of product with regard to checking and reviews performed.

The status of completed, tested and inspected construction should be kept as an ongoing record in the daily inspection reports. Nonconforming materials or construction should be recorded with location noted on inspection reports or nonconformance reports as applicable.

While some operations may be easily tagged in the field as to their inspection status, most are best recorded in the construction management or resident engineer's office through status reports, payment documents, marked up specifications, contract drawings or as-built drawings.

2.2.11 Element 11: Nonconformance

Procedures should be established and maintained to control nonconforming work, in order to ensure that such work is not inadvertently used or installed.

Nonconforming work should be identified, documented, and evaluated to determine appropriate disposition. Where practicable, nonconforming items should be segregated. Those activities affected by the nonconforming work should be notified. The responsibility for review and authority for the disposition of nonconforming work should be defined in documented procedures. Disposition of nonconforming work can include reworking it to meet requirements, accepting it with or without repair, using it for alternative applications, or scrapping it. A determination to accept nonconforming work, as is or with repair, should have the concurrence of the engineer of record. It may be advantageous to the owner to negotiate some form of compensation for accepting nonconforming work (e.g., additional spare parts).

Disposition of nonconforming work should be documented. Reworked or repaired work should be re-inspected in accordance with documented procedures.

Comment:

Contract documents should specify the definition of a nonconformance, including equipment, process, and contract nonconformances. When appropriate a board, made up of owner, contractor, consultant, and other applicable personnel should be established to determine the disposition of a nonconformance. Nonconformance conditions should be documented on nonconformance forms in reports, letters, memos, corrective action lists, audit findings, etc. It is imperative that all nonconformances be resolved in cooperation with project management and quality personnel.

2.2.12 Element 12: Corrective Action

Corrective action procedures should be established, documented, and maintained. These include procedures for investigation of the cause of nonconforming work and the corrective action needed to prevent recurrence, and procedures for analysis to detect and eliminate potential causes of nonconforming work. This element also includes implementing and recording changes in procedures resulting from corrective action.

Corrective action procedures should be established for:

- Investigating the cause of nonconforming product and taking the corrective actions needed to prevent recurrence
- Analyzing processes to detect and eliminate potential causes of nonconforming product
- Initiating preventative actions to deal with problems to a level corresponding to the risks encountered
- Ensuring that corrective actions are taken and that they are effective
- Implementing and recording changes in procedures resulting from corrective action.

Comment:

Corrective action should be taken with respect to nonconforming work in order to eliminate potential problems. One of four types of disposition may result from corrective actions: use-as-is, rework, repair, or scrap.

2.2.13 Element 13: Quality Records

Procedures should be established and maintained for quality records. These procedures should identify which records should be kept, responsibility for production and collection, and responsibility for indexing, filing, storage, maintenance, and disposition of quality records.

Quality records should be maintained to show achievement of quality objectives and appropriate functioning of the quality management system. Supplier, contractor, and subcontractor quality records should be included when pertinent.

Quality records should be legible and should specify the work involved. They should be kept in an environment to minimize deterioration and damage. Retention times and final disposition should be established and recorded.

Where specified by contract, quality records should be made available to the purchaser or purchaser's representative.

Following are examples of the types of quality records requiring control:

- Inspection reports
- Test data
- Qualification records
- Calibration records
- Nonconformances
- Corrective actions
- Audit reports.

Comment:

A useful tool for keeping track of the QA records is a QA Records List. This is a list of every document generated as a result of implementing the quality program. Note that all applicable records should be tracked and controlled, including those of contractors and subcontractors. Similarly, applicable contract documents should be tracked and controlled in accordance with grantee retention policies.

2.2.14 Element 14: Quality Audits

An internal audit should be established to ensure that the elements of the quality management system are functioning as intended.

Each audit should be scheduled. The frequency should depend upon the status and importance of the activity being audited. The audits and follow-up actions should be documented and conducted in accordance with documented procedures. The results of the audits should be presented to the personnel having responsibility in the area being audited. Responsible management personnel should take timely corrective action on the deficiencies found by the audit.

Comment:

Quality audits serve as a tool to reinforce quality requirements and should address root causes of non-conformances identified during the audit. Quality audits should be independent, scheduled, and performed to standards and/or checklists. Qualified quality personnel should conduct the QA audit in order to ensure that it provides substantive results. A final report that identifies the results of the audit should be generated, distributed, and tracked for disposition. The QA audit is not the same as a financial audit.

2.2.15 Element 15: Training

The grantee should establish and maintain procedures for identifying the training needs and provide for the training of all personnel performing activities affecting quality.

All personnel performing activities affecting quality should be qualified on the basis of appropriate education, training, and/or experience, as required. Appropriate training and qualification records should be maintained.

Comment:

A training matrix can be used as a tool for determining which personnel require which training. The training matrix lists the relevant personnel within the agency or within project consultants and contractors versus various quality related procedures. Figure 2-1 is an example of a training matrix.

Figure 2-1 – Training Matrix

	PROCEDURE NUMBER							
	1	2	3	4	5	6	7	8
CEO	CR		RA					
Project Manager	CR	RA	RA	RA	RA	RA	CR	RA
Project Engineer	CR	RA	RA	RA	RA	RA	CR	
Resident Engineer	CR	CR	RA	RA				
Inspectors		CR		RA	RA			RA
QA Personnel	RA	RA	CR	RA	RA	RA	RA	RA
	Key: CR is "classroom" RA is "read and acknowledge"							